# ALEPH UNIVERSITY

## ACADEMIC CATALOG
VOLUME 2 | NO. 1 | January 2025 - December 2025

# CONTENTS

**WE ARE
ALEPH UNIVERSITY**

# LEADERS SERVING AND TRANSFORMING SOCIETY

# ABOUT

## ALEPH UNIVERSITY

Aleph University was founded to satisfy the need for innovators and professionals with high ethical standards, and with advanced skills and practical knowledge for the development of better technologies. Aleph University is founded on the pillars of excellence, empowerment, and commitment to service for a better future of our communities.

Aleph University educational principles and philosophy follow Christian values of love, justice, and service to others. Aleph University seeks to honor God, our creator, through faith in the sacrifice and resurrection. Aleph University aims for the positive transformation of the individuals and communities through the power of love, knowledge and service given and inspired by God.

Aleph University LLC was incorporated on October 11, 2022, as a privately owned, independent corporation under the laws of the State of Florida, and registered with the Florida Department of State, Division of Corporations.

Aleph University offers academic degree programs duly licensed by the Commission for Independent Education of the State of Florida. Aleph University was established to serve the community in the United States and abroad. Aleph University´s faculty have advanced degrees in their fields of expertise and meet all standards set by the Department of Education of the State of Florida.

Aleph University is committed to the development of human potential, through an educational methodology based on new information technologies, virtual interaction, high level academic content, practice and community service, and oriented to the most demanded work opportunities. Our academic programs require a practical training component or internship in a business or manufacturing company in a field that is closely related to the field of study.

## Our Name

Aleph University takes its name from the first letter of the Hebrew alphabet, the letter Aleph, which represents unity, power, strength, and leadership. In ancient Hebrew the Aleph letter pictograph represents an Ox, which implies strength and power in the work performed. When two oxen are yoked together for pulling a wagon or plow, the older and more experienced one leads the other. Within a group or family, the leader or father is seen as the elder who is yoked to the others as the leader and teacher.

At Aleph University we follow the educational principle and method of an experienced leader guiding and inspiring a student to become a leader and professional that excels and transforms its workplace and community. The leader, instructor, or faculty member is engaged and committed to transfer knowledge to develop new leaders. The educational leader transmits success principles to Aleph students and provides opportunities for the younger ones to learn, develop, contribute, and service others.

# PURPOSE STATEMENT

Aleph University strives to provide a learning environment that is conducive to the development of students' intellectual, social, and personal growth. It encourages students to explore their interests, develop their skills, and become responsible citizens. Aleph University also seeks to foster a sense of community and collaboration among its students.

## Mission

Aleph University is committed to offering educational programs and forming strong leaders in the community through fundamentals of success, leadership, knowledge, practical experience, and service with the highest academic and ethical standards. Aleph University aims to develop skills and competencies, empowering students to enhance, excel and succeed in their professional careers, inspiring them to commit to serving with excellence and integrity.

## Vision

To create a positive impact in the community and society educating and forming strong leaders and professionals that influence and inspire others, bringing elements of change and transformation for a better place to live.

## Institutional Objectives

We strive to create an environment that encourages our students to develop their skills and knowledge, to think critically and to be socially responsible citizens. We believe that our graduates should be empowered to use their talents to make a positive difference in their communities and the world. We strive to foster:

- The transformation and the power of human quality, through ethics, social responsibility, and service to the community.

- The effort, discipline, persistence, and the transformation and development of the potential of our graduates to impact society.

- The curiosity and creativity to think outside the box with innovation and sustainability.

- The development of faculty members and the updating of educational resources.

- We are focusing on continuously developing and offering academic programs of quality and relevance that meet the needs of the communities for a positive transformation through continuous interaction with business leaders and stakeholders.

# INSTITUTIONAL PRINCIPLES

Our institutional principles represent the core values, beliefs, and practices that guide the university operations and decision-making. We aim to develop in the students the following pillars:

## EMPOWERMENT

We believe that Aleph students are individuals who will contribute to society. We are committed to fostering students' inner development by providing them with the principles and values they need to thrive and inspire others.

- We are dedicated to the transformation, inner growth, and development of each student.
- We lead by example and guidance, embracing ethical values that inspire others.
- We support our students, helping them solve challenges and overcome obstacles through mentoring and coaching programs.

## EXCELLENCE

We strive to provide a high-quality education that prepares students for success in their chosen fields.

- Our programs are created with the highest academic standards, developing a global dimension and the integration of knowledge.
- We promote a culture of learning and research that encourages critical thinking, creativity, and innovation.
- We foster the curiosity of students to think outside the box and value innovation, creativity, and sustainability in their educational process.

## COMMITMENT

As leaders of the future, we commit to creating a better world for all. We will strive to be ethical, responsible, and inclusive in our decision-making, and to promote equity and justice in our communities. We will use our influence to foster collaboration and understanding, and to create a culture of service.

- We inspire our students to contribute to their community becoming leaders of influence.
- We form strong business leaders and successful professionals, applying knowledge with high ethical values, committed to quality and excellence in everything they do.
- We believe in the capacity of our graduates to transform society. We value effort, discipline, and persistence through recognition.

# FACILITIES

Aleph University is located at 490 Sawgrass Corporate Parkway, Suite 130 Sunrise, FL 33325. The main office is easily accessible from major motorways and is close to the Fort Lauderdale International Airport. The main office can be found taking the I-595 and 869 Expressways. Both on-site and off-street parking are available. Aleph University operates Monday through Friday from 8:00 a.m. to 5:00 p.m. and on Saturdays, when weekend courses and academic activities are offered.

Our main office is comprised of four administrative offices and a conference and classroom area. A distinctive meeting room and a contemporary welcome area are both present. Large windows in the main space let in plenty of natural light, allowing guests to take in the nearby parks and modern buildings. Both staff and students will appreciate the welcoming atmosphere in the conference-room/classroom.

which includes furniture with handy charging outlets for laptops and

The online campus resources include the computer server housed in a Tier 3 data center, Learning Management Systems (LMS) and interactive tools enabling the delivery of synchronous and asynchronous sessions. Additionally, the university provides a wireless network infrastructure, and rooms are furnished with speakers, Smart Boards, and wireless technology.

## ALEPH UNIVERSITY
School ID # 12808
490 Sawgrass Corporate Parkway, Suite 130 Sunrise, FL 33325
Phone: (786) 416-5587
Web: www.alephuniversity.us
Office hours: 8:00 a.m.- 5:00 p.m.
Monday to Friday (EST)

## License and Accreditation

Aleph University is licensed by the Commission for Independent Education, Florida Department of Education, License No.12808 . Additional information of the institution may be obtained by contacting the Commission at:

## Commission for Independent Education

Florida Department of Education
325 West Gaines Street, Suite 1414
Tallahassee, Florida 32399-0400
Toll free telephone number: (888) 224-6684

Aleph University is not accredited. Accreditation is a rigorous independent review process taking from three to five years for approval depending on circumstances. Accredited universities may be entitled to offer Title IV federal financial assistance, thus Aleph does not offer Title IV assistance at this time.

## Statement of Legal Control

Aleph University is privately owned. The mailing address of this limited liability corporation is:

490 Sawgrass Corporate Parkway, Suite 130 Sunrise, FL 33325
Phone: (786) 416-5587
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# OUR METHOD

## Instructional Delivery Methods

Aleph University offers a blended instructional method with ICT mediated sessions, allowing students to access educational resources and participate in educational activities. This approach conveniently enables students to learn from any location at any time, enriching the learning process through the interaction with tutors.

The following educational methods are implemented at Aleph University:

| INSTRUCTIONAL DELIVERY METHOD | DEFINITION |
| --- | --- |
| Synchronous Online | Instructional activities are provided in online live sessions where the students interact with tutors at a scheduled day and time. |
| Asynchronous Online | Course content is delivered online with no scheduled meetings. Students study and learn the instructional material independently and autonomously. |
| Blended learning (Synchronous Online and Asynchronous Online) | According to the nature of the program and course, content will be delivered online with synchronous scheduled sessions, supplemented with additional asynchronous activities and resources. |

## Learning Methodology

Aleph University employs an active learning environment that encourages critical thinking through interaction in the learning community.

A variety of pedagogical learning scenarios are promoted, including self-study, think-pair-sharing, work in small groups, problem solving, debates and research seminars. Students can access several sources of information, learning alternatives, and activities to enhance their learning experi-

The teaching and learning approach include a traditional tutorial method enriched with practical learning approaches such as the Harvard Case Study Method and Project-Based Learning:

## 1.  Harvard Case Study Method:

This method employs discussion of real-life situations encountered by professionals in their workplace. Requires the student preparation and group work with peers.

## 2.  Project-Based Learning:

This method fosters a deep conceptual understanding of abstract concepts through class projects. Students will actively develop their understanding by learning about and applying key class concepts to solve challenging everyday problems.

## The principal instructional strategies during the teaching and learning process include:

### Critical thinking:

Students develop critical thinking skills by practicing questioning assumptions, challenge the evidence, reasoning, analyzing complex problems and arguments, consider alternative perspectives, Practice synthesizing information from multiple sources, engage in discussions with peers and instructors, explore different perspectives, and consider alternative viewpoints. Students are expected to read from various sources and critically to gain exposure to diverse ideas and perspectives.

### Ethics and service commitment:

As engaged members of society, students will demonstrate awareness of personal responsibility in our society. Service commitment refers to the duty to have a constructive influence on the society through excellence, making meaningful contributions to their fields and communities.

### Diversity:

By demonstrating their commitment to diversity, students can contribute to the creation of a more inclusive and respectful academic community and learning from the experiences and perspectives from diverse backgrounds.

## Evaluation Methods

The evaluation methods used by Aleph University, include quizzes, projects, mid-terms and final exams, as well as participation in chats and forums. The instructor's evaluation methods will be indicated on the syllabus or course outline. All exams and quizzes are administered through our password protected online platform.

Evaluation can include several types of questions such as:

- Multiple Choice
- True/False
- Matching Short Answer
- Essay, Calculations
- and project-base learning rubrics.

Aleph University expects students to adhere to the time line and retake policies provided by the course teacher in the syllabus course.

The course faculty reserves the right to allow assignment make-up and exam, assignment retakes.

# UNIT OF CREDIT

Aleph University uses the semester credit hour to ensure compliance with the credit hour requirements for awarding master's degree programs. This policy applies to all credit courses and programs offered at the University, as per rule 6E-1.003 of the Commission for Independent Education of Florida.

"6E-1.003 Definition of Terms. (…) (55) "Semester Credit Hour" means either: (a) A unit consisting of a minimum of fifteen hours of instruction appropriate to the level of credential sought, during a semester, plus a reasonable period of time outside of instruction which the institution requires a student to devote to preparation for learning experiences, such as preparation for instruction, study of course material, or completion of educational projects; or (b) Planned learning experiences equivalent to the learning and preparation described in paragraph 6E-1.003(44)(a), F.A.C., above, as determined by duly qualified instructors responsible for evaluating learning outcomes for the award of credits".

A credit hour is an amount of work represented in intended learning outcomes and verified by evidence of student achievement that is an institutionally established equivalency that reasonably approximates:

- Not less than 1 hour of classroom or direct faculty instruction and a minimum of 2 hours of out of class student work each week for approximately 15 weeks for one semester, or the equivalent amount of work over a different amount of time, or

- At least an equivalent amount of work as outlined in item above for the academic activities established by the institution including internships, practice, and other academic work leading to the award of credit hours.

## Transferring Credits

Transferability of credits refers to the process of transferring earned academic credits from one educational institution to another. The purpose of transferability is to allow students to continue their education in a different academic institution.

## Transfer in from Another College or University

To transfer credits earned from another college or university to Aleph University, a student must submit a written request to the Admissions Department (admissions@alephuniversity.us), pay the established fees (USD $250), and provide an official or certified copy of their course descriptions and transcripts, which must include unit credits and completed grades. If applicable, examinatiom of the foreign transcript could be required.

Acceptance of transfer credit is determined by Aleph University according to the following criteria:

1. **Course and Credit equivalency:**

Aleph University reviews the program outline and credit total of the previously acquired course which must have a similar content and rigor to the one offered in Aleph University. If the courses are not equivalent, the credits may not transfer.

2. **Grade requirement:**

Aleph University requires a minimum grade to transfer credits. Our Institution only accepts credits with a minimum grade of B or equivalent to a 3.0 on a scale of 4.0.

# UNIT OF CREDIT

**3.    Foreign Transcript Validation:**

The examination of the foreign transcript must be performed by a service that is a member of the Association of International Credential Evaluators (AICE), the American Association of Collegiate Registrars and Admissions Officers (AACRAO), or the National Association of Credential Evaluation Services. The student must submit an evaluation for each course taken to transfer credits from a university outside the United States (NACES).

## Transferring to Another Institution

Credit transfer between institutions is not standardized and might differ from one institution to another. The final decision regarding which credits will be recognized and used in a degree program belongs to the receiving institution. It is responsibility of students to contact the receiving institution to verify that the transfer of credits will be accepted according to the applicable credit transfer policy.

# Academic Calendar

## 2025

The Academic Calendar contains important dates for refunds, withdrawals, payment, and beginning of classes. The academic year covers a 12-month period that begins in January. Some courses might only be offered during certain terms. As some courses have prerequisites, having a course timetable is crucial to achieving academic objectives. Students should feel free to consult with advisors to assist in their educational plans.

The academic calendar includes a list of the most recognized religious holidays. However, this list is not all-inclusive; students may choose to observe a holiday from a traditionnot reflected in this list. The usual holidays consist of Independence Day, Veteran's Day, Memorial Day, Labor Day, Thanksgiving Day, Christmas holidays, Martin Luther King, Jr. Day, and a Spring Break of one week during Holy Week.

| Semester | Program | Registration | Start Date | End Date |
| --- | --- | --- | --- | --- |
| Spring 1st Term | | Continuing Registration | January 13 | March 8 |
| Spring 2nd Term | | Continuing Registration | March 17 | May 9 |
| Summer 1st Term | All Master's Degree Programs | Continuing Registration | May 19 | July 12 |
| Summer 2nd Term | | Continuing Registration | July 21 | September 13 |
| Fall Term | | Continuing Registration | September 22 | November 15 |
| Winter Term | | Continuing Registration | November 24 | January 31, 2026 |

| Academic Period | Spring 1st Term | Spring 2nd Term | Summer 1st Term | Summer 2nd Term | Fall Term | Winter Term |
|---|---|---|---|---|---|---|
| Classes Begin | January 13 | March 17 | May 19 | July 21 | September 22 | November 13 |
| Classes End | March 8 | May 10 | July 12 | September 13 | November 15 | January 31 2026 |
| Returning and New Students Registration | November 1 - January 13 | February 3 - March 17 | April 7 - May 19 | June 9 - July 21 | August 11 - September 22 | October 13 - November 13 |
| Orientation | January 13 | March 17 | May 19 | July 21 | September 22 | November 24 |
| Fee Payments | January 16 | March 20 | May 22 | July 24 | September 25 | November 27 |
| Add Courses (at or after start time) | January 13 - 23 | March 17 - 27 | May 19 - 29 | July 21 -31 | September 22 - October 2 | November 24 - December 4 |
| Deadline to Drop Courses with Refund | January 29 | April 3 | June 4 | August 4 | October 8 | December 10 |
| Reeding Week | February 17-21 | April 21 - 25 | June 23 - 27 | August 25 -29 | October 27 - 31 | December 15 - 19 |

## Statutory Holidays (no classes)

- New Year's Day: Wednesday, January 1
- Martin Luther King Jr. Day: Monday, January 20
- Memorial Day: Monday, May 26
- Independence Day: Friday, July 4
- Labor Day: Monday, September 1
- Indigenous Peoples' Day/Columbus Day: Monday, October 13
- Thanksgiving Day: Thursday, November 27
- Christmas Day: Thursday, December 25

# GRADING SYSTEM

And Progress Policy

## Grading Policy

The Office of the Registrar records student grades and gives a final report at the conclusion of each term. Grades ranging from A+ to F are used to report the standing of a student upon the completion of each course. The numeric value of each letter grade is used to calculate the Grade Point Average.

## Grading Scale

Grade Point Averages (GPA) are computed at the end of each term and on a cumulative basis. The numerical values of letter grades are:

| LETTER GRADE | 4.0 SCALE GPA | PERCENTAGE GRADE |
|---|---|---|
| A + | 4.0 | 97-100 |
| A | 4.0 | 93-96 |
| A- | 3.7 | 90-92 |
| B+ | 3.3 | 87-89 |
| B | 3.0 | 83-86 |
| B- | 2.7 | 80-82 |
| C+ | 2.3 | 77-79 |
| C | 2.0 | 73-76 |
| C- | 1.7 | 70-72 |
| D+ | 1.3 | 67-69 |
| D | 1.0 | 63-66 |
| D- | 0.7 | 60-62 |
| F | Below 60 | 0-59 |

## Grade Point Average Calculation

The GPA is calculated by multiplying the course unit value for each course by the numerical equivalent of the grade received. The total for all courses is then divided by the total number of course units taken. Aleph University uses the same grading scale for grading assignments and activities. A letter grade (A through F) is issued for every course taken and it determines the final measure of a student's performance in a specific course. Credit is granted for courses in which the student earns a passing grade (A through D-).

Only those courses for which credit is earned count towards program completion requirements. The letter grades received in each course go into the computation of a Grade Point Average (GPA).

To compute the GPA, each letter grade is assigned a number of grade points according to the Grading Policy-scale.

### To obtain the cumulative GPA:

A. Multiply grade value by the number of credits for total grade points.

B. Divide the total number of grade points by the number of credits carried. (S-U Optio grades are not calculated in the GPA.)

C. The GPA value is displayed to the hundredths place and not rounded up (i.e., 3.248 = 3.24).

### Other grades may be assigned as follows:

**Pass/No Pass (P/NP):** This grade may be assigned to some courses such as internships or seminars. Courses designated P/N do not count when computing the student's GPA.

**Withdraw Pass (WP):** It denotes a student who, at the time of withdrawal given in the course syllabus, has met the criteria for that course. When credit is awarded, the grade is not taken into account for calculating GPA.

**Withdraw Fail (WF):** Implies that the student failed the course as a result of academic dishonesty and poor performance.

**Transfer Credit (TC):** It indicates the student has transferred credits from another institution for credit toward a degree at Aleph University. Credit is awarded, but GPA does not reflect changes as it is omitted from the calculation.

**Incomplete (I):** assigned at the discretion of the instructor when the student is unable to complete course work before the end of the term because of unusual extenuating circumstances. A student who receives a "I" grade (for Incomplete) has informed the lecturer in writing. The student must complete the required final test or assignment within the first 20 days of the next term to replace the incomplete with a final grade. If not, the "I" will convert to an "F". The professor has the responsibility of removing all Incompletes.

# EMPOWERMENT

# EXCELLENCE

# COMMITMENT

ALEPH UNIVERSITY

# STANDARDS OF ACADEMIC PROGRESS

To remain in good standing, a graduate student must keep their cumulative GPA at 3.0 or higher. Students are not allowed to obtain a course final grade of less than 2.3 on more than two (2) courses. Students who fall short of minimal requirements for Grade Point Average, class completion, or coursework may be placed on academic probation (as defined hereinafter).

## Cumulative GPA for Graduation

There are minimum grade and GPA requirements for all programs according to the Minimum Grade and GPA Requirements Policy. The minimum grade requirement for graduate programs is a cumulative grade point average (CPGA) of 3.0 on a scale of 4.0 quality points.

## Satisfactory Academic Progress

Aleph University keeps track of each student's academic development to make sure that it meets degree completion requirements. Students enrolled are required to maintain the bare minimum of academic standards and a satisfactory rate of course completion. Depending on their degree plan and academic standards. Academic Progress is an overview of student program roadmap to graduation. In Academic Progress, students can check their program prerequisites, graduation requirements, courses they have taken, courses they have registered for, and courses they still need to take to finish their program of study. Only students pursuing degrees are subject to satisfactory academic progress (SAP).

Aleph University assesses academic advancement based on qualitative and quantitative standards. In the academic realm, these requirements are grade point average (CGPA), maximum program length and successful course completion rate:

**CGPA:** To graduate from a master's level program, students must obtain a cumulative grade point average (CGPA) of 3.00.

**Completion Rate:** To remain in Good Academic Standings, students must maintain a cumulative completion rate of at least 67% of all credits attempted to remain on Good Academic Standing. The completion rate is calculated by dividing the number of credits earned by the number of attempted credits.

**Maximum Program Length:** Students must finish their whole master's degree within the maximum time for finishing an academic program which is equal to finishing 1.5 times the number of credits attempted that are necessary for finishing, and it varies based on the student's particular degree of study.

## Academic Honors

To promote excellence and outstanding academic performance, the Academic Dean will recognize the following categories of academic honors for students.
Graduation honors are awarded for academic work performed by the student:

**Summa Cum Laude:** GPA 3.90 or above
**Magna Cum Laude:** GPA 3.75 to 3.89
**Cum Laude**: GPA 3.60 to 3.74

In order to receive the master's degree with distinction, a student must maintain a 3.88 or higher GPA. The notation "With Distinction" is posted with the degree on the transcript, and also appears on the diploma.

## Academic Warning

This status is assigned at the end of the term to students whose CGPA or course completion rate drops below the minimum required standards. The Academic Dean develops an Academic Success Plan for academic progress recovery. It includes specific steps such as: mandatory tutoring, scheduled periodic advising, and a smaller number of course enrollments until the CGPA and/or completion rate reaches the minimum required to be removed from the Warning status. This process must be done preferably before registering, but no later than the last day to drop/add for the next term.

Aleph University maintains the right to include or remove students from various statuses as follows:

1. Academic Warning
2. Academic Probation
3. Probation Continued
4. Academic Suspension

## Academic Probation

Academic Probation indicates that the student's performance is below the minimum standard set by Aleph University. Students who have attempted at least 3 full credit equivalents and have a cumulative GPA of less than 2.5 are placed on academic probation.

Academic probation is a warning signal. When a student is placed on Academic Probation the student may continue taking courses, according to their academic success plan, and undergo evaluation at the conclusion of their initial monitoring period. Students who improve their cumulative GPAs and completion rates to the required levels or higher will be removed from probation and placed to regular status.

## Probation Continued

A student who is on probation for an additional semester will be required to meet with the Academic Dean three times during the term to discuss if they are making an adequate progress. The student will be dismissed from the university if they do not achieve the required grade point average, satisfy the minimal completion rates during each successive semester of probation, or follow the guidelines of the Academic Success Plan.

The probationary classification ("Warning" or "Probation") will be carried over to the following term if a student in one of these categories ("Warning" or "Probation") achieves the minimum semester or evaluation grade point standard but is unable to raise the cumulative grade point average to the required level.

## Academic Suspension

An academic suspension applies after a student on academic probation or academic probation continued status does not achieve a minimum GPA of 2.0 in the most recent term. Students in the suspension term are not eligible to take courses. The duration of Academic Suspension is detailed as follows:

- 1st suspension:     4 months
- 2nd suspension:   12 months
- 3rd suspension:    Refused further registration.

The student will be dismissed from the program if the minimum requirements are not met after one semester of being on probation but may later re-enroll after a period. In addition, the student will be dismissed from Aleph University if it is ultimately determined that it is mathematically impossible for them to fulfil the minimal requirements of Satisfactory Academic Progress to graduate. Aleph University retains the ability to add or remove a student from academic monitoring based on their academic performance.

## Time Limits for Degree Completion

To graduate, students must have completed the program within 3 years of the date of enrollment for the master's degree. Students who exceed the allowed time limit must apply for readmission and will be subject to the conditions in effect at the time of their re-entry.

## Re-Entry Policy

Aleph University students must develop all coursework on schedule in order to finish their program in a reasonable time frame. To be considered a regular student, learners must enroll in at least one (1) course per term. After two consecutive terms without registering for any course, the student must pay the corresponding re-entry fee (see Student Fees & Financial Resources) and take at least one (1) course in the following term. Otherwise, the student will be considered inactive and notified of it. After three consecutive semesters without enrolling in any course, the student will be considered withdrawn.

In case of previous withdrawal by the student or the university, students who wish to re-enter must request re-entry in writing to the Academic Dean. Based on previous attendance, academic, and financial records, the petition will be examined and either accepted or denied. For re-entry the student must pay the corresponding fee and meet all the admission requirements.

Students re-entering the University will also receive an Enrollment Agreement detailing the current tuition and fee schedule at the time of re-entry.

## Mitigating Circumstances

The student is required to detail and provide proof of all the factors that affected the academic achievement in a letter. The Academic Dean must be contacted in order to request a waiver of the acceptable progress requirements. No waivers will be issued for graduation requirements.

In cases of health or family issues, or extreme events outside the student's control, the Academic Dean may grant or extend a leave of absence for up to three academic terms.

# ACADEMIC POLICIES

## Syllabus

The syllabus is a principal source of information for students. It is a guide to navigating the course successfully. Students will receive a copy of the course syllabus, course outlines, and objectives at the beginning of the program.

## Responsibilities of the students

Aleph University is committed to helping its students expand their knowledge, enrich their culture, increase their creativity, enhance their ability to think and find answers logically and analytically and become responsible citizens and leaders of their community.

To achieve our vision, Aleph University and its members must work together to maintain a respectful, healthy, safe learning, teaching, and work environment, where academic integrity is the principal guide.  It is expected that students assume the following responsibilities:

1. Participating in chats, forums, and other activities.

2. Regularly review the course outline and the informative board.

3. Read the recommended materials for every week, such as case studies, book chapters, presentations.

4. Respect the due dates for every activity and assignment. Late submissions will not be accepted, and the system automatically blocks the opportunity to send activities after their due date.

## Attendance

Students are expected to attend all classes and activities in online and blended courses throughout the academic term and are responsible for satisfying all academic objectives defined by the syllabus. In the event that a student cannot attend a scheduled activity or class, the student must contact the professor and leave a message with the student's name, the date, and the motive for why they cannot attend the class. Acceptable reasons for absence from or failure to engage in a class or activity include:

1. Illness
2. Serious accidents or emergencies affecting the student or their relatives
3. Military obligation

4.  Severe weather conditions that prevent class or activity participation
5.  Religious holidays
6.  Participation in official university activities
7.  And court-imposed legal obligations (e.g., jury duty or subpoena)
8.  Other reasons (e.g., a job interview or club activity) may be deemed acceptable if the instructor approves

For all planned absences the student must inform the professor as early as possible before the class or activity takes place. For all unplanned absences because of accidents or emergencies, students should contact their professor as soon as conditions permit.

Students shall be permitted a reasonable amount of time to make up the material or activities covered during absence from class or activity or inability to engage in class activities for the reasons outlined above. The student assumes responsibility for the work missed from non-attendance. A student presenting the professor with a documented reason for absence may be allowed to make up for missed work.

## Class Cancellation

Aleph University may cancel a scheduled class in case of extenuating circumstances. The University will provide notice of the cancellation at least one week before the first scheduled course meeting.

## Dropping, Adding, Withdrawing from Courses

Students are allowed to drop individual courses. The following policy outlines the procedures for dropping, adding, and withdrawing from courses:

## Dropping Courses:

1.  Students may drop a course without academic penalty according to the academic calendar deadlines.
2.  Failure to attend a class does not constitute a drop.
3.  After the deadline to drop a course in a term, students may still drop a course, but they will receive a "W" grade on their transcript, indicating that they withdrew from the course.
4.  Students must complete a Drop Form, which can be obtained from the Registrar's Office, and obtain approval from their academic advisor before dropping a course.
5.  Students who drop a course may be eligible for a tuition refund, according to the University's Refund Policy.

## Adding Courses:

1.  Students may add a course according to the academic calendar deadlines.
2.  Students must obtain approval from their academic advisor before adding a course.
3.  Late additions to a course may be allowed with approval from the course professor and the Academic Dean.

## Withdrawing from Courses:

1. Students may withdraw from a course after the second week of the semester and up to the last day of classes for the semester.
2. Students must complete a Withdrawal Form, which can be obtained from the Registrar's Office, and obtain approval from their academic advisor before withdrawing from a course.
3. Students who withdraw from a course will receive a "W" grade on their transcript, indicating that they withdrew from the course.
4. Students who withdraw from a course may be eligible for a tuition refund, according to the University's Refund Policy.
5. Exceptions to this policy may be made in cases of extenuating circumstances, such as a serious illness or family emergency. Students should consult with their academic advisor and the Registrar's Office in such cases.

## Leave of Absence (LOA)

A leave of absence (LOA) is a pause during an academic term or between academic terms. Students may request a LOA for a variety of reasons, including but not limited to:

- Health reasons
- Personal or family emergencies
- Military service
- Internship or co-op opportunity
- Pursuing a study abroad program
- Financial hardship

To be eligible for a LOA, students must:

1. Have completed at least one academic term.
2. Be in good academic standing.

Students who wish to take a LOA must submit a written request to their academic advisor or the Dean of Students, according to the following procedure:

- The request should include the reason for the LOA, the anticipated duration of the LOA, and any supporting documentation.

- The request will be reviewed by the Academic Dean, who will determine whether the request is granted. The decision will be communicated to the student in writing.

Students who wish to take a LOA must submit a written request to their academic advisor or the Dean of Students, according to the following procedure:

- The request should include the reason for the LOA, the anticipated duration of the LOA, and any supporting documentation.

- The request will be reviewed by the Academic Dean, who will determine whether the request is granted. The decision will be communicated to the student in writing.

- If the request is granted, the student will be required to complete any necessary paperwork, including a Leave of Absence Form.

- Students who take a LOA will have their enrollment status changed to "not enrolled" for the duration of the LOA.

- Students who wish to return from a LOA must submit a written request to their academic advisor or the Dean of Students at least 30 days prior to the start of the semester in which they wish to return.

- The request will be reviewed by the academic advisor or the Dean of Students, who will determine whether the student is eligible to return. The decision will be communicated to the student in writing.

- Students who are granted permission to return from a LOA will be required to complete any necesary paperwork and meet any conditions for return, such as meeting with an academic advisor or attending an orientation session.

- Students who do not return from a LOA by the agreed-upon date will need to apply for read mission.

- Students who take a LOA may be eligible for a tuition refund, depending on the University's refund policy.

- Exceptions to this policy may be made in cases of extenuating circumstances, such as a serious illness or family emergency. Students should consult with the Academic Dean in such cases.

# INTERNSHIPS

## Internships

Following the successful completion of all the program courses, students will be guided to participate in an internship in a business that can provide non-paid work opportunities in the students' field of study, to gain practical skills and apply knowledge.

To secure an internship, a student may apply to the prospective employer. Internships should be completed in the four months following the completion of the final semester of classes. An internship is a supervised work experience that provides students with the opportunity to gain practical skills and knowledge in their field of study.

In the event of impossibility to secure an internship, the Academic Dean will assign a project in place of the internship.

The standard internship is worth six credits. To be granted those credits, students must:

- Work at their internship for a minimum of 300 hours.

- Submit the appropriate forms to the internship coordinator.

- Perform work directly related to their field of study.

Throughout an internship, a student must submit to the internship coordinator three documents:

- The Internship Agreement Form at the beginning of the internship.

- The Internship Progress Report Form after 150 hours of work has been completed.

- The Internship Final Report Form when the internship has been finalized.

## Credits for prior learning from work experience

Aleph University may award credits for prior work experience. This needs to be evaluated by the Academic Dean and needs to align with the program objectives, contents, and level of the course that may be credited. A maximum of three (3) credits may be awarded.
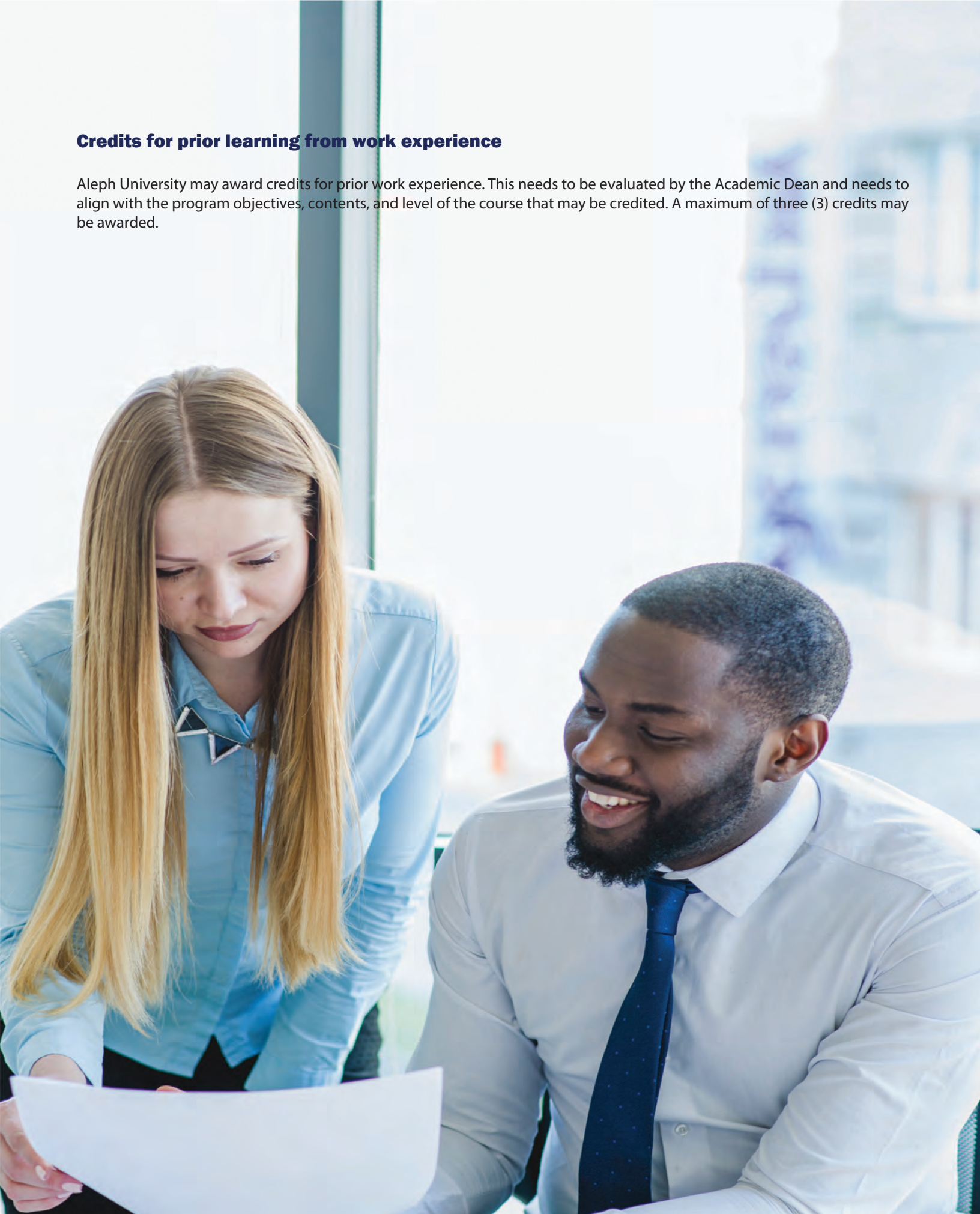
# ADMISSIONS
## Policy and Criteria

The admission criteria at Aleph University are based on the institutional mission, goals, academic merit, and the Florida Commission for Independent Education rules for the acceptance and enrollment of students in higher education academic programs. Aleph University's admissions policy assures that only students who are reasonably capable of completing and benefiting from the educational offerings are enrolled. The admissions process requires an admission interview of prospective students to evaluate their ability to achieve and benefit from the program.

## ADMISSION REQUIREMENTS

The general requirements for admission and readmission are:

- **Application:**
Online applications for admission must be received by the Admissions Department.

- **Identification document:**
Copy of a government issued identification document.

- **Fee Payment:**
A non-refundable application fee should be paid with the Admission Application.

- **Transcripts:**
Official transcripts from all attended educational institutions must be submitted according to the instructions on the application. In order to be admitted to a Masters' program, the applicant must have completed a bachelor's or under-graduate degree at a duly licensed academic institution, having obtained a minimum of 3.0 GPA. For enterance to the Master of Science in Medical Devices, Regulatory Affairs, and Health Information Technologies program, the candidate student must have obtained an engineering, science, mathematics, or technology related undergraduate degree.

- **Personal Statement:**
A statement of purpose explaining why the chosen academic program would enable the applicant to reach their career goals.

- **Interviews:**
All applicants should have an interview with the Admissions Director to get a better understanding of their interests, goals, and personalities.

## Language Proficiency Requirements

To enroll at Aleph University, prospective students whose first language is not English must possess college-level English ability. English language proficiency can be demonstrated as follows:

| Event | Date |
|---|---|
| Language Testing System (IELTS) Academic Module | The minimum requirement is an overall band of 6.5, with no band below 6.0. For information visit www.ielts.org (external link). |
| Test of English as a Foreign Language (TOEFL) | Internet-based Test or Home Edition:<br>• Minimum Requirement: total score of 92 + 20 on Writing<br>• Discretionary Range: total score 82-91<br><br>Paper-delivered Test:<br>• Results will be reviewed on an individual basis.<br>• Applicants will be notified if their discretionary range score satisfies the English language requirement. |
| **Pearson Test of English Academic Score Report** | The minimum requirement is a score of 50. |
| **Duolingo English Test** | The minimum requirement is an overall score of 120. Sub score results must be submitted.<br>For information visit:<br>englishtest.duolingo.com (external link) |

Additional ways to prove English proficiency include:

1. Students who have successfully finished four years of high school in the US or another English-speaking country.
2. Having completed 30 semester credits from an English-taught college or university that is duly accredited.
3. Proof that the applicant has completed a B-2 level course in a duly licensed university or institution.
4. Pursuing a B-2 level certification within the first two academic terms from an English language study program, such as Aleph University's English course.

## Admission Interview

An Admission Interview is conducted to assess the fit between the prospective student's career goals and the academic program learning outcomes, determining the applicant's ability to benefit from the program. Admission interviews provide the University with an opportunity to learn more about the applicant beyond the information provided in their application, as well as a chance for the applicant to gain a deeper understanding of the university and ask questions about enrollment.

## Transcripts

An official copy of the student's academic records is required during enrollment. The prospective student must submit the official academic transcript within the first academic term if it is not available at the time of enrollment. Official academic transcripts in a language other than English, should be officially translated into English.

If transcripts are not received after the enrollment agreement is signed, the student will be placed on conditional enrollment. The relevant section of the enrollment agreement, which the student must sign accepting this circumstance, shall be updated. The student must submit any outstanding documentation within the first academic term in order to be properly admitted.

The conditional enrollment condition will be removed once the required paperwork is submitted and the Director of Admissions signs the enrollment agreement to confirm that the requirement has been met.

## Notice of Admission

Aleph University will provide a notice of admission for a certain term when an admission application is accepted. After submitting all requirements, applicants will be informed of their acceptance or rejection within 3 weeks.

The University may conditionally enroll students who meet certain admission requirements but require providing additional documents or academic support. Prior to completing 9 semester credits, students must submit any outstanding documents. Failure to meet these requirements may result in revocation of the student's conditional enrollment status.

## Enrollment Agreement

Upon admission, admitted applicants will receive the Enrollment Agreement and the Academic Catalog. The enrollment agreement outlines the terms and conditions of a student's enrollment in a program or course of study. It includes important information such as the student's program of study, the cost of tuition and fees, payment options and deadlines, the start and end date of the program, and any other relevant policies or requirements.

## Visiting Students

To promote academic collaboration and enhance the educational experience Aleph University offers a Visiting Students Program, for students enrolled at another college or university interested in registering a course at Aleph University to credit it back to their college or university of origin, according to the applicable agreements meeting eligibility criteria.

## Non-Discrimination Statement

Aleph University is committed to providing a welcoming environment for all members of our community. We strive to create a diverse and inclusive academic community that values and respects all individuals. Based on the principles of non-discrimination, inclusion, and diversity, Aleph University does not discriminate against anyone because of their race, disability, national or ethnic origin, creed, color, sex, social or political condition, or religious or social trade union beliefs.

# TECHNICAL REQUIREMENTS FOR ONLINE COURSES

To ensure an optimal learning experience, our Learning Delivery Methods, such as Learning Management System (LMS) and virtual campus, the students are required to have access to a computer that meet or exceed the following technical requirements:

## Minimum Requirements for Online Learning

All learners will require regular access to a personal computer with a strong internet connection to successfully complete online courses. High speed broadband access (LAN, Cable or DSL) is highly recommended for the optimal learning experience.

## Windows PC and Mac*

- Compatible Operating System: Windows 8 or 10, OS X
- Web Browser: Firefox, Chrome, Internet Explorer 11, Microsoft Edge, or Safari
- Good hardware specifications:

    - Intel i5 or equivalent processor
    - Minimum 8 GB of RAM
    - 250 GB solid state hard drive (SSD)
    - Wireless 802.11ac
    - USB 3.0
    - Webcam and microphone

## Mobile Devices

Depending on the learning management system being used to deliver a program, students may access and interact with most course elements, such as readings, multimedia, email and discussions through tablets and smartphones. While tablets, smartphones and other mobile devices may allow for some completion of coursework, they are not guaranteed to work in all areas.

## Software

Students are given their course materials in Adobe PDF, Microsoft Office, Google files, or other appropriate formats. It is advised to have the appropriate software tools to access and take part in the various educational program.

# ACADEMIC PROGRAMS

The University follows the requirements set forth by the Commission for Independent Education. The graduate programs in Aleph University have a flexible learning model, offering opportunities to undertake research supervised by leaders in the field. Upon completion of graduate programs, postgraduate students will exhibit capacity for abstraction, analysis, and synthesis, in each research and action process in which they participate, through the application of knowledge in professional practice. The programs offered by Aleph University are offered under two schools:

## School of Basic Science and Engineering:

- Master of Science in Medical Devices, Regulatory Affairs, and Health Information Technologies (M.Sc)
- Master of Science in Regulatory Affairs and Quality Assurance in Medical Technologies (M.Sc)

## School of Business:

- Master of Science in Innovation and Entrepreneurship in Medical Technologies (M.Sc)

# School of Basic Science and Engineering

# Master of Science in Medical Devices, Regulatory Affairs, and Health Information Technologies

## Program description

The Master of Science in Medical Devices, Regulatory Affairs, and Health Information Technologies at Aleph University is a comprehensive program designed to provide students with the knowledge of a broad range of modern engineering principles to analyze and solve problems in biology, medicine and engineering, to deliver more effective and efficient medical care. Students will have the tools and knowledge they need to make a meaningful impact in the field of biomedical engineering.

The program is 30 credit hours in duration and is offered in three streams of concentrations allowing students to specialize in their chosen area of interest: Medical Devices, RA/QA, Health Information Technologies.

## Program Objective

Biomedical engineering is meant to serve society, positively affect living systems, and apply superior technology to the intricate problems of medical care and medical devices. The Master of Science in Medical Devices, Regulatory Affairs, and Health Information Technologies at Aleph University provides students with a solid education in biomedical engineering, through a combination of fundamental courses and concentrations, exercises, and research projects, graduates of the program are well-prepared to pursue careers in a variety of fields, including medical device design, pharmaceuticals, healthcare, technology, research, and academia.

Upon completion of this program, students will be able to:

- Apply expertise in engineering principles, mathematics, science to solve challenges in biology and medicine
- Design and perform biomedical engineering experiments.
- Work on the design and development of medical devices, such as prosthetic limbs, pacemakers, imaging systems, or surgical instruments.
- Design a biomedical component, technology, or device to improve health care considering all the external factors that influence the field such as the political, ethical, and social issues maintaining ethical behavior.

## Career Opportunities

Graduates of a Master of Science in Medical Devices, Regulatory Affairs, and Health Information Technologies can pursue a range of career opportunities in the field of biomedical engineering, including:

- Biomedical Engineer
- Research and Development Engineer
- Quality Assurance Engineer
- Clinical Engineer
- Product Manager
- Bio-mechanical Engineer

## Learning Outcomes

1. **Biomedical Engineering Fundamentals:** Students will be able to understand the fundamental ideas of engineering and how they apply to the design, development, and evaluation of biomedical devices and instruments used in the diagnosis, treatment, and monitoring of medical conditions.

2. **Regulatory Requirements:** Students will be able to understand the regulatory requirements for medical devices and drugs and be able to navigate the process of obtaining regulatory approval.

3. **Communication and Interpersonal Skills:** Students will be able to work and communicate in interdisciplinary teams with engineers and other healthcare professionals.

4. **Research Skills:** Students will be able to organize and carry out research projects, assess and analyze data.

5. **Professionalism and Ethics:** Students will be able understand the ethical principles and standards of conduct in the field of biomedical engineering and be able to apply these principles in their professional practice

| Track | Course Type | Code | Course Name | Credits | Pre Requisite |
|-------|-------------|------|-------------|---------|---------------|
| GENERAL REQUIREMENTS | Core | HUM 500 | ETHICS AND VALUES SEMINAR | 2 | |
| | Core | ENT 510 | LEADERSHIP, TEAMWORK AND SUCCESS PRINCIPLES SEMINAR | 2 | |
| | Core | BME 601 | MEDICAL SCIENCES | 3 | |
| | Core | BME 610 | MEDICAL PHYSICS | 3 | BME 601 |
| | Core | BME 611 | MEDICAL DEVICES | 3 | BME 601 |
| | Core | BME 700 | SPECIAL TOPICS SEMINAR | 2 | BME 601 |
| | Core | BME 710 / 720 | INTERNSHIP OR CAPSTONE PROJECT | 3 | ENT 510 |
| | Core | ENT 621 | INNOVATION AND ENTREPRENEURSHIP | 2 | BME 611 |
| MEDICAL DEVICES TRACK | Elective | BME 530 | BIOMEDICAL INSTRUMENTATION | 2 | BME 611 |
| | Elective | BME 540 | BIOMEDICAL SIGNAL ANALYSIS | 2 | BME 530 |
| | Elective | BME 630 | ENGINEERING COMPLIANCE | 2 | BME 530 ENT 621 |
| | Elective | BME 619 | CLINICAL ENGINEERING AND TECHNOLOGY MANAGEMENT | 2 | BME 530 |
| RA/QA TRACK | Elective | RAQ 520 | QUALITY MANAGEMENT SYSTEMS | 2 | |
| | Elective | RAQ 532 | PRODUCT SAFETY AND PERFORMANCE TESTING | 2 | RAQ 520 |
| | Elective | BME 611 | MEDICAL DEVICE REGULATIONS | 2 | RAQ 520 |
| HEALTH INFORMATION TECHNOLOGIES TRACK | Elective | BME 620 | MEDICAL IMAGING SYSTEMS | 2 | BME 620 |
| | Elective | BME 625 | DIAGNOSTIC ULTRASOUND INSTRUMENTATION | 2 | BME 620 |
| | Elective | BME 621 | HEALTH INFORMATION TECHNOLOGIES | 2 | BME 620 |
| | Elective | BME 622 | MEDICAL INFORMATICS, TELEMEDICINE AND E-HEALTH | 2 | BME 620 |
| | Elective | BME 627 | SCIENCE AND TECHNOLOGIES IN HEALTHCARE | 2 | RAQ 520 |

2 electives are required*

**List of Courses**

# Master of Science in Regulatory Affairs and Quality Assurance in Medical Technologies

## Program description

The Master of Science in Regulatory Affairs and Quality Assurance in Medical Technologies equips students with the knowledge and skills necessary to navigate the complex regulatory landscape and manage compliance with applicable laws, regulations, and standards in the devices and life sciences industry. The program focuses on the study of the regulatory and quality requirements related to the development, approval, marketing and manufacturing of products in various industries, such as pharmaceuticals, biotechnology, medical devices, food, and cosmetics. This program is designed to provide students with the knowledge and skills necessary to understand and comply with complex regulatory environments to ensure that products meet regulatory and quality requirements and relevant laws and regulations. Students can advance their knowledge of international regulatory affairs laws and procedures while also gaining the leadership skills necessary to succeed in the fields of regulatory science and quality assurance. The 30-credit Medical Device Regulatory Affairs stream specialization of the Master of Science in Medical Devices, Regulatory Affairs, and Health Information Technologies is available.

With concentrations on Medical Devices and Pharma, the Master of Science in Regulatory Affairs and Quality Assurance in Medical Technologies at Aleph prepares interdisciplinary professionals to address current and future challenges and opportunities in the market.

The curriculum in the Master of Science in Regulatory Affairs and Quality Assurance in Medical Technologies program includes courses that cover topics such as ethics and leadership, regulatory strategy, clinical trials, quality assurance, risk management, product development, global regulations, and statistical analysis. Students will also learn about quality management systems, validation processes, and auditing techniques.

## Program Objective

The Master of Science in Regulatory Affairs and Quality Assurance in Medical Technologies program prepares students to become leaders in the regulatory field, prepared to manage the regulatory processes required to market compliant medical devices and products, as well as to work with a government agency to assure consumer safety. The program provides students with the knowledge and skills needed to navigate complex regulatory environments, ensure compliance with applicable regulations, and maintain high-quality standards for products. Graduates of this program play a crucial role in ensuring that products are safe, effective, and meet regulatory and quality requirements.

Upon completion of this program, students will be able to:

- Recognize the legal, regulatory requirements and quality assurance procedures for all stages of devices.

- Demonstrate ability to apply guidelines and test all facets of clinical trials for devices.

- Navigate the complex regulatory landscape and manage compliance with applicable laws, regulations, and standards in the devices and life sciences industry.

## Career Opportunities

Graduates of the Master of Science in Regulatory Affairs and Quality Assurance in Medical Technologies program can pursue a range of career opportunities in the fields of regulatory affairs, quality assurance, and compliance, including roles such as regulatory affairs specialist, quality assurance manager, compliance officer, and clinical research associate. The graduates may work in a variety of settings, including pharmaceutical, biotechnology and medical device companies, government agencies, contract research organizations, and consulting firms. Some career opportunities include:

- Regulatory Affairs Specialist/Manager

- Quality Assurance Specialist/Manager

- Compliance Officer/Manager

- Clinical Research Associate/Manager

- Medical Writer

- Regulatory Consultant

- Government Regulatory Agency Staff

- Quality Control Analyst

## Learning Outcomes

1. **Regulatory Frameworks:** Students will be able to understand the laws and regulations governing the industries they are interested in, such as the Food and Drug Administration (FDA) in the United States.

2. **Quality Control and Assurance:** Students will have a solid understanding of quality systems, including the design, implementation, and monitoring of quality control measures to ensure compliance with regulations and standards.

3. **Risk Assessment and Management:** Students will be able to identify potential risks and hazards associated with the products they are working on and develop strategies to mitigate them.

4. **Project Management:** Students will be able to manage projects related to regulatory compliance and quality control, including budgeting, scheduling, and team management.

5. **Communication and Interpersonal Skills:** Students will be able to communicate effectively with diverse stakeholders, including regulatory authorities, industry professionals, and the public. Students will be able to write clear and concise scientific and technical documents, including regulatory submissions, reports, and standard operating procedures.

6. **Ethics and Professionalism:** Students will be able understand the ethical principles underlying regulatory affairs and quality assurance and demonstrate professionalism in their interactions with stakeholders.

| Track | Course Type | Code | Course Name | Credits | Pre Requisite |
|---|---|---|---|---|---|
| GENERAL REQUIREMENTS | Core | HUM 500 | ETHICS AND VALUES SEMINAR | 2 | |
| | Core | ENT 510 | LEADERSHIP, TEAMWORK AND SUCCESS PRINCIPLES SEMINAR | 2 | |
| | Core | RAQ 500 | INTRODUCTION TO REGULATORY AFFAIRS | 2 | |
| | Core | RAQ 510 | PHARMACEUTICAL AND MEDICAL DEVICE REGULATIONS | 2 | RAQ 520 |
| | Core | RAQ 520 | QUALITY MANAGEMENT SYSTEMS | 2 | RAQ 500 |
| | Core | RAQ 530 | RISK MANAGEMENT | 2 | RAQ 520 |
| | Core | RAQ 532 | PRODUCT SAFETY AND PERFORMANCE TESTING | 2 | RAQ 520 |
| | Core | RAQ 600 | MEDICAL PRODUCT DEVELOPMENT PROCESS | 2 | RAQ 520 |
| | Core | RAQ 514 | MEDICAL PRODUCT LABELING REGULATIONS | 2 | RAQ 520 |
| | Core | RAQ 710 / 720 | INTERNSHIP OR CAPSTONE PROJECT | 2 | |
| MEDICAL DEVICE TRACK | Elective | BME 611 | MEDICAL DEVICES | 2 | RAQ 500 - RAQ 520 RAQ 530 |
| | Elective | BME 630 | ENGINEERING COMPLIANCE | 2 | RAQ 520 - RAQ 530 |
| | Elective | RAQ 610 | DESIGN CONTROLS | 2 | RAQ 520 - RAQ 530 |
| | Elective | RAQ 620 | MEDICAL DEVICE REGULATIONS | 2 | RAQ 520 - RAQ 530 |
| | Elective | RAQ 630 | 510(K) PREMARKET NOTIFICATION PROCESS | 2 | RAQ 620 - RAQ 610 BME 630 - BME 611 |
| PHARMACEU-TICAL TRACK | Elective | RAQ 640 | PHARMACEUTICAL REGULATIONS | 2 | RAQ 500 - RAQ 510 |
| | Elective | RAQ 645 | CLINICAL DEVELOPMENT OF DRUGS AND BIOLOGICS | 2 | RAQ 500 - RAQ 510 |
| | Elective | RAQ 650 | BIOSTATISTICS AND CLINICAL TRIAL DESIGN | 2 | RAQ 500 - RAQ 510 |
| | Elective | RAQ 655 | FOOD REGULATIONS | 2 | RAQ 500 - RAQ 510 |
| GENERAL | Elective | RAQ 660 | REGULATORY WRITING AND COMMUNICATION | 2 | RAQ 640 - RAQ 645 RAQ 650 - RAQ 655 |
| | Elective | RAQ 665 | POST MARKET SURVEILLANCE AND ADVERSE REPORTING | 2 | RAQ 640 - RAQ 645 RAQ 650 - RAQ 655 |
| | Elective | RAQ 670 | CLINICAL EVALUATION PLAN AND REPORTING | 2 | RAQ 640 - RAQ 645 RAQ 650 - RAQ 655 |
| | Elective | BME 627 | SCIENCE AND TECHNOLOGIES IN HEALTHCARE | 3 | |

# List of Courses

# School of Business

# Master of Science in Innovation and Entrepreneurship in Medical Technologies

## Program description

In the Master of Science in Innovation & Entrepreneurship in Medical Technologies, students will be prepared, led, and assisted to achieve their goals, whether they are interested in launching their own startups or becoming an organization's chief innovator. With a focus on teamwork, product launches, and new business ventures, Aleph University promotes the knowledge, wisdom, and innovative attitude necessary to see possibilities, make connections, and use technology to create lasting solutions.

Students who enroll in this program will develop their innovative, and entrepreneurship skills. Students who complete this program will have in-depth knowledge and applicable experience in cutting-edge innovation and entrepreneurship with a focus in technology-based ventures.

The Master of Science in Innovation & Entrepreneurship in Medical Technologies is 30 credit hours in duration and is offered in three concentrations: Biomedical Startups, Entrepreneurship, New Technology Startups.

## Program Objective

Empower students to become world-leading entrepreneurs and build and manage successful technology-based businesses. Through fundamental courses and concentrations, students will have the skills and knowledge to develop their own innovation initiatives, to take on the challenges of an ever-evolving business landscape, helping students to innovate in their professional fields.

Upon completion of this program, students will be able to:

- Developing practical skills such as business planning, financial management, marketing, and leadership.

- Developing an entrepreneurial mindset and recognize global opportunities.

- Apply methodologies Lean Startup and Design Thinking Innovation.

- Provide students with a deep understanding of the entrepreneurial process, including the stages of ideation, validation, and commercialization.

- Analyze and evaluate market trends and develop strategies to address market needs.

## Career Opportunities

Graduates of a Master of Science in Innovation & Entrepreneurship in Medical Technologies can pursue a range of career opportunities in the fields of innovation and entrepreneurship, including:

- Startup Founder/Entrepreneur
- Innovation Manager
- Business Consultant
- Social Entrepreneur
- Product Manager
- Marketing Manager
- Project Manager
- Innovation Policy Advisor

## Learning Outcomes

1. **Innovation and Entrepreneurship:** Students will be able to understand the nature and process of innovation, including how to identify opportunities for innovation, develop innovative ideas, and evaluate their potential, understanding the principles of entrepreneurship, including how to develop business plans, raise capital, and manage a startup venture

2. **Design Thinking:** Students will be able to apply design thinking methods to the process of innovation and entrepreneurship, including problem identification, ideation, prototyping, and testing.

3. **Market Research:** Students will be able to conduct market research, analyze market data and trends, customer needs, and use this information to develop products and services that meet customer demands.

4. **Financial and Business Management:** Students will be able to understand the financial and business management principles necessary for successful entrepreneurship, including financial analysis, accounting, and business strategy.

5. **Communication and Interpersonal Skills:** Students will be able to communicate effectively with customers, investors, and other stakeholders, and work collaboratively in interdisciplinary teams.

6. **Professionalism and Ethics:** Students will be able understand the ethical principles and standards of conduct in the field of innovation and entrepreneurship and be able to apply these principles in their professional practice.

| Track | Course Type | Code | Course Name | Credits | Pre Requisite |
|---|---|---|---|---|---|
| FOUNDATION | Core | HUM 500 | ETHICS AND VALUES SEMINAR | 2 | |
| | Core | ENT 510 | LEADERSHIP, TEAMWORK AND SUCCESS PRINCIPLES SEMINAR | 2 | |
| | Core | ENT 710 | NEW VENTURE CREATION AND DEVELOPMENT | 3 | |
| | Core | ENT 620 | ENTREPRENEURIAL FINANCE | 2 | ENT 710 |
| | Core | ENT 730 | ENTREPRENEURIAL BUSINESS STRATEGY | 3 | ENT 710 |
| | Core | ENT 735 | DESIGN THINKING AND INNOVATION | 3 | ENT 710 |
| | Core | ENT 750 | PRODUCT DEVELOPMENT | 2 | ENT 735 |
| | Core | ENT 710 / 720 | INTERNSHIP OR CAPSTONE PROJECT | 3 | |
| ELECTIVES | Elective | ENT 700 | BIOMEDICAL STARTUPS: FROM IDEA TO EXIT | 2 | ENT 710 |
| | Elective | ENT 630 | LEGAL ISSUES FOR ENTREPRENEURS | 2 | ENT 710 |
| | Elective | ENT 681 | LEADERSHIP AND NEW VENTURES MANAGEMENT | 2 | ENT 710 |
| | Elective | ENT 682 | ENTREPRENEURIAL MARKETING | 2 | ENT 710 |
| | Elective | ENT 683 | INNOVATION AND SUSTAINABILITY | 2 | ENT 620 |
| | Elective | ENT 684 | INTERNATIONAL ENTREPRENEURSHIP | 2 | ENT 681 |

# Student Fees & Financial Resources

## Student Fees

The amounts listed below are an estimate of costs for the 2024 academic year. The cost of the academic term may vary depending on the registered credit hours.  The fees are not refundable after the term's refund date.

| Fees | Cost (Per Term US) | Description |
|---|---|---|
| Application | $ 90 | Non -refundable |
| Credit Hour cost | $360 | Per Credit Hour |
| Total tuition estimate | $10,800 | Master program (30 credit    hours) |
| Technology  Fee  estimate | $ 200 | Refundable |
| Total Budget estimate | $ 11, 090 | |

## Other Fees

If a student registers after the regular registration deadline, the student will be assessed a Late Payment Fee.

| Other Administrative Fees (when applicable) | US |
|---|---|
| Transfer Credit Evaluation | $ 250 |
| Re -entry Fee | $ 100 |
| Late  Payment fee | $ 100 |
| Change of Program Fee | $ 100 |
| Official Academic Transcript | $ 35 |
| Graduation Fee | $ 300 |
| Replacement/Duplicate Diploma | $ 100 |

## Payment Policy

### Pay in full

Before the stated payment deadline, the entire amount due for the academic term must be paid.

### Payment plan

Students can benefit from a payment plan to cover tuition costs and fees, with a minimum non-refundable deposit payment of 50% of the tuition cost and fees per term prior to the first day of the academic period. The payment plan is an agreement that allows students to defer the payment of the remaining balance in up to two (2) instalments. The last instalment must be paid until maximum eight (8) weeks after the start of the term. The dates for the scheduled instalments are defined according to the applicable payment plan.

Students will be permitted to register and keep their registration for the whole term if the payment plan is in good standing. Classes and services might be suspended due to a missing payment. If a student is late paying their remaining balance or an installment, they will be assessed a Late Payment Fee.

Students must follow the conditions and payment amounts outlined in the payment plan schedule. In case of having any questions or issues, students may email to admin@alephuniversity.us

## Payment options

Tuition and fees payment methods include credit and debit cards, money order, personal check, wire transfers, and cashier's check.

Tuition and fees payment methods include credit and debit cards, money order, personal check, wire transfers, and cashier's check.

If a student's financial obligations are in default (defined by not paying a financial obligation within 30 days of the due date), ALEPH UNIVERSITY may declare the entire balance due without further notice and require full payment immediately.

In the event a student account is delinquent, ALEPH UNIVERSITY, as well as outside agencies working on its behalf, have the right to communicate with the student via email and/or phone regarding an outstanding balance. When an account is turned over for collection, the student is obligated to pay collection expenses.

## Scholarships

Aleph University may grant a partial scholarship to a limited number of graduate applicants. To recognize academic achievement, involvement in the community, leadership, volunteer work, and in some situations, to help with financial need. The applicant must adhere to the following conditions to apply:

- Aleph University established admissions standards.

- Give details about his or her yearly household income.

- Submit two (2) letters of recommendation from people who are not family or close friends.

- Send in a 500–800 word autobiographical essay outlining your educational background, career experience, and aspirations for the future.

The scholarship committee will assess essays on the basis of their originality, composition, clarity, argument, and topical relevance and will determine the percentage of the awarded scholarship, if applicable. The scholarship granting process is at the total discretion of Aleph University. The recipients selected will be notified in written form via email.

In order to keep the scholarship, the student must adhere to all University rules and policies, maintain a cumulative grade point average (CGPA) of 3.7 and be in good financial standing for any fees and tuition costs not covered by the scholarship.

## Cancellation & Refund Policies

Aleph University follows the Commission for Independent Education rule paragraph 6E-1.0032(8)(l), F.A.C. and subsection 6E-1.0032(6), F.A.C. ), which determines refund policies.

If enrollment for a course is insufficient to cover the costs associated with offering it, Aleph University maintains the right to cancel it. In this scenario, the student will receive a full refund of the tuition and refundable fees they paid for enrollment in the individual course. While students are still enrolled, a program will not be canceled by the University.

## Withdrawal by the Student

Any cancellation or withdrawal must be made by contacting Aleph University by email to admin@alephuniversity.us

Aleph University charges Tuition per term. If a refund is requested within the first seven (7) calendar days of signing the enrolment agreement, a full refund of all paid tuition fees is granted. After seven (7) calendar days no refund is granted.

Payment of all refunds shall be made within 30 calendar days of the date the refund request has been approved.

## Termination by the University

Aleph University has the right to terminate any student's enrollment if they violate the Catalog rules, laws, and regulations regarding satisfactory student development, student integrity, or academic honesty.

## Complaints Procedure

Aleph University is continuously improving the student experience and services. The University receives and responds to the students' concerns and complaints of in a timely and constructive manner. A student may use this approach if they believe that a choice or action that negatively affects them personally is unlawful, unfair, or creates unreasonable difficulties.

Only students who are actively enrolled are covered by these complaint procedures. Complaints made verbally, anonymously, or on behalf of another student will not be treated formally and in accordance with established processes. Students may report complaints concerning:

a.  A decision made by Aleph University affecting students.

b.  Learning procedures involving quality, grading and availability of supplies.

c.  The quality, timing, and pertinence of services received by students.

d.  Wrongful conduct by a student or staff member.

e.  Denied didactic services as stipulated in the enrollment agreement.

f.  Lack of appropriate notifications.

g.  Violation of student rights.

h.  Other not enlisted which impacts the student and may be deemed responsibility of Aleph University.
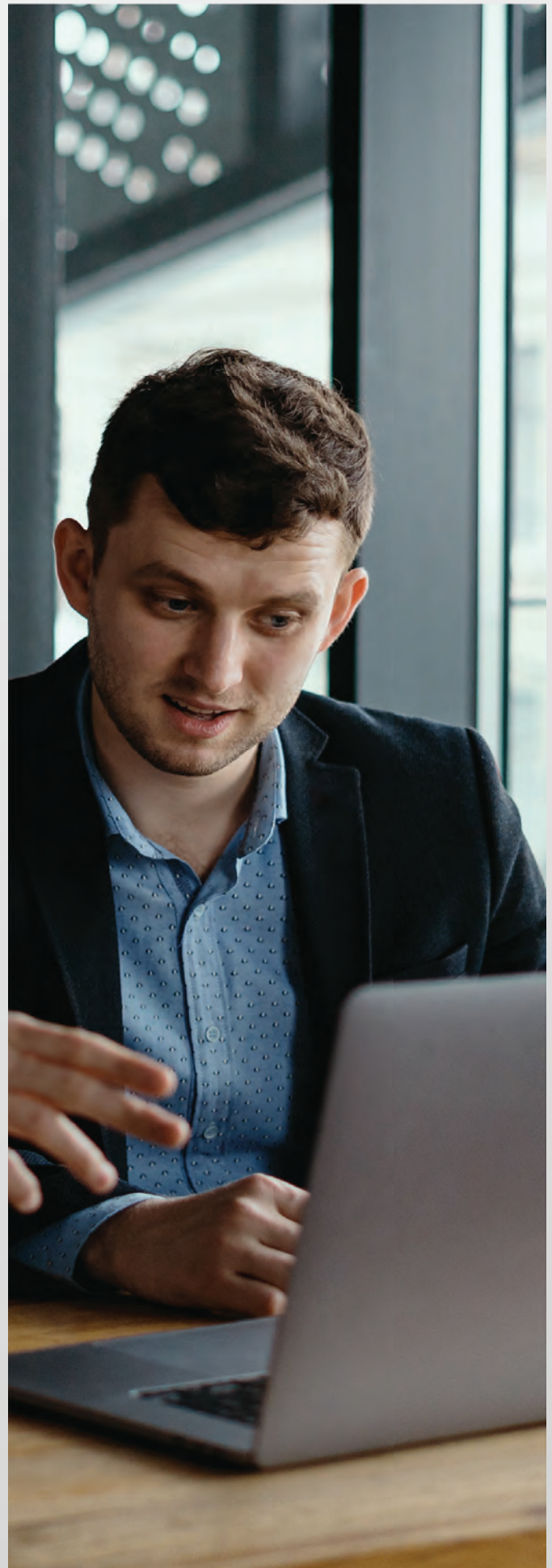
## Procedure

### 1.    Academic complaints:

Students must first communicate their concerns about their grades to the course professor, who must respond to the student within five business days. If the professor is not able to resolve the student's complaint, the professor, will submit the complaint to the Academic Dean, in writing. The Academic Dean must deliver an answer to the student's complaint within 10 days.

### 2.    Administrative complaints:

The student must fill the complaint form, including the student's contact information (phone number, email, and address), by directing an email to admin@alephuniversity.us attaching the complaint form. The complaint should describe the alleged act or condition in detail expressing how it affects the student. The designee of the unit from which the complaint originated will assess the complaint and answer the student in writing in a period of 15 business days. This timeline may be extended if the situation requires so.

### 3.    General complaints:

In case of complaints of other nature, students should address them in writing by directing an email to the Academic Dean at academic@alephuniversity.us. The Academic Dean examines the information considering Aleph University policies and regulations to define a course of action. The reply to the complaint is sent to the student and recorded in the student file. A student complaint log is used to record the complaints.

In case the Academic Dean is incapable of resolving the student's appeal, the Dean will refer it to the President. The President must offer the student an answer within 15 business days. If the President is not able to resolve the appeal, the President will refer it, in turn, to the Board of Directors. The Board of Directors must offer the student an answer within 15 days which will be the final decision.

After exhausting all other avenues in the procedure, students can submit their complaints/grievances to the Commission for Independent Education, as the last resource:

Commission for Independent Education
Florida Department of Education
325 West Gaines Street, Suite 1414
Tallahassee, Florida 32399-0400
Toll free telephone number: (888) 224-6684

## Key principles in dealing with Student Complaints

The key principles resolving Students Complaints are based on principles of natural justice, as follows:

a.  Aleph University will act fairly and reasonably in all circumstances.

b.  Aleph University will follow its own procedures in all circumstances, except where reasonable amendments are necessary, provided they do not cause prejudice to the parties and continue to result in a fair process.

c.  Decisions will be taken on the balance of probabilities.

d.  Complainants will not suffer any disadvantage or recrimination as the result of making a complaint in good faith.

# Student Code of Conduct

Upon enrollment at Aleph University, each student agrees to comply with its institutional policies and regulations. Students are expected to maintain high standards of conduct responsibility fostering civility and promoting the safety of the community.

## Standards of Student Conduct

Aleph University has defined standards of conduct to make sure that the exercise of one's rights does not trespass the rights of others or the community. Are duties of the students: the consistent attendance to class, the respectful interaction with student colleagues, and university staff, and fulfillment of assignments and projects.

The behaviors listed below will not be tolerated:

1. Unauthorized use of any institutional resources, or properties including the institution name, logo, or seal.

2. Commercial usage of course material. Selling, preparing, copying, or distributing for any commercial purpose course lecture notes, video or audio recordings unless authorized by the institution in advance in writing.

3. Copyright Violation. Federal copyright law restricts the use and/or distribution of copyrighted video and audio recordings without appropriate licenses.

4. Unapproved work publication. To openly publish work completed at or for Aleph University from the end of the student's final term of study.

5. False or Misleading Information. Providing false, misleading, or else deceitful information to Aleph University or concerning it to others.

6. Contracting on Behalf of Aleph University. Any attempt to enter a contract on behalf of the University without appropriate approval.

7. Disruptive Conduct. Obstruction or disturbance of teaching, research, administration, disciplinary procedures, or other University events.

8. Bribery. Giving, offering, promising, requesting, accepting any financial or other benefit with an intention to affect the execution of any act or omission.

9. Disorderly Conduct. Disrespecting instructors or students verbally or by writing. Disrespect through insubordination (defiance of authority or denial to obey class rules).

10. Unsuitable attire. Failure to wear suitable clothing which complies with decent dress standards. Students and/or guests may be required to leave University property or University sponsored events for failure to comply with this regulation.

11. Stalking/cyberstalking behavior. Constantly engaging in conduct directed at another person causing a credible threat with the intent to place that person in reasonable fear for his or her safety, or the safety of his or her family.

12. Sexual harassment: unwanted sexual advances, requests for sexual favors, or any other conduct of a sexual nature that is unwanted and creates a hostile or intimidating learning environment. In the event of reports of any such conduct the institution will carry out the required investigation and respond with the necessary measures including disciplinary action up to and including termination or expulsion.

## Academic Misconduct

Adherence to acceptable standards of academic honesty is an essential aspect of the educational process. Students must guarantee that all coursework, such as exams, assignments and other, are personal and original work done in accordance with adequate academic practices. Students who commit acts of academic dishonesty, also known as cheating, will be subject to disciplinary action. Cheating includes, but is not limited to, the following:

1. Taking a test or examination for another student or having a student take a test or examination on one's behalf.

2. Obtaining answers to test/examination questions through unauthorized materials, unauthorized information or from another student.

3. Submitting the same work previously presented for grading in another course without the professor's knowledge and/or permission.

4. Obtaining a test/examination, in whole or in part, in advance of its administration, without the professor's permission.

5. Altering grades or answers on an assignment to regrade.

6. Forging a signature or altering an assessment or report.

7. Failing to follow the instructions of the professor or proctor concerning test-taking practices.

## Policy and Penalties for Academic Misconduct

Depending on the nature and extent of the act of the fault, disciplinary actions can be imposed. These include, but are not limited to, the following:

1. Failing grade given for the test/examination with no opportunity to re-write it. This may cause them to fail the course. This penalty will be imposed following consultation with the program coordinator.

2. Requirement that the student completes a coach session on ethics for Academic Integrity.

3. Immediate suspension from the program for a period of not less than the end of the current term in which the student is registered. This penalty will result in automatic failing grades in all courses the student is registered for, and no fees will be refunded for that term. This penalty will only be imposed with approval of the Academic Dean of Aleph University.

4. Expulsion from Aleph University resulting in a permanent notation on the student's record. This penalty will result in automatic failing grades in all courses the student is registered for, and no fees will be refunded for that term. Infringement of local, state, or federal laws while enrolled in the University may result in immediate dismissal of the student responsible. Students expelled from Aleph University will not be allowed to re-apply.

5. A track record of any disciplinary action taken because of an act of academic dishonesty will be kept on the student's file in the Registrar's Office. Records will be held intact for five (5) years following the student's last academic activity.

# Student Identity Verification Policy

Aleph University has established a process to authenticate identities in compliance with the provisions of the United States Federal Higher Education Opportunity Act, regarding the verification of student identity in distance learning, to ensure that the student who has been admitted to the University is the same person who participates in, completes, and receives credit for the programs. For this purpose, Aleph University may choose one or more of the following methods:

1. Secure login with username and password
2. Proctored examinations
3. New or emerging technologies and practices that are effective in verifying student identification.

## Verification Process

The student identity verification process ensures that the enrolled students are taking online courses and exams in a secure and honest manner, it involves the following:

**1. Initial Verification:** Applicant students must provide basic information such as their name, date of birth, and Social Security number (SSN) or other government-issued identification number.

**2. Authentication:** Upon admission, students will be required to authenticate their identity using a secure login and password or other authentication method such as multi-factor authentication for the learning management system (LMS) and required platforms. Students are responsible for maintaining the security of their username, password, and other access credentials. The University will provide instructions on how to set up and use these authentication methods.

**3. Synchronous interaction:** Through this interaction via videoconference, the identity is verified and validated for participation in courses requiring synchronous interaction.

**4. Proctored Exams:** To ensure the integrity of online exams, the University may require proctored exams for certain courses. Proctored exams can be conducted either online or in-person at an approved testing center. Online proctoring may involve the use of video monitoring, audio monitoring, and screen sharing to ensure that the student is not cheating.

**5. Student Conduct:** Students must abide to Aleph University code of conduct. This includes provisions regarding on academic dishonesty, plagiarism, and other forms of academic misconduct. Students who violate the code of conduct may be subject to disciplinary action, which could include revocation of their student status.

**6. Data Privacy:** The verification process must comply with federal and state laws regarding the privacy and security of student data. This includes the Family Educational Rights and Privacy Act (FERPA), which requires that student records be kept confidential and secure. and any other applicable laws or regulations regarding the confidentiality of personally identifiable information, and Aleph University's Privacy Policy.

# Privacy Policy

Aleph University is committed to respecting student's privacy and protecting their personal information. The Privacy Policy describes the policies and procedures regarding the collection, use, and disclosure of personal information when using our website, applications, and services.

The University may collect personal information when students apply for admission, register for classes, or sign up for our newsletters. The collected personal information may include name, address, phone number, email address, date of birth, Social Security number, academic records, and other information relevant to the academic or administrative interaction with the University. The University may also collect certain information automatically when visiting our website or use our services, such as IP address, browser type, device type, and operating system, this information is used to improve our services and to provide a better user experience.

The University takes reasonable measures to protect the confidentiality of disclosed personal information. Aleph University complies with the Family Educational Rights and Privacy Act (FERPA), a Federal law designed to protect the privacy of a student's education records, including academic, financial, and financial aid records. This law protects personal information from being distributed to third parties without your consent unless permitted by law. Accordingly, FERPA regulation requires a Student to expressly authorize the Institution, in writing, to disclose their education records and the personally identifiable information therein to third parties. This form must be completed and returned to the University before any information can be released to a third party (i.e., spouse, employer, etc.). This form remains on file with the University.

Aleph University may update this Privacy Policy. The updated Privacy Policy will be posted on the website with the effective date.

Students can contact us at admin@alephuniversity.us in case they have any questions or concerns about the Privacy Policy.

# Graduation Process

The process through which a degree is granted to students is called the Graduation Process, and it might take two months. To start this degree conferral process, students must formally apply to graduate by filling out an application form and paying the required Graduation Fee (see Student Fees & Financial Resources) as soon as the term in which they intend to graduate opens.

## Graduation Requirements

Aleph University students must begin the Graduation process by filing a Petition for Graduation and must successfully fulfil the following requirements:

1. Complete all the required courses for their degree program.
2. Complete the language requirement as specified on the language track.
3. Earn a cumulative GPA of at least 3.0
4. Fulfil all financial obligations to Aleph University.

Students are responsible for making sure that the Academic Dean and Registrar offices have received all necessary paperwork. A student's graduation date could be postponed until the conclusion of the next term if all graduation requirements are not met.

## Graduation Ceremony & Degree

### Graduation Date

Professional programs will use the date of their official commencement ceremony as the date of graduation. This date will appear on both the transcript and diploma as the official date of graduation, as required by professional accreditation guidelines.

### Graduation Ceremony

Students who wish to have a graduation ceremony can opt to come to the Aleph University offices for a private graduation ceremony. If for any reason a degree needs to be reprinted due to loss, etc. there is a fee for replacement (see Student Fees & Financial Resources).

# Diplomas
# Student Acknowledgement

According to the Department of Education, the Commission for Independent Education of the State of Florida has granted Aleph University under license #12808 approval to offer master's programs and award the pertinent diplomas. Since every nation has its own laws and regulations which control educational matters, Aleph University disclaims any responsibility for the non-acceptance, validation, homologation, or equivalence of issued diplomas, outside of the United States of America. Students may request from Aleph University transcripts and diplomas authenticated by the State of Florida with the apostille.

Upon the conclusion of a Master's program last term, Aleph University posts final grades that determine whether a student has met the academic requirements to graduate and obtain a diploma. If there are no financial holds, the Office of the University Registrar will process diplomas for students graduating in the respective term after the degree is posted to the student´s transcript.

## Certified Electronic Diploma

It is an official and secure electronic version of the AU original paper Diploma (signed and certified PDF) used for easy verification purposes. Students may order an eDiploma (usually available 4 weeks after graduation) for a one-time charge. The eDiploma can be shared digitally with prospective employers and uploaded to employment networking sites.

# Student Services

Aleph University services assist students in succeeding academically and personally by providing them with the resources and support they require to overcome academic challenges that may arise during their completion of their programs. Furthermore, these services can assist students in developing important skills such as time management, study skills, and leadership skills, which can be beneficial both during and after their academic careers. The following student services are provided by Aleph:

## Academic Advising

Aleph University assists students in personal and professional self-realization, which leads to the success of future leaders. Aleph is committed to providing quality academic advising, support, and assistance to students in achieving their educational goals and resolving challenges through Orientation and Counseling, based on the pillars of caring, commitment, empowerment, inclusivity, integrity, professionalism, and respect.  Explore Aleph University supports below:

## Mental Health and Wellbeing

Counseling Services provides free, caring, confidential, professional assistance for a wide range of personal and mental health issues, including anxiety, depression, relationships, emotional distress, and loneliness. There are numerous ways to get help:

- **Individual Online Consultations:**

Individual sessions may be recommended by the counselor as part of the student wellness plan. Students can talk to a counselor during these sessions for short-term support to help them thrive as learners.

Students are encouraged to evaluate their own self-care, considering how healthy habits are present in their lives. Exercise, healthy eating, healthy sleeping, fulfilling social activities, mindfulness practice, time management, and other stress-management tools are promoted.

## Career Counseling

Students can benefit from career counseling to help them chart a career path. Aleph University's team of trained professionals can assist students who are unsure about their Master of choice, are unsure about their career goals, or are thinking about switching programs to ensure a successful professional career outcome.

Aleph University can assist students in the following ways:

- **Current and Recent Students.** Full career counseling services are available only to students who have been enrolled in a Master. Students must make an appointment with a Counselor through the Academic Advising Department.
- **Future Students:** Individuals who are considering enrolling in a Master at Aleph University and would like assistance selecting an option can schedule a 30-minute information session with a career advisor.
- **Student Orientation:** New students must attend Orientation, where they will discuss their personal goals, course requirements, and receive advice from university officials. Students must:

1. Finish the student Academic advising orientation prior to their first term of enrollment.

2. Keep access to the university email account and read official university correspondence sent to this address.

3. Consult with an advisor upon admission to a program at Aleph University.

4. Seek advice if they are having academic difficulties to avoid academic probation or off-track status, or to understand their options if they are already on probation or off-track.

5. Keep their own personal academic records, such as transcripts, degree audits, transfer work evaluations, and notes from previous advising sessions.

## 2. Student Representative

A Student Representative reflects the interests of students by first listening to peers' ideas, problems, and insights. They participate in student forums to identify issues to escalate to their program leaders.

They also serve on management-level committees and ensure that students are involved in all major decisions. The Academic Dean, in collaboration with professors, appoints the Student Representative for a two-year term.

## 3. Study Skills Lab

Aleph University provides Study Skills Lab to help students develop and strengthen fundamental study skills. Students can access these resources online in the Moodle Platform, where they will receive top tips, videos, and exercises for mastering key topics such as time management, stress management, studying and test-taking, reading and note-taking, presentation skills, resilience, and sleep.

## 4. English Lab

For all students requiring English as a second language, Aleph University provides the English Lab, where coaches assist students in learning the fundamentals of the language, including reading, speaking, and comprehension, at low cost - individual and small group - online classes. Students must make an appointment with the Academic Advising Department to access this service.

## 5. Online and Educational Resources

Aleph University offers a variety of online and educational resources for master's students to help them improve their knowledge and skills. Some of our resources are as follows:

**1.Moodle:** To find student's course outlines, learning materials, assignments, and email. Aleph students may also participate in interactive quizzes, virtual discussions, collaborate on projects, and receive feedback from instructors through online communication tools such as email, forums, video conferencing, recordings, presentations, among others.

**2.Library databases:** Aleph University provides online access to Aquinas Online library databases. Aquinas is a leading and major provider of library that offers an extensive selection of e-books, articles, research materials, and academic journals, magazines, and other content in a variety of fields, allowing students to stay up to date on the most recent research and developments.

**3.LinkedIn Learning:** Aleph University offers access to LinkedIn Learning, an online learning platform that improves student outcomes and provides online learning opportunities for faculty and staff in areas such as business, technology, and creative skills.

## E-Library Service

A complete e-library service is available at our website using student credentials to login. The "Online Catalog" facilitates the consultation of textbooks that are part of the National System of Libraries. The resources of e-Library comprise the most up-to-date databases. Students can access academic documents through interlibrary agreements, open access initiatives and shared repositories that are visible from the "E-Library" web page.

# Career Services

Aleph University's Career Services Department assists students and graduates in preparing for job and career success. Students benefit from the ability to learn as much as possible about the profession for which they are preparing. Graduates and alumni can benefit from assistance with job searches, promotions, and dealing with layoffs. Employers benefit from graduates who are ready to work. The Admissions Department maintains current information about the job-search process, services, and placement success.

## Our Career Services leaders can assist students in the following areas:

1. Career counseling and coaching: One-on-one sessions with a career counselor are available to assist students and alumni in exploring career options, identifying their strengths and weaknesses, and developing a career plan.

2. Resume and cover letter assistance: Career services may provide workshops or individual appointments to assist students and alumni in creating effective resumes and cover letters.

3. Job and internship search assistance: Career services can assist students and alumni in their search for job and internship opportunities. Job search workshops, career fairs, and networking events may be included.

4. Interview preparation: Career services may offer resources and assistance to students and alumni to help them prepare for job interviews, such as mock interviews and interview coaching.

5. Workshops on career development: Career services may provide workshops and events to assist students and alumni in developing skills such as networking, professional communication, and leadership.

6. Employer connections: Career services may have relationships with employers and organizations that can help students and alumni connect with potential job or internship opportunities.

Aleph University makes no guarantees about job placement. Graduates may face employment barriers due to language barriers, market constraints, and other economic factors.

**DISCLOSURE: COMPLETING A COURSE OR PROGRAM IN A LANGUAGE OTHER THAN ENGLISH MAY REDUCE EMPLOYABILITY WHERE ENGLISH IS REQUIRED.**

# Support Services

## Accessibility

At Aleph University, accessibility is fundamental to our commitment to caring, supporting, and respecting every community member. The student requiring individualized attention should contact the Office of Student Services of Aleph University, stating their unique requirements to be considered. Aleph University provides students with disabilities programmatic and physical access in compliance with section 504 of the Rehabilitation Act of 1973, as amended, the Americans with Disabilities Act of Amended, of 2008, and the Rehabilitation Act Amendments of the Workforce Invesment Act of 1998.

Since Aleph University is an online institution, we do not have to provide physical accommodations. We do, however, support students with disabilities through the Academic Committee, who assesses the student's needs and recommends an appropriate study plan tailored to each individual case. Furthermore, the professor is informed in writing of the student's disability and the suggested actions to take so that the student can achieve his/her learning objectives. A copy of all issued communications will be kept in the student's file.

There are various challenges that users with an impairment might experience while accessing their educational online program:

- **Visual:** Visual impairments can be partial or full blindness, color blindness, cataracts or age.

- **Mobility and dexterity:** In case of web users these impairments relate to movement and control that affects using mouse or keyboards due to limited movement, shakes, difficulty holding a mouse or difficulty with fine control, missing a limb.

- **Auditory:** Impairments that hinder a person´s ability to hear, deafness or partial deafness.

- **Cognitive:** Generally considered something that affects a person's brain, e.g., dyslexia, memory issues, problem solving issues, attention deficits, hyperactivity, reading disabilities, etc.

We encourage students with disabilities to visit the Accessibility Resources site and learn more about accessibility at the university. Professors and students can reach this site at www.alephuniversity.us/accesibility and find valuable general tips that support accessible education, such as:

## Accessible Classroom

Incorporate the tips in this section to start making classes more accessible today and in the future.

- When referring to information on a screen or white board, verbalize what is written for students with limited vision.
- Remove the images on the presentation to assist blind students or with low vision.
- Provide lecture notes in advance.

## Accessible Online Documents

An accessible document is usable by all students, regardless of their ability.  Aleph follows these techniques to generate accessible documents:

- Use bold font to show emphasis.
- Use a simple and sans serif font (e.g. Arial, Tahoma, or Verdana).
- Maintain high contrasts, black text on white background.
- Use at least 12-point type for documents.
- Use at least 30-point for presentations.
- Add alternative text to all images.
- Use real text rather than text within graphics.

## Technical Support

There are several tools available for students to learn how to navigate the University's online platform. These include:

1. **Informational courses:** Free and non-credit informational courses are available for all students and instructors. These courses are not related to academic content, but rather are a tool to better understand the online platform.

2. **Support Forum:** The support forum allows students and instructors to post a platform- related question or problem at any time. Questions posted in the support forum receive a response within 1 business day.  Students, faculty and staff can submit support cases when they are experiencing technical problems with a laptop, a computer, hardware in a classroom, a wireless connection, logging into an account or issues with other IT services.

   - Support cases are how we track client service. To submit a service request students can write an email to it@alephuni-versity.us. Students must include their student ID, the service they may be experiencing issues with, and any other related information.

   - The issue will be logged in the system and an IT agent will contact you, generally within 3 business days.

3. **Chats:** For real-time support, students and instructors can use a free online voice and chat system that connects users with technical support staff.

4. **FAQs, Demos, Manuals.**

ALEPH UNIVERSITY

# Student Records and Transcripts

Records for students enrolled at Aleph University are compiled and stored permanently by the institution in Florida. The academic record includes application for admission, the term, scheduling information, each course in which the student is enrolled and credit value, transcripts, grade, degree audits among others.

Additional copies of an official transcript (stamped "Student Copy") may be requested by students and alumni contacting the Registrar and will be issued only if the student is in good financial standing. Student Copy Transcripts can also be requested online accessing the Transcript request form.

A fee is charged (see Student Fees & Financial Resources) for each additional transcript required after graduation.

Only at the student's request will Aleph University provide official copies to another college, employer, institution, or agency.

## Family Educational Rights and Privacy Act

To protect and manage the personal information of all students as directed by the freedom of information and protection of privacy, Aleph University complies with the Family Educational Rights and Privacy Act of the 1974 Buckley Amendment, Public Laws 93-380, and Section 438. All students' records are confidential.

# University Officials and Faculty

## Organization and Administrative Structure

### Administrative Staff

The administrative staff consists of:

Jorge Millan, PhD
President

William Soller, PhD
Chief Academic Officer

Zhanna Martirosyan, DBA
Academic Dean

Lina Parra, PhD
Instructional Design

Angela Zappala, BS
Marketing Director

Alexis Murillo, BS
Finance Director

Jimena Garcia
Admissions Director

Marianne Millan, BS
Student Services Director

Members of the staff participate in the following committees:

1. Administrative Committee: Responsible for overseeing and monitoring Aleph's administrative and financial affairs.
2. Admissions Committee: Responsible for determining and overseeing admissions and recruitment activities.
3. Academic and Continuing Education Committee: oversees and monitors academic matters and policy pertaining to continuing education.
4. Community Committee: Responsible for coordinating community service and internship opportunities.

## Faculty

The curriculum is overseen by Aleph University's faculty members. Faculty members at the University are qualified profession-als with proven industry experience, as well as experience with virtual technologies and learning management systems. In order to lead an online learning environment, faculty members should have a reasonable level of technical expertise and be able to use the tools necessary for teaching, interacting, and creating a learning community.

Faculty hiring procedures are based on the general guidelines for hiring in campus and distance education faculty policy. To be considered for a faculty position at University, candidates must provide official transcripts, evidence of work and teaching experience, and verifiable references. Faculty teaching graduate degree courses must possess a minimum of four years of related practical work experience and, an earned doctorate degree in the subject area taught.

New faculty members participate in a series of online orientation activities based on their prospective assignments at Aleph University, including activities such as orientation, online instruction, professional development plan, cultural awareness, and Family Educational Rights and Privacy Act (FERPA) and related laws and regulations related to privacy training.

## Faculty Listing

| Faculty Member | Course(s) Taught | Obtained degree and Awarding Institution |
|---|---|---|
| Jorge Millan, PhD | HUM 500, ENT 510, BME 611, BME 700, BME 710 / 720, ENT 621, BME 530, BME 540, BME 630, RAQ 532, BME 620, BME 625, BME 622, ENT 510, RAQ 600, BME 611, RAQ 610, RAQ 530, ENT 510, ENT 710, ENT 735, ENT 750, ENT 710 / 720, ENT 700, ENT 630, ENT 681, ENT 682, ENT 683, ENT 684 | • PhD in Biomedical Engineering, University of Miami, Coral Gables, Florida<br>• MSc in Electrical Engineering, University of Pennsylvania, Philadelphia, Pennsylvania<br>• MSc in Physics, University of Puerto Rico, Mayaguez, Puerto Rico<br>• BSc in Physics, Universidad del Valle, Cali, Colombia (1988) |
| William Soller, PhD | RAQ 520, BME 611, RAQ 500, RAQ 510, RAQ 520, RAQ 514, RAQ 710 / 720, RAQ 620, RAQ 630, RAQ 640, RAQ 645, RAQ 650, RAQ 655, RAQ 660, RAQ 665, RAQ 670, BME 627, RAQ 530 | • PhD in Medical Sciences, Cornell University, NY, USA (1973)<br>• Bachelor of Arts (BA), Colby College, Waterville, ME |
| Lina Parra, PhD | HUM 500, ENT 620, ENT 730 | • PhD in Public Administration, Nova Southeastern University, Davie, FL<br>• MSc in Curriculum & Instruction: Educational Technology, Florida Gulf Coast University, Fort Myers, FL<br>• MSc in Public Administration, Nova Southeastern University, Davie, FL<br>• Bachelor of Science in Management, Barry University, Miami Shores, FL<br>• Associates of Arts in Management Information Systems, Miami Dade College, Miami, FL |
| Oscar Ramírez, PhD | BME 610, RAQ 520 | • PhD in Physic Science, Universidad del Valle, Cali, Colombia<br>• MSc in Physics, University of Puerto Rico at Mayagüez, Mayagüez, P.R., USA<br>• **BSc in Physics, Universidad del Valle, Cali, Colombia** |
| Julio Jimenez, MD | BME 601, BME 619, BME 621, BME 627 | • Specialization in Pediatrics, Fundación Universitaria San Martin, Bogotá Colombia<br>• Specialization in Hospital Management, Pontificia Universidad Javeriana, Bogotá Colombia<br>• MD, Fundación Universitaria San Martin, Bogotá Colombia |

## Course Descriptions Per Program

The course numbering system in this Catalog is composed of three letters and three numbers. The letters denote the abbreviations of the subject matter and, the numbers denote the numeric course number and corresponding level.

## Prefix Level

0 – 99     Pre-College or Non-College credit
100 - 199 Freshman
200 - 299 Sophomore
300 - 399 Junior
400 - 499 Senior
500 - 599 Entry-level graduate course
600 - 799 Core level graduate courses

Definition of Prefixes: BME-Biomedical Engineering; RAQ-Regulatory Affairs and Quality Assurance; ENT-Innovation and Entrepreneurship.

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SCHOOL OF BASIC SCIENCE AND ENGINEERING
_____

### I. Master of Science in Medical Devices, Regulatory Affairs, and Health Information Technologies

**HUM 500 Ethics, and Values Seminar.** The Ethics, and Values Seminar course is designed to discuss the role of ethics and values in leadership, and how leaders can make ethical decisions that positively impact their organizations and the society. The curriculum in the Ethics, and Values Seminar course covers topics such as ethical decision-making, ethical leadership, values-based leadership, organizational culture, social responsibility, and sustainability. Students also analyze case studies and engage in discussions and activities that help them develop their critical thinking, communication, and problem-solving skills. The students gain an understanding of the importance of ethical leadership and how it can promote trust, respect, and accountability within an organization. Graduates of this course are equipped to lead with integrity, make ethical decisions that positively impact their organizations, and contribute to the development of a more just and sustainable society. In the regulatory affairs and quality assurance context, students apply ethical principles in medical device and pharmaceutical companies to always seek accountability and responsibility for patient safety and product effectiveness.

**ENT 510 Leadership, Teamwork and Success Principles Seminar.** This course is designed to provide students with an understanding of the key principles and practices of effective leadership, teamwork, effort, and commitment to success and effective service, and how they contribute to individual and organizational success. The course typically covers topics such as leadership styles, communication skills, team dynamics, conflict resolution, goal setting, project management and good service principles. The course includes case studies, group projects, and experiential learning activities that allow students to practice and apply these principles in real-world scenarios. Additionally, students may explore various leadership and teamwork theories and models, and how they can be used to build successful teams and achieve organizational goals. Students will develop the skills needed to be effective leaders and team members, including the ability to communicate clearly, listen actively, motivate others, and resolve conflicts. They will also gain an understanding of how to set and achieve goals, build trust and collaboration, and adapt to changing circumstances. In the regulatory affairs and quality assurance context, students apply leadership and teamwork principles to influence leaders and team members to bring medical device and pharmaceutical companies into compliance with regulations.

**BME 601 Medical Sciences.** This course covers the fundamental principles of anatomy, physiology, and their application to medical practice. The course begins with an introduction to human anatomy and physiology, including the structure and function of cells, tissues, organs, and organ systems. Students will learn about the physiology of the cardiovascular, respiratory, digestive, and nervous systems, as well as the endocrine and reproductive systems. Throughout the course, students will be provided with practical examples and case studies to help them apply their learning to real-world situations. By the end of the course, students will have a solid understanding of the basic sciences that underpin medicine and healthcare and will be able to apply this knowledge to their future studies and professional practice.

**BME 610 Medical Physics.** This course covers the fundamental principles of physics as they relate to medicine. It is an interdisciplinary field that combines physics, engineering, and biology to develop and apply new technologies and techniques for the diagnosis and treatment of diseases. Including. The course covers the fundamental principles of physics as they relate to medicine, including radiation physics, protection, medical imaging, radiation therapy and biomedical instrumentation.

**BME 611 Medical Devices.** This course provides students with the knowledge about the different types of medical devices, including diagnostic and therapeutic devices, and the various components that make up these devices. They will also be introduced to the various materials and technologies used in the manufacture of medical devices. The course will cover electrophysiology devices, medical imaging, medical implants, clinical laboratory equipment, hospital equipment and therapeutic devices and their risk and benefits. Students will have a comprehensive understanding of various types of medical devices, their use in healthcare applications, the medical device industry and the processes involved in designing, manufacturing, and bringing medical devices to market.

**BME 700 Special Topics Seminar.** This course is designed to allow students to explore in-depth topics of interest that may not be covered in regular courses or that require specialized expertise. It typically involves a series of lectures or seminars that are presented by faculty members, researchers, or experts in the field, with opportunities for students to engage in discussion and debate. The students are required to complete readings, writing assignments, and presentations. Students may also be required to participate in group projects or individual research projects related to the seminar topic. The course is designed to provide students with the opportunity to explore a particular area of interest in depth and to engage in critical thinking and discussion with peers and experts in the field.

**BME 710 Internship.** Designed to provide students with hands-on experience in their chosen field of study through a supervised internship placement with a relevant organization, the course aims to bridge the gap between academic learning and real-world work experience and to develop students' professional skills, knowledge, and networks. During the internship, students will work under the guidance of a supervisor from the host organization and a faculty advisor from Aleph University. The internship will involve a range of tasks and responsibilities, which may include research, data analysis, project management, event planning, and communication with stakeholders. Students will be required to complete a set number of hours of work during the internship, as determined by the University. At the end of the internship, students will be required to submit a written report or presentation, which will reflect on their learning experiences and the outcomes of the internship. The report may include a description of the organization, the tasks and responsibilities performed, the challenges faced, and the lessons learned.

**BME 720 Capstone Project.** Students are required to complete a capstone project, which involves a case study focused on a biomedical engineering application. The project may involve collaborating with a company or organization in the industry and require students to apply their knowledge and skills to real-world situations.

**ENT 621 Innovation and Entrepreneurship.** This course focuses on the process of creating and developing new ideas, products, and businesses. The course is designed to provide students with the skills and knowledge needed to identify opportunities, develop innovative solutions, and bring new products and services to market. The course includes covers the fundamentals of Creativity and idea generation; Market research and analysis; Business planning and strategy; Funding and financing; Intellectual property; Entrepreneurial leadership and management. With practical exercises and case studies the concepts learned in the classroom are reinforced. These exercises may include developing a business plan, pitching to investors, and launching a startup. This course provides students with the skills and knowledge needed to identify opportunities, develop innovative solutions, and bring new products and services to market.

**BME 530 Biomedical Instrumentation.** This course focuses on the design, development, and application of instruments used in the diagnosis, treatment, and monitoring of medical conditions. The course covers fundamentals of biomedical instrumentation and topics such as medical imaging, Electrocardiography (ECG), Electromyography, Blood pressure and Respiratory instrumentation. This course is designed to provide students with the knowledge and skills needed to design and develop biomedical instrumentation for use in medical settings.

**BME 540 Biomedical Signal Analysis.** Biomedical signal analysis is a course that focuses on the processing and analysis of signals generated by the human body, such as ECG, EEG, EMG, and other physiological signals. The course is designed to provide students with the knowledge and skills needed to process and analyze biomedical signals for clinical and research applications. The course in biomedical signal analysis also includes exercises and projects to reinforce the concepts learned in the classroom, processing and analysis of real biomedical signals, the development of signal processing algorithms, and the evaluation of signal processing techniques. This course provides students with the knowledge and skills needed to process and analyze biomedical signals for clinical and research applications.

**BME 630 Engineering Compliance.** The engineering compliance course is designed to provide individuals with the knowledge and skills needed to ensure that medical devices comply with applicable laws, regulations, and standards. The course covers topics such as the regulatory framework for engineering, risk management, safety and quality standards, and documentation and record-keeping. Students will learn about the different types of medical device regulations and standards that apply to medical devices, including safety, and data privacy regulations. They will also be introduced to the various compliance requirements for different types of medical devices, such as materials, manufacturing, and software development. The course may also cover topics such as auditing and inspection, corrective and preventive action, and continuous improvement. Students will learn about the importance of complying with regulations and standards and how to identify and address compliance issues. Students will have a comprehensive understanding of engineering compliance and the processes involved in ensuring that medical devices meet regulatory requirements and industry standards.

**BME 619 Clinical Engineering and Technology Management.** This course that focuses on the management of medical technology in healthcare settings. Designed to provide students with the knowledge and skills needed to manage the lifecycle of medical devices and systems, from planning and acquisition to maintenance and retirement, the course also includes case studies and real-world examples to reinforce the concepts learned in the classroom. This course provides students with the knowledge and skills needed to manage the lifecycle of medical devices and systems in healthcare settings.

**RAQ 520 Quality Management Systems.** This course is designed to provide students with a comprehensive understanding of the principles and practices of quality management in medical device manufacturers. The course will cover the various components of a Quality Management System (QMS), including planning, control, assurance, and improvement. The course will cover the regulatory requirements and industry standards for QMS, including ISO 9001, FDA regulations, and Good Manufacturing Practices (GMP). Students will learn about the role of QMS in ensuring compliance with these requirements and standards, and in achieving organizational goals such as customer satisfaction, continuous improvement, and operational efficiency. Students will be provided with practical examples and case studies to help them apply their learning to real-world situations. Students will have a solid understanding of the principles and practices of QMS, and will be able to design, implement, and maintain a QMS in compliance with regulatory requirements and industry standards.

**RAQ 532 Product Safety and Performance Testing.** This course is designed to provide students with an understanding of the principles and practices of safety and performance testing for medical devices. This course typically covers the regulatory requirements and guidelines for safety and performance testing and reporting, as well as the methods and tools used to assess the safety and performance of medical products. Students will also learn about the different types of safety and performance testing, including in vitro, animal, human, bench and medical device testing, and the role of safety and performance testing in ensuring the safety and effectiveness of medical products. Students will gain an understanding of the importance of safety and performance testing in ensuring the safety and effectiveness of medical products, and the role of regulatory affairs and quality assurance professionals in overseeing and managing these tests.

**BME 612 Medical Device Regulations.** This course focuses on the regulatory framework governing the design, development, and commercialization of medical devices. The course is designed to provide students with an understanding of the regulations and standards that govern medical devices in various markets, as well as their compliance and enforcement, and emerging issues in medical device regulations. This course includes case studies and real-world examples to reinforce the concepts learned in the classroom, providing students with the knowledge and skills needed to navigate the regulatory landscape governing medical devices.

**BME 620 Medical Imaging Systems.** This course focuses on the principles, technologies, and applications of medical imaging. Designed to provide students with an understanding of the various imaging modalities used in medical diagnosis and treatment, the course also includes exercises and projects to reinforce the concepts learned in the classroom. The course provides students with the knowledge and skills needed to understand the principles, technologies, and applications of medical imaging.

**BME 625 Diagnostic Ultrasound Instrumentation.** This course focuses on the principles, technologies, and applications of ultrasound imaging to provide an understanding of the design and operation of ultrasound instrumentation used in medical diagnosis and treatment. The course includes Introduction to ultrasound imaging, instrumentation, image formation, doppler ultrasound, ultrasound safety, and emerging trends in ultrasound instrumentation. The course also includes exercises and projects to reinforce the concepts learned in the classroom. These exercises may include the evaluation of ultrasound performance.

**HIM 621 Health Information Technologies.** This course focuses on the design, development, and implementation of information technologies in healthcare settings. The course is designed to provide students with an understanding of the role of information technologies in healthcare, as well as the skills needed to design and implement health information systems. The course includes an introduction to introduction to health information technologies, health information system design, implementation, health data analytics, health information system security and privacy, and emerging trends in health information technologies. The course also includes exercises and projects to reinforce the concepts learned in the classroom.

**HIM 622 Medical Informatics, Telemedicine And E-Health.** The course focuses on the use of information and communication technologies (ICT) as well as medical informatics tools and concepts in healthcare delivery. Designed to provide students with an understanding of how these technologies are used to improve the quality and efficiency of healthcare delivery, as well as the challenges associated with their implementation, the course covers the areas of medical informatics, telemedicine, and e-health, ethical and legal issues, and emerging trends in the field. The course also includes exercises and projects to reinforce the concepts learned in the classroom.

**BME 627 Science and Technologies in Healthcare.** This course provides an introduction to medical sciences covering basics of human anatomy and physiology, disease process and diagnosis, wellness systems and therapy devices. The course includes introduction to healthcare technologies, which provides an overview of the role of technologies in healthcare, including the different types of healthcare technologies, such as medical devices, digital health tools, and healthcare information systems. Topics include healthcare technologies, medical imaging, telemedicine and digital health, medical informatics, robotics and automation, and computers and software in medicine. The course provides participants with a basic understanding of medical sciences and a comprehensive understanding of the role of technologies in healthcare, their benefits and limitations, and the challenges in their implementation.

## II. Master of Science in Regulatory Affairs and Quality Assurance in Medical Technologies

**HUM 500 Ethics, Values and Leadership Seminar.** The Ethics, and Values Seminar course is designed to discuss the role of ethics and values in leadership, and how leaders can make ethical decisions that positively impact their organizations and the society. The curriculum in the Ethics, and Values Seminar course covers topics such as ethical decision-making, ethical leadership, values-based leadership, organizational culture, social responsibility, and sustainability. Students also analyze case studies and engage in discussions and activities that help them develop their critical thinking, communication, and problem-solving skills. The students gain an understanding of the importance of ethical leadership and how it can promote trust, respect, and accountability within an organization.

Graduates of this course are equipped to lead with integrity, make ethical decisions that positively impact their organizations, and contribute to the development of a more just and sustainable society. In the regulatory affairs and quality assurance context, students apply ethical principles in medical device and pharmaceutical companies to always seek accountability and responsibility for patient safety and product effectiveness.

**ENT 510 Leadership, Teamwork and Success Principles Seminar.** This course is designed to provide students with an understanding of the key principles and practices of effective leadership, teamwork, effort, and commitment to success and effective service, and how they contribute to individual and organizational success. The course typically covers topics such as leadership styles, communication skills, team dynamics, conflict resolution, goal setting, project management and good service principles. The course includes case studies, group projects, and experiential learning activities that allow students to practice and apply these principles in real-world scenarios. Additionally, students may explore various leadership and team-work theories and models, and how they can be used to build successful teams and achieve organizational goals. Students will develop the skills needed to be effective leaders and team members, including the ability to communicate clearly, listen actively, motivate others, and resolve conflicts. They will also gain an understanding of how to set and achieve goals, build trust and collaboration, and adapt to changing circumstances. In the regulatory affairs and quality assurance context, students apply leadership and teamwork principles to influence leaders and team members to bring medical device and pharmaceutical companies into compliance with regulations.

**RAQ 500 Introduction to Regulatory Affairs.** This course is designed to provide students with an overview of the regulatory environment and the key principles and practices of regulatory affairs in the medical device, food and pharmaceutical companies. The course covers the regulations and requirements related to the development, approval, marketing and manufacturing of medical products in various industries, such as pharmaceuticals, biotechnology, medical devices, food, and cosmetics. The course covers topics such as regulatory agencies and their roles, regulatory processes and submissions, clinical trials, quality assurance, risk management, intellectual property, product labeling, and advertising and promotion. Students will also learn about the global regulatory landscape and main regulatory requirements across major markets globally. Students will gain an understanding of the importance of regulatory compliance and the role of regulatory affairs professionals in ensuring that products meet regulatory requirements. The students also learn about the key challenges and opportunities in the regulatory environment, including regulatory affairs roles for the development, marketing and manufacturing of safe and effective products for consumers.

**RAQ 510 Pharmaceutical and Medical Device Regulations.** This course is designed to provide students with an in-depth understanding of the regulations and requirements related to the development, approval, marketing and manufacturing of pharmaceuticals and medical devices. This course covers the regulations and guidelines established by regulatory agencies such as the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and other international regulatory bodies such as Canada, and Australia. The course covers topics such as the drug development process, clinical trials, regulatory submissions and approvals, quality control and assurance, adverse event reporting, labeling and packaging, and post-marketing surveillance. Students also learn about the differences between regulations for pharmaceuticals and medical devices, as well as the impact of emerging technologies on regulatory compliance. Students will gain an understanding of the complex regulatory landscape for pharmaceuticals and medical devices, and the role of regulatory affairs professionals in ensuring compliance with applicable regulations. They will also learn about the ethical considerations and social responsibilities associated with developing and marketing pharmaceuticals and medical devices to ensure that products meet the highest standards of safety, efficacy, and quality.

**RAQ 520 Quality Management Systems.** This course is designed to provide students with a comprehensive understanding of the principles and practices of quality management in organizations. The course will cover the various components of a Quality Management System (QMS), including planning, control, assurance, and improvement. The course will cover the regulatory requirements and industry standards for QMS, including ISO 9001, FDA regulations, and Good Manufacturing Practices (GMP). Students will learn about the role of QMS in ensuring compliance with these requirements and standards, and in achieving organizational goals such as customer satisfaction, continuous improvement, and operational efficiency. Students will be provided with practical examples and case studies to help them apply their learning to real-world situations. Students will have a solid understanding of the principles and practices of QMS, and will be able to design, implement, and maintain a QMS in compliance with regulatory requirements and industry standards.

**RAQ 530 Risk Management.** This course is designed to provide students with an understanding of the principles and practices of risk management as they apply to medical products, including pharmaceuticals and medical devices. This course covers the regulatory requirements, standards and guidelines for risk management, as well as the methods and tools used to assess and mitigate risks associated with medical products. The course also covers topics such as risk assessment and analysis, risk communication, risk mitigation strategies, risk monitoring and management, and post-marketing surveillance. Students also learn about the different types of risks associated with medical products, including clinical, safety, quality, and regulatory risks, and the role of risk management in addressing these risks. Through this course and key case studies, students will gain an understanding of the importance of risk management in ensuring the safety and effectiveness of medical products, and the role of regulatory affairs and quality assurance professionals in managing and mitigating risks. They will also learn about the key challenges and opportunities in medical product risk management, including the impact of emerging technologies on risk management practices.

**RAQ 532 Product Safety and Performance Testing.** This course is designed to provide students with an understanding of the principles and practices of safety and performance testing for medical devices. This course typically covers the regulatory requirements and guidelines for safety and performance testing and reporting, as well as the methods and tools used to assess the safety and performance of medical products. Students will also learn about the different types of safety and performance testing, including in vitro, animal, human, bench and medical device testing, and the role of safety and performance testing in ensuring the safety and effectiveness of medical products. Students will gain an understanding of the importance of safety and performance testing in ensuring the safety and effectiveness of medical products, and the role of regulatory affairs and quality assurance professionals in overseeing and managing these tests.

**RAQ 600 Medical Product Development Process.** This course is designed to provide students with an understanding of the stages and processes involved in the development of medical products, including pharmaceuticals and medical devices. This course typically covers the regulatory requirements and guidelines for product development, as well as the methods and tools used to design and develop medical products. Students will also learn about the different stages of product development, including innovation and discovery, research and development, prototype development, product testing and regulatory approval. The course also covers case studies that illustrate risks and failures of weak product development practices. Students will gain an understanding of the importance of a structured product development process in ensuring the safety and effectiveness of medical products, and the role of regulatory affairs and quality assurance professionals in overseeing and managing the development process. Overall, a Medical Product Development Process course provides students with the knowledge and skills needed to effectively design and manage the development of medical products, and to ensure compliance with regulatory requirements and guidelines.

**RAQ 514 Medical Product Labeling Regulations.** This course is designed to provide students with an understanding of product labeling regulations established by regulatory agencies to ensure that medical products are accurately labeled and provide important information to users, including patients and healthcare professionals so medical products are used safely and effectively, and that users are informed of potential risks and benefits. The course covers labeling regulations which are overseen by the Food and Drug Administration (FDA) in the US. The course presents discussions and knowledge on labeling requirements including user's manuals, product markings, labels, graphics and symbols, promotional brochures, website promotional content, and product unique device identification labels, among others. Examples of labeling, product description, intended use, product claims, product specifications, and safety warnings will be given. Case studies of product mislabeling, and legal implications are provided. Students will gain an understanding of the importance of a proper product labeling process in ensuring the safety and effective use of medical products, and the role of regulatory affairs and quality assurance professionals in overseeing and managing product labeling. Overall, the course provides students with the knowledge and skills needed to effectively develop and manage product labeling to ensure compliance with regulatory requirements and guidelines.

**RAQ 710 Internship.** Designed to provide students with hands-on experience in their chosen field of study through a supervised internship placement with a relevant organization, the course aims to bridge the gap between academic learning and real-world work experience and to develop students' professional skills, knowledge, and networks. During the internship, students will work under the guidance of a supervisor from the host organization and a faculty advisor from the academic institution. The internship will involve a range of tasks and responsibilities, which may include research, data analysis, project management, event planning, and communication with stakeholders.

Students will be required to complete a set number of hours of work during the internship, as determined by the academic institution. At the end of the internship, students will be required to submit a written report or presentation, which will reflect on their learning experiences and the outcomes of the internship. The report may include a description of the organization, the tasks and responsibilities performed, the challenges faced, and the lessons learned.

**RAQ 720 Capstone Project.** Students are required to complete a capstone project, which involves a case study focused on a regulatory or quality assurance issue or challenge. The project may involve collaborating with a company or organization in the industry and require students to apply their knowledge and skills to real-world situations.

**BME 611 Medical Devices.** This course provides students with knowledge about the different types of medical devices, including diagnostic and therapeutic devices, and the various components that make up these devices. They will also be introduced to the various materials and technologies used in the manufacture of medical devices. The course will cover electrophysiology devices, medical imaging, medical implants, clinical laboratory equipment, hospital equipment and therapeutic devices and their risk and benefits. Students will have a comprehensive understanding of various types of medical devices, their use in healthcare applications, the medical device industry and the processes involved in designing, manufacturing, and bringing medical devices to market.

**BME 630 Engineering Compliance.** The engineering compliance course is designed to provide individuals with the knowledge and skills needed to ensure that medical devices comply with applicable laws, regulations, and standards. The course covers topics such as the regulatory framework for engineering, risk management, safety and quality standards, and documentation and record-keeping. Students will learn about the different types of medical device regulations and standards that apply to medical devices, including safety, and data privacy regulations. They will also be introduced to the various compliance requirements for different types of medical devices, such as materials, manufacturing, and software development. The course may also cover topics such as auditing and inspection, corrective and preventive action, and continuous improvement. Students will learn about the importance of complying with regulations and standards and how to identify and address compliance issues. Students will have a comprehensive understanding of engineering compliance and the processes involved in ensuring that medical devices meet regulatory requirements and industry standards.

**RAQ 610 Design Controls.** The course is designed to provide students with an understanding of the principles and practices of designing medical devices in compliance with regulatory requirements and standards. This course typically covers the FDA's Design Control requirements and the ISO 13485 standard, which outlines the requirements for a quality management system for medical devices. The curriculum covers topics such as design and development planning, design inputs, design outputs, design verification, design validation, design transfer, and design changes. Students also learn about the importance of risk management in the design process and the tools and techniques used to manage risk. Students will gain an understanding of the importance of designing medical devices that meet regulatory requirements and the needs of end-users, as well as the role of regulatory affairs and quality assurance professionals in overseeing and managing the design process. They will also learn about the key challenges and opportunities in medical device design, including the impact of emerging technologies on design practices. The course provides students with the knowledge and skills needed to effectively design and develop medical devices that meet regulatory requirements and are safe and effective for their intended use.

**RAQ 620 Medical Device Regulations.** This course is designed to provide students with an understanding of the regulatory landscape for medical devices, including the requirements and guidelines set forth by regulatory bodies such as the FDA (Food and Drug Administration) and the EU (European Union). This course typically covers the regulatory requirements and guidelines for medical devices throughout the product lifecycle, from design and development to post-market surveillance. The curriculum covers topics such as classification of medical devices, the regulatory submission process, quality systems and compliance, labeling and advertising requirements, post-market surveillance and reporting, and international regulations and standards. Through this course, students will gain an understanding of the importance of regulatory compliance in ensuring the safety and effectiveness of medical devices, and the role of regulatory affairs and quality assurance professionals in overseeing and managing compliance.

**RAQ 630 510(K) Premarket Notification Process.** This course is designed to provide students with an understanding of the regulatory requirements and processes for obtaining product clearance from the FDA (Food and Drug Administration) to market medical devices in the United States through the 510(k) pathway. This course typically covers the topics such as the legal and regulatory framework for medical device clearance in the United States, the role of the FDA in the clearance process, and the types of devices that are eligible for clearance through the 510(k) pathway.

Students will gain an understanding of the importance of regulatory compliance in obtaining clearance for medical devices, and the role of regulatory affairs and quality assurance professionals in overseeing and managing the clearance process. They will also learn about the key challenges and opportunities in the 510(k) premarket notification process, including the impact of emerging technologies on clearance practices.

**RAQ 640 Pharmaceutical Regulations.** This course is designed to provide students with an in-depth understanding of the regulatory requirements for bringing pharmaceutical products to market. Covering various aspects of drug development, including preclinical studies, clinical trials, and post-marketing surveillance. The students will study the laws and regulations governing the pharmaceutical industry, including the Federal Food, Drug, and Cosmetic Act and other relevant laws. The course will also cover topics related to drug safety and efficacy, including pharmacovigilance, adverse event reporting, and risk management. Students will learn about the requirements for drug labeling, packaging, and advertising, as well as the procedures for obtaining regulatory approval for new drugs, biologics, and medical devices. Students will develop a strong understanding of the regulatory landscape for the pharmaceutical industry and will be able to apply this knowledge to ensure compliance with regulations and to effectively communicate with regulatory agencies.

**RAQ 645 Clinical Development of Drugs and Biologics.** This course is designed to provide students with an understanding of the processes involved in bringing new drugs and biologics to market, with a focus on the clinical development phase of drug development. Students will learn about the regulatory requirements for conducting clinical trials, including the design and conduct of clinical studies, data collection and analysis, and the reporting of trial results. They will also learn about the ethical and legal considerations associated with clinical research, including the protection of human subjects and the requirements for obtaining informed consent. The course will cover the different phases of clinical development, from early-phase studies to late-phase trials and will explore the specific challenges associated with each phase. Students will have a comprehensive understanding of the clinical development process for drugs and biologics and will be equipped with the knowledge and skills necessary to contribute to the successful development of new treatments.

**RAQ 650 Biostatistics and Clinical Trial Design.** This course is designed to provide students with an understanding of statistical methods and their application in the design, conduct, and analysis of clinical trials. Students will learn about the principles of statistical inference, including hypothesis testing, confidence intervals, and p-values. They will also learn about common statistical methods used in clinical research, including linear regression, logistic regression, and survival analysis. The course will cover the different phases of clinical trial design, from study design and sample size determination to the analysis and interpretation of trial results. Students will learn about the different types of clinical trials, including randomized controlled trials, observational studies, and adaptive designs. Students will be equipped with the knowledge and skills necessary to design and analyze clinical trials in a variety of therapeutic areas.

**RAQ 655 Food Regulations.** This course is designed to provide students with an understanding of the regulatory frameworks and requirements for ensuring the safety and quality of food products. Students will learn about the various federal and state agencies responsible for overseeing the production, distribution, import, packaging, storage and labeling of food products. The course will cover the different phases of food production, from ingredient sourcing to manufacturing and distribution, and will explore the specific regulatory requirements and challenges associated with each phase. Students will also learn about food safety hazards, including microbiological, chemical, and physical hazards, and the preventive measures used to control them. Students will have a comprehensive understanding of food regulations and will be equipped with the knowledge and skills necessary to navigate the complex regulatory landscape governing the safety and quality of food products.

**RAQ 660 Regulatory Writing and Communication.** This course is designed to provide students with an understanding of the principles and best practices for writing and communicating regulatory documents. The students will learn about the various types of regulatory documents, including clinical study reports, regulatory submissions, and safety reports, and the specific requirements and expectations for each. They will also learn about the different audiences for regulatory documents, including regulatory agencies, healthcare professionals, and the general public.The course will cover the different phases of regulatory writing, from planning and drafting to reviewing and editing, and will explore the specific challenges associated with each phase, learning about the importance of clear and concise communication in regulatory writing, as well as the ethical considerations and legal implications associated with regulatory communications. Students will have a comprehensive understanding of regulatory writing and communication and will be equipped with the knowledge and skills necessary to produce clear, concise, and effective regulatory documents.

**RAQ 665 Post Market Surveillance and Adverse Reporting.** This course is designed to provide learners with an understanding of the regulatory requirements related to monitoring medical devices and pharmaceuticals once they have been released to the market. The course will cover the principles of post-market surveillance, including the need for vigilance in monitoring product safety, effectiveness, and quality, and the importance of timely identification and reporting of adverse events. The students will learn about the regulatory frameworks governing post-market surveillance in different jurisdictions, including the FDA in the United States, the EMA in the European Union, and other international regulatory bodies. The course will also cover the process of adverse event reporting, including the types of adverse events that must be reported, the timeline for reporting, and the mechanisms for reporting, such as the FDA's MedWatch system, and risk management tools and techniques, such as risk assessments and risk-benefit analyses, as well as the importance of effective communication and collaboration with stakeholders, such as healthcare professionals, patients, and regulatory agencies. Students will have a comprehensive understanding of the importance of post-market surveillance and adverse event reporting, as well as the skills and knowledge necessary to establish and maintain effective post-market surveillance systems in compliance with regulatory requirements.

**RAQ 670 Clinical Evaluation Plan and Reporting.** This course is designed to provide an in-depth understanding of the process of developing a clinical evaluation plan (CEP) and the subsequent reporting of clinical data. The course will cover the regulatory requirements, standards, and guidelines for clinical evaluation of medical devices and pharmaceuticals. Students will learn about the critical components of a CEP, including study design, selection of study population, choice of endpoints, statistical analysis plan, and risk management. The course will also cover the documentation requirements for a CEP, including the development of the clinical investigation plan, the clinical protocol, and the informed consent form. The course will cover the reporting of clinical data, including the preparation of the clinical study report (CSR). Students will learn about the regulatory requirements for reporting clinical data, including the guidelines for reporting adverse events and serious adverse events. Students will be provided with practical examples and case studies to help them apply their learning to real-world situations. Students will have a solid understanding of the regulatory requirements, standards, and guidelines for clinical evaluation and reporting, and will be able to develop a CEP and report clinical data in compliance with regulatory requirements.

**BME 627 Science and Technologies in Healthcare.** This course provides the student with an introduction to medical sciences covering basics of human anatomy and physiology, disease process and diagnosis, wellness systems and therapy devices. The course includes introduction to healthcare technologies, which provides an overview of the role of technologies in healthcare, including the different types of healthcare technologies, such as medical devices, digital health tools, and healthcare information systems. Topics include healthcare technologies, medical imaging, telemedicine and digital health, medical informatics, robotics and automation, and computers and software in medicine. Overall, the course on Science and Technologies in Healthcare would provide participants with a basic understanding of medical sciences and a comprehensive understanding of the role of technologies in healthcare, their benefits and limitations, and the challenges in their implementation.

**BME 627 Health Information Technologies.** The course on Health Information Technologies provides a comprehensive overview of the role, applications, and implementation strategies of information technologies in the healthcare sector. With the increasing digitization of healthcare systems worldwide, understanding the various technologies and their impact on patient care, data management, and healthcare operations is essential. This course aims to equip participants with the knowledge and skills necessary to leverage health information technologies effectively to improve healthcare delivery, enhance patient outcomes, and optimize organizational performance. Topics covered include: Introduction to Health Information Technologies, Electronic Health Records (EHR) Systems, Health Information Exchange (HIE), Telehealth and Telemedicine, Health Analytics and Business Intelligence, Health Information Privacy and Security, Mobile Health (mHealth) Applications, Health Information Technology Implementation, Emerging Technologies in Healthcare, and Ethical and Legal Issues in Health IT.

## III. Master of Science in Innovation & Entrepreneurship in Medical Technologies (M.Sc.)

**HUM 500 Ethics, Values and Leadership Seminar.** The Ethics, and Values Seminar course is designed to discuss the role of ethics and values in leadership, and how leaders can make ethical decisions that positively impact their organizations and the society. The curriculum in the Ethics, and Values Seminar course covers topics such as ethical decision-making, ethical leadership, values-based leadership, organizational culture, social responsibility, and sustainability. Students also analyze case studies and engage in discussions and activities that help them develop their critical thinking, communication, and problem-solving skills. The students gain an understanding of the importance of ethical leadership and how it can promote trust, respect, and accountability within an organization. Graduates of this course are equipped to lead with integrity, make ethical decisions that positively impact their organizations, and contribute to the development of a more just and sustainable society. In the regulatory affairs and quality assurance context, students apply ethical principles in medical device and pharmaceutical companies to always seek accountability and responsibility for patient safety and product effectiveness.

**ENT 510 Leadership, Teamwork and Success Principles Seminar.** This course is designed to provide students with an understanding of the key principles and practices of effective leadership, teamwork, effort, and commitment to success and effective service, and how they contribute to individual and organizational success. The course typically covers topics such as leadership styles, communication skills, team dynamics, conflict resolution, goal setting, project management and good service principles. The course includes case studies, group projects, and experiential learning activities that allow students to practice and apply these principles in real-world scenarios. Additionally, students may explore various leadership and teamwork theories and models, and how they can be used to build successful teams and achieve organizational goals. Students will develop the skills needed to be effective leaders and team members, including the ability to communicate clearly, listen actively, motivate others, and resolve conflicts. They will also gain an understanding of how to set and achieve goals, build trust and collaboration, and adapt to changing circumstances. In the regulatory affairs and quality assurance context, students apply leadership and teamwork principles to influence leaders and team members to bring medical device and pharmaceutical companies into compliance with regulations.

**ENT 710 New Venture Creation and Development.** This course focuses on the process of starting a new business. It covers the various steps involved in launching a new venture, including ideation, market analysis, feasibility analysis, business planning, and implementation. Students will learn about the different types of businesses, such as sole proprietorships, partnerships, and corporations, and the legal and regulatory requirements for each. They will also explore the challenges that entrepreneurs face during the startup phase and the strategies for overcoming them, such as building a strong team, securing funding, and managing cash flow. In this course, students will learn the skills needed to create and develop new ventures. This includes identifying market opportunities, assessing market needs, developing a business model, and executing the plan effectively. Students will also explore strategies for raising capital, building a team, and managing risks. Through case studies and real-world examples, students will gain a deep understanding of the challenges and opportunities involved in starting a new venture.

**ENT 620 Entrepreneurial Finance.** This course provides an in-depth understanding of the financial aspects of entrepreneurship. Students will learn how to evaluate the financial viability of a new venture, analyze funding options, and prepare financial projections. The course covers various sources of financing for startups, including angel investors, venture capitalists, and crowdfunding. Students will also learn about the different stages of financing, from seed funding to exit strategies. The course will explore the challenges of managing finances in an entrepreneurial context, including the trade-off between risk and return, managing cash flow, and financial decision-making under uncertainty. Students will also learn how to analyze financial statements and use financial ratios to assess a company's financial health. Throughout the course, students will engage in hands-on exercises, case studies, and simulations to apply their knowledge in practical situations. The course will also emphasize ethical and social responsibility considerations in financial decision-making for entrepreneurs.

**ENT 630 Legal Issues for Entrepreneurs.** This course covers the legal and regulatory aspects of starting and running a new venture. This course is designed to provide students with an understanding of the legal framework surrounding entrepreneurship and to help them navigate legal issues that may arise when starting or running a business, including the business organizations, and explore key legal issues such as intellectual property law, contract law, and employment law. Students will learn how to identify potential legal risks and develop strategies for mitigating them. The course will also cover emerging legal issues for entrepreneurs, such as cybersecurity, data privacy, and regulation of emerging technologies.

**ENT 730 Entrepreneurial Business Strategy.** This course covers the strategic planning and decision-making skills necessary for entrepreneurs to start, manage, and grow a successful business. Through a combination of lectures, case studies, and hands-on projects, students will learn how to develop a comprehensive business strategy, analyze market trends, and identify opportunities for growth. The course will cover topics such as business model generation, value proposition design, competitive analysis, and market segmentation. Students will also learn how to develop a financial plan, including revenue models, cost structures, and cash flow projections. They will explore different financing options for startups, such as angel investing, venture capital, and crowdfunding. The course will emphasize the importance of market research, customer discovery, and testing assumptions through experimentation.

**ENT 735 Design Thinking and Innovation.** The course is designed to teach students the principles and practices of design thinking, a problem-solving approach that emphasizes empathy, collaboration, experimentation, and iteration. Through a combination of lectures, case studies, and hands-on projects, students will learn how to apply the design thinking process to real-world problems, identify unmet needs, and develop innovative solutions. They will also learn about the importance of user-centered design, prototyping, and testing. The course will cover topics such as human-centered design, ideation, prototyping, testing, and implementation. Students will also learn about the importance of interdisciplinary collaboration, communication, and creativity in the design thinking process. In addition to technical skills, this course will emphasize the importance of soft skills such as empathy, communication, and teamwork.

**ENT 750 Product Development.** This course is designed to teach students the principles and practices involved in developing and launching successful new products, whether they be physical products, software, or services. Through a combination of lectures, case studies, and hands-on projects, students will learn how to develop and refine product concepts, conduct market research, build, and test prototypes, and bring products to market. They will also learn about the various stages of the product development process, including ideation, design, engineering, and commercialization. The course will cover topics such as user-centered design, prototyping and testing, intellectual property protection, market analysis, and project management. Students will also learn about the different types of products, including consumer goods, industrial products, and software applications. In addition to technical and entrepreneurial skills, this course will emphasize the importance of collaboration and interdisciplinary teamwork. Students will work in small groups to develop and refine product concepts and will have the opportunity to interact with industry experts and potential customers.

**ENT 710 Internship.** Designed to provide students with hands-on experience in their chosen field of study through a supervised internship placement with a relevant organization, the course aims to bridge the gap between academic learning and real-world work experience and to develop students' professional skills, knowledge, and networks. During the internship, students will work under the guidance of a supervisor from the host organization and a faculty advisor from the academic institution. The internship will involve a range of tasks and responsibilities, which may include research, data analysis, project management, event planning, and communication with stakeholders. Students will be required to complete a set number of hours of work during the internship, as determined by the academic institution. At the end of the internship, students will be required to submit a written report or presentation, which will reflect on their learning experiences and the outcomes of the internship. The report may include a description of the organization, the tasks and responsibilities performed, the challenges faced, and the lessons learned.

**ENT 720 Capstone Project.** Students are required to complete a capstone project, which involves a case study focused on a regulatory or quality assurance issue or challenge. The project may involve collaborating with a company or organization in the industry and require students to apply their knowledge and skills to real-world situations.

**ENT 700 Biomedical Startups: From Idea to Exit**. This course focuses on the unique challenges of starting and growing a biomedical startup. Students will learn how to identify and evaluate biomedical opportunities, navigate regulatory hurdles, and secure funding. They will also explore strategies for commercializing biomedical products and bringing them to market. Students will learn about the different types of biomedical startups, including those focused on drug development, medical devices, and digital health. They will also explore the regulatory environment for biomedical startups, including the FDA approval process and other regulatory hurdles. Through case studies, guest lectures, and hands-on projects, students will gain a deep understanding of the process of launching and growing a biomedical startup. They will learn how to identify and validate business opportunities, build and test prototypes, and secure funding from investors and other sources. In addition to entrepreneurship skills, this course covers the principles of biomedical science and engineering, including topics such as biotechnology, bioinformatics, and biomedical imaging. Students will learn how to leverage this knowledge to develop innovative products and solutions that address real-world healthcare challenges.

**ENT 681 Leadership and New Ventures Management.** This course covers the skills and qualities required to lead and manage a new venture. Students will learn how to build and manage a team, communicate effectively, and make tough decisions. They will also explore the importance of vision, values, and culture in driving business success. Students will learn about the different types of leadership styles and their application in new venture management. They will also explore topics such as team building, decision making, conflict resolution, and effective communication. Through case studies, guest lectures, and hands-on projects, students will gain a deep understanding of the unique challenges and opportunities of leading new ventures. In addition to leadership skills, this course covers the principles of new venture management, including finance, operations, and strategy. Students will learn how to develop and implement business plans, manage resources, and make strategic decisions that drive growth and innovation.

**ENT 682 Entrepreneurial Marketing.** This course covers the principles of marketing for new ventures. Students will learn how to develop a marketing strategy, identify target customers, and create compelling marketing messages to develop effective marketing strategies and build successful businesses. Students will learn how to identify and analyze target markets, develop marketing plans, and create compelling marketing messages that resonate with customers. They will also explore different marketing channels, such as social media, content marketing, and email marketing, and learn how to leverage these channels to build brand awareness and drive customer engagement. Students will develop the skills needed to create and execute effective marketing campaigns, measure the success of their marketing efforts, and adjust their strategies based on customer feedback and market trends.

**ENT 683 Innovation and Sustainability.** This course provides students with an understanding of the principles of sustainability and the role of innovation in creating sustainable solutions. Students will learn about the environmental, social, and economic challenges facing organizations and communities today and explore innovative strategies for addressing these challenges. The course covers a range of topics, including sustainable business models, life cycle assessment, green chemistry, renewable energy, and sustainable product design. Students will learn how to apply these principles in the context of new ventures, as well as in established organizations. They will also explore the role of policy and regulation in promoting sustainability and innovation. Overall, this course provides students with the knowledge and skills needed to become leaders in the emerging field of sustainability and innovation.

**ENT 684 International Entrepreneurship.** This course focuses on the skills and strategies needed to start and grow a business in a global context. Students will learn about the unique challenges and opportunities of entrepreneurship. The course covers a range of topics, including business planning, marketing and branding, intellectual property law, international trade, and cross-cultural communication. Students will learn how to develop a business idea, create a business plan, and raise capital. They will also explore strategies for building a brand, reaching customers, and creating a competitive advantage in a global marketplace. Through case studies, guest lectures, and hands-on projects, students will develop the skills needed to identify opportunities, develop and pitch creative concepts, and navigate the global business environment.

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