ALEPH UNIVERSITY

ONLINE

School of Basic Science and Engineering

# 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 provides students with the knowledge and skills necessary to navigate the complex regulatory landscape and ensure compliance with applicable laws, regulations, and standards in the devices and life sciences industry.

The program focuses on the study of regulatory and quality requirements related to the development, approval, commercialization, and manufacturing of products in various industries, such as pharmaceuticals, biotechnology, medical devices, food, and cosmetics. Designed to equip students with the knowledge and skills needed to understand and comply with complex regulatory environments, the program ensures that products meet regulatory and quality requirements, as well as relevant laws and regulations.

Students have the opportunity to enhance their understanding of international regulatory laws and procedures while acquiring the leadership skills necessary for success in the fields of regulatory science and quality assurance. Additionally, the program offers a specialization in Medical Device Regulatory Affairs of 30 credits within the Master of Science in Medical Devices, Regulatory Affairs, and Health Information Technologies. With this concentration in Medical Devices, Aleph University's prepares interdisciplinary professionals to address current and future challenges and opportunities in the market.

## Program Objectives

• Recognize the legal, regulatory, and quality assurance requirements for all stages of devices.
• Demonstrate the ability to apply guidelines and test all facets of device clinical trials.
• Navigate the complex regulatory landscape and manage compliance with applicable laws, regulations, and standards in the devices and life sciences industry.

## Career Opportunities

Obtaining a Master of Science in Regulatory Affairs and Quality Assurance in Medical Technologies positions you to take on crucial roles in quality assurance and regulatory compliance in various industries. Here are some job opportunities associated with this field of study:

• **Regulatory Compliance Specialist:**
- Work on interpreting and implementing industry-specific regulations and standards.
- Ensure company operations and products comply with relevant laws and standards.

• **Quality Assurance Manager:**
- Oversee and manage quality control programs.
- Develop and implement policies and procedures to ensure product or service quality

• **Regulatory Documentation Specialist:**
- Prepare and submit regulatory documents to relevant government agencies.
- Ensure documentation meets regulatory requirements.

• **Quality and Compliance Auditor:**
- Conduct internal and external audits to ensure compliance with regulations and quality standards.
- Develop and execute corrective action plans as needed.

• **Process Validation Specialist:**
- Validate manufacturing processes and systems to ensure consistency and compliance with specific regulations.
- Collaborate closely with production and development teams.

• **Good Manufacturing Practice (GMP) Compliance Manager:**
- Ensure facilities and processes comply with GMP and other applicable regulations.
- Implement and maintain quality systems according to regulations.

• **Pharmacovigilance Specialist:**
- Monitor and report adverse effects and safety issues related to pharmaceutical and medical products.
- Ensure the company complies with pharmacovigilance requirements.

• **Regulatory Affairs Consultant:**
- Provide consulting services to companies seeking advice on regulatory and compliance issues.
- Stay updated on regulatory changes and assist companies in adapting.

• **Environmental Compliance Specialist:**
- Ensure company operations comply with environmental and regulatory requirements.
- Participate in risk assessment and implementation of sustainable practices.

• **Regulatory Business Development Manager:**
- Identify market opportunities and business development strategies based on existing and emerging regulations.
- Collaborate with research and development teams to ensure the commercial viability of new products.

These job opportunities are applicable across various industries, such as pharmaceuticals, medical devices, food and beverages, chemicals, and more. The growing importance of complying with regulations and quality standards has increased the demand for professionals with expertise in regulatory affairs and quality assurance.

## Learning Methodology

Aleph University employs an active learning environment that fosters critical thinking through interaction within the learning community. A variety of pedagogical learning scenarios are promoted, including self-study, idea exchange, small group work, problem-solving, debates, and research seminars. Students have access to various sources of information, learning alternatives, and activities to enhance their learning experience.

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.

**Harvard Case Study Method**

This method employs the discussion of real-life situations that professionals face in their workplace. It requires student preparation and group work with their peers.

**Project-Based Learning**

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

## Admissions Process

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.

The general admission and readmission requirements are as follows:

- **Application:**

Online admission applications must be received by the Admissions Department..

- **Identification Document:**

Copy of a government-issued identification document.

- **Fee Payment:**

A non-refundable application fee must be paid with the Admission Application.

- **Transcripts:**

Official academic records from all attended educational institutions must be submitted according to the application instructions. To be admitted to a Master's program, the applicant must have completed a bachelor's degree from an appropriately accredited academic institution, having obtained a minimum GPA of 3.0.

- **Personal Statement:**

A statement of purpose explaining why the chosen academic program would enable the applicant to achieve their professional goals.

- **Interviews:**

All applicants must have an interview with the Director of Admissions to better understand their interests, goals, and personalities.

- **English Proficiency:**

International students must meet language proficiency requirements.

Language Proficiency Requirements: To enroll at Aleph University, prospective students whose first language is not English must possess college-level English ability.

## List of Courses

| Concentrations | Course Type | Code | Course Name | Credits |
|---|---|---|---|---|
| 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 |
| | Core | RAQ 520 | QUALITY MANAGEMENT SYSTEMS | 2 |
| | Core | RAQ 530 | RISK MANAGEMENT | 2 |
| | Core | RAQ 532 | PRODUCT SAFETY AND PERFORMANCE TESTING | 2 |
| | Core | RAQ 600 | MEDICAL PRODUCT DEVELOPMENT PROCESS | 2 |
| | Core | RAQ 514 | MEDICAL PRODUCT LABELING REGULATIONS | 2 |
| | Core | RAQ 710 / 720 | INTERNSHIP OR CAPSTONE PROJECT | 2 |
| MEDICAL DEVICE TRACK | Elective | BME 611 | MEDICAL DEVICES | 2 |
| | Elective | BME 630 | ENGINEERING COMPLIANCE | 2 |
| | Elective | RAQ 610 | DESIGN CONTROLS | 2 |
| | Elective | BME 612 | MEDICAL DEVICE REGULATIONS | 2 |
| | Elective | RAQ 630 | 510(K) PREMARKET NOTIFICATION PROCESS | 2 |
| PHARMACEUTICAL TRACK | Elective | RAQ 640 | PHARMACEUTICAL REGULATIONS | 2 |
| | Elective | RAQ 645 | CLINICAL DEVELOPMENT OF DRUGS AND BIOLOGICS | 2 |
| | Elective | RAQ 650 | BIOSTATISTICS AND CLINICAL TRIAL DESIGN | 2 |
| | Elective | RAQ 655 | FOOD REGULATIONS | 2 |
| GENERAL | Elective | RAQ 660 | REGULATORY WRITING AND COMMUNICATION | 2 |
| | Elective | RAQ 665 | POST MARKET SURVEILLANCE AND ADVERSE REPORTING | 2 |
| | Elective | RAQ 670 | CLINICAL EVALUATION PLAN AND REPORTING | 2 |

1 elective is required*

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