Radex Institute Education Student Handbook

| Regulatory Affairs

Volume 3

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This Catalog is current at the time of publication. Radex Institute Education reserves the right to make changes at any time to any provision of this Catalog, including the amount of tuition and fees, academic programs and courses, school policies and procedures, faculty and administrative staff, the school calendar and other dates, and other provisions. Radex Institute Education reserves the right to make changes in instructional materials, to modify curriculum and to combine or cancel classes, as needed. The Catalog and enrollment agreement constitute a binding contract between this institution and the student and no further modification or representation except as herein expressed by both parties will be recognized

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Mission Statement

Radex Institute Education's mission is to have an academic environment stimulating the production and application of knowledge, research, and innovation, promoting social responsibility, and contributing to sustainable development by optimizing our capabilities and resources.

Goal and Objectives

The goal and mission of the Regulatory Affairs Postgraduate Certificate program are centered around preparing students for successful careers in regulatory affairs within various industries, including pharmaceuticals, medical devices, biotechnology, and healthcare. The program aims to achieve the following objectives:

Goal:

To provide students with specialized knowledge and skills in regulatory affairs, enabling them to navigate complex regulatory frameworks, ensure compliance with applicable laws and regulations, and facilitate the timely approval and commercialization of regulated products.

Objectives:

1. Develop Expertise: The program seeks to develop students' expertise in regulatory affairs by providing comprehensive instruction in regulatory principles, laws, guidelines, and best practices relevant to different industries and geographic regions.
2. Foster Critical Thinking: Through a curriculum that emphasizes problem-solving, case studies, and real-world applications, the program aims to foster critical thinking skills, enabling students to analyze regulatory issues, anticipate challenges, and develop effective regulatory strategies.
3. Promote Ethical Practice: The program is committed to promoting ethical conduct in regulatory affairs by emphasizing the importance of integrity, transparency, and accountability in interactions with regulatory agencies, stakeholders, and the public.
4. Facilitate Professional Growth: By offering opportunities for practical experience, networking, and professional development, the program aims to facilitate students' growth as regulatory professionals, empowering them to advance their careers and make meaningful contributions to their organizations and the broader regulatory community.
5. Keep Pace with Industry Trends: The program is dedicated to staying current with industry trends, emerging technologies, and regulatory developments, ensuring that students are equipped with the knowledge and skills needed to adapt to evolving regulatory requirements and address emerging challenges.
6. Enhance Global Competence: Recognizing the global nature of regulatory affairs, the program aims to enhance students' global competence by providing insights into international regulatory frameworks, harmonization initiatives, and cross-border regulatory considerations.

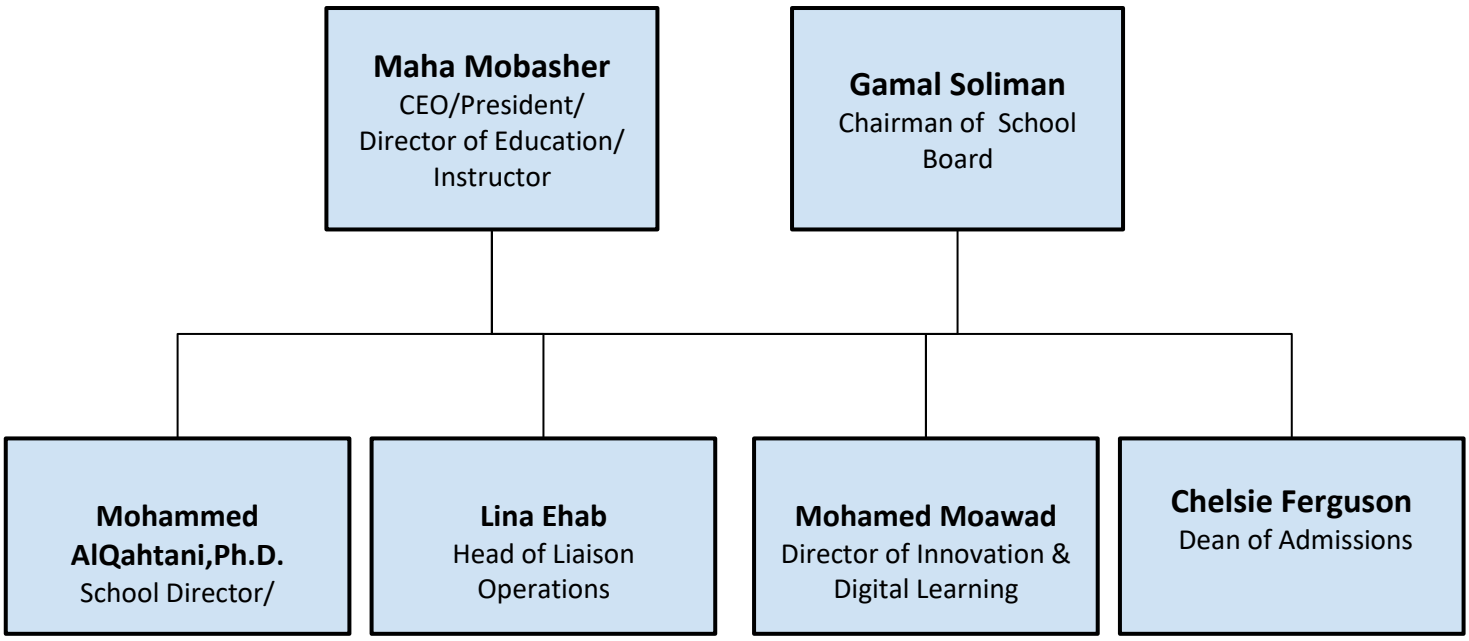
By pursuing these goals and fulfilling its mission and objectives, the Regulatory Affairs Postgraduate Certificate program strives to prepare graduates to excel as regulatory affairs professionals, contributing to the safe, effective, and timely delivery of regulated products to markets worldwide.

About the institute:

Radex Institute Education for Global Regulatory Affairs was first founded in 2020 in Florida, USA and has provided training in the integrated regulatory affairs in the pharmaceutical, medical devices, dietary supplement and cosmetics field to many students from USA, Europe, and Middle East.

The team of Radex Institute Education for Global Regulatory Affairs Consultations and Training that consists of highly qualified regulatory affairs professionals have decided to bring their knowledge and expertise in global regulatory affairs regulations to Florida, USA, and that is how Radex Institute Education was formed in January 2020.

Organizational Hierarchy



Our CEO at a Glimpse

Dr. Maha Mobasher, the President/Director of Education of Radex Institute Education :

- MS/ PhD student in Pharmaceutical Sciences: Nova Southeastern University, Ft. Lauderdale, Florida.
- MS in Chemistry with a Minor in Business Administration: Seton Hall University, South Orange, New Jersey.
- MS In science and education: King's College, London United Kingdom.

- Expert preparing the quality section for the FDA submission of many generic drugs.
- Eight (8) years of experience within the pharmaceutical industry and global pharmaceutical companies. Integrated specialty focused on developing, manufacturing, and distributing generic and brand products including: development, research, examination, quality control and assurance, prepared and conducted cGMP and SOP training sessions, provides scientific support to new product development, fill/finish tech transfer and manufacturing of parenteral products for external or internal manufacturers, and partnering with Technical Operations, Quality, Regulatory, and other functions to support the flawless introduction of manufacturing processes into production sites
- Adjunct Professor at Broward Community College teaching Chemistry and Biochemistry for nursing majors.
- Adjunct Professor at Nova Southeastern University in the Science department teaching pharmaceutical sciences for pharmacy school and pre-med students.

Statement of Legal Control

Radex Institute Education Inc. is a Florida corporation that operates Radex Institute Education. Dr. Maha Mobasher serves as its President.

Licensure Statement

Radex Institute Education is licensed by the Commission for Independent Education, Florida Department of Education License # 10333. Additional information regarding this university may be obtained by contacting the Commission at: 325 West Gaines Street, Tallahassee, FL 32309-0400 or by calling toll free: 888-224-6684.

Non-Discrimination, ADA, and Equal Opportunity

Students at Radex Institute Education can expect an environment free of discrimination based on race, color, religion, national origin, sex, sexual orientation, age, political affiliation or belief, veteran status, marital status, ethnic background, or disability. Radex Institute Education does not tolerate discrimination towards faculty, staff, students, or any other individuals associated with the company. Students are required to adhere to the Radex Institute Education nondiscrimination policy.

Radex Institute Education is committed to upholding the standards set forth in Section 504 of the Rehabilitation Act of 1973 and the Americans with Disabilities Act (ADA) of 1990 (together, the "Disability Laws"), and similar state laws, which are designed to eliminate discrimination against qualified individuals with disabilities. Radex Institute Education provides equal opportunity for qualified persons with disabilities. Radex Institute Education will make reasonable accommodations for a qualifying student with a disability, as appropriate. Accommodations must be formally requested by the student in writing. Such requests, along with supporting documentation, should be directed to the Director.

Radex Institute Education does not discriminate against any student or applicant based on race, color, religion, national origin, sex, sexual orientation, age, political affiliation or belief, veteran status, marital status, ethnic background, or disability. Radex Institute Education abides by these policies in the administration of its student admissions, financial aid, and career placement programs, as well as in all other student-related services and educational programs and opportunities. The Director serves as the Institute's Equal Opportunity Officer. Contact information is Dr. Maha Mobasher, email: mmobasher@pearauniversity.org

School Holidays 2024-2025

Radex Institute Education will be closed:

New Year's Day	January 1
Martin Luther King Day	January 17
Memorial Day	May 30
Independence Day	July 4
Labor Day	September 5
Columbus Day	October 11
Veterans Day	November 10
Thanksgiving Day	November 24
Christmas Eve	December 24
Christmas Day	December 25
New Year’s Eve	December 31

Academic Calendar 2024-2025

Regulatory Affairs of Drugs and Medical Devices Program USA, Europe & MENA Region: One start per calendar year. USA, Europe & MENA Region programs start in Fall / Spring / Summer.

Changes to the School Schedule

The school may at any time change or modify the Student/Academic Calendar to the extent the school determines necessary, in its discretion, by any reason: including, without limitation, any natural disaster or inclement weather; (b) fire; (c) riot; (d) local, state or national emergency; (e) business necessity; (f) war; (g) act of terrorism; (h) civil insurrection; (i) strike or other labor difficulty; (j) rule, order, regulation and/or law of any governmental entity; and/or (k) school-sponsored activity. The school will promptly notify the student body as soon as practical following any determination by the school to change or modify the Student/Academic Calendar.

Admissions Requirements and Procedures

Application Process

Applicants may complete the application and submit all required documents online through our website www.pearauniversity.org

Students applying for admission for Regulatory Affairs of Drugs and Medical Devices Program (USA & Europe) must meet the following requirements:

1. Students with a Bachelor's or College degree in any life science such as Pharmacy, Biotechnology, Biology, Chemistry, or any equivalent major with a GPA of at least 2.75 from an accredited institution.
2. All applicants must provide official transcripts.
3. All applicants must provide a valid government issued photo form of identification.

Students applying for admission for MENA Region Regulatory Affairs of Drugs and Medical Devices Program must meet the following requirements:

1. Students with a Bachelor's or College Degree in any life science such as Pharmacy, Biotechnology, Biology, Chemistry, or any equivalent majors with a GPA of at least 2.75 from an accredited institution.
2. All applicants must provide official transcripts.
3. All applicants must provide a valid government issued photo form of identification.

Application Fee/Tuition

The application fee is 50 USD$.
The program tuition fees are USD 6,650 paid in monthly installments per school year at the beginning of each academic term. The costs encompass all programs in-person, blended, and virtual services. Textbooks are not included in the tuition costs.

Acceptance

All applicants who have met all applicable admissions requirements may complete their enrollment by signing an Enrollment Agreement and paying the registration fee. An enrollment becomes official only after the Enrollment Agreement has been reviewed, accepted and signed by the Institute's Director or other authorized school representative. The school will provide the student a copy of the fully executed Enrollment Agreement.

Transfer of Credits Policy

The transferability of credits you earn at Radex Institute Education is at the discretion of the institution to which you may seek to transfer. Acceptance of the Graduate Certificate you earn at Radex Institute Education is also at the discretion of the institution to which you may seek to transfer. Suppose the Graduate Certificate that you earn at this institution is not accepted at the institution to which you seek to transfer. In that case, you may be required to repeat some of your coursework at that institution. For this reason, you should make certain that your attendance at this institution will meet your educational goals.

Credit for Prior Experiential Learning

CREDITS BE TRANSFERRED TO RADEX:

There are several methods by which coursework from another school can transfer to RADEX.

Direct Equivalent: Here at RADEX, direct department credit will be granted for transfers. Example: DB at RADEX can be awarded for a database course from a prior college. Your transcript will include the evaluation as DB and the course's credit hours.

Departmental Credit: At RADEX, transfer credit will be given departmental credit. Example: Here at RADEX, credit for a prior institution's Regulatory Affairs course may be awarded. The evaluation and the total amount of credit hours for the course will show up as WEB on your transcript.

No Credit-Transfer credit will be granted as no credit if the grade received is less than a C or if the course itself was not transferable (nothing comparable at RADEX, accreditation problem, duplicate course). Your transcript will show the evaluation as TUN NOCR.

Credit by Department Recommendation Only: When a course needs to be assessed by a particular RADEX academic department before deciding whether and how it might transfer, transfer credit will only be granted for department recommendations. The assessment will show up as CBDRO "Credit by Department Recommendation Only" on your transcript.

Prior to registering for classes, all incoming transfer students are required to meet with an academic advisor. Your academic advisor(s) will use departmental credits and direct equivalents to help you get the most out of your transfer credits toward your degree. Students who need help with a course that is marked as CBDRO are advised to consult with their academic advisor(s). They can help find the right department and contact to ask for a review of the course(s) in question. For the best assessment of credit, an official course description and/or syllabus will be needed.

Academic Information

Credit Hours

Radex Institute Education utilizes qualitative and quantitative measurements to assess student progress and offers all programs on a semester credit hour basis. The standard measurement of a credit hour for academic purposes is: 15 classroom hours of lecture equal 1-semester credit and consists of learning new material or theory, 30 classroom hours of lab equals 1 semester credit and consists of supervised practice of newly introduced principles/theory, 45 externship hours equals 1 semester credit and consists of supervised work experience activities related to skills/knowledge acquired during the program.

Course Numbering System

The course numbering system uses a seven-digit alphanumeric identifier. The prefixes are a three-letter designator that represent the type of course and the suffixes are numbers that represent the sequence in which they are taught

Distance Education

Radex Institute Education offers all coursework via online offerings. Students log in to the school's Learning Management System regularly to perform learning activities including live lectures, watching videos, reading online resources, assigned reading, E-Library, and interactive assignments. Regular contact with course instructors takes place via web meetings, email, and phone.

Grading System

Radex Institute Education uses the following grading scale:

A	94-100	4.0	Exceptional work
A-	90-93	3.7	Excellent
B+	87-89	3.5	Very good
B	83-86	3.0	Meets expectations
B-	80-82	2.7	Average
C+	77-79	2.5	Average
C	70-76	2.0	Average
D+	67-69	1.3	Must retake course
D	63-66	1.0	Must retake course
D-	60-62	0.7	Must retake course
F	Below 60		Failing

Evaluation Standards

- Mid-Term Exam: 30%
- Attendance:10% (Instructor will record attendance each session)
- Assignments: 10%
- Class Workshops: 10%
- Quizzes:10%
- Final Exam: 30%

Students must attend all classes and complete all coursework. Students MUST have a passing grade (C or better).

Incomplete Grade Policy

Students have the opportunity to petition to receive an incomplete grade if they are unable to complete course assignments by the end of the semester. To petition, students and faculty members review the assignments that are outstanding and the last date the student would be allowed to submit the assignments. The faculty member and student sign the designated Incomplete Grade form stating the details and the faculty member submits the form to the school's Director. Incomplete grades should be given only if students have a chance to complete the work within two weeks of the course end date. If work is not submitted two weeks after the end of the semester, then the instructor must contact the student to work out a plan for completing the work. All work must be submitted by the end of the following semester. Failure to do so changes the Incomplete to a Failing grade.

Standards of Satisfactory Academic Progress

The minimum standards considered for satisfactory progress in a course or program for credit earned and to graduate are:

- Eighty percent (80%) participate in online discussion boards.
- Completion of all tests and assignments at 80% or better.
- Final grades and student evaluations are issued at the end of each program.
- A student must maintain a GPA of 2.0.

As long as a student meets the minimum standards, a student is allowed to remain in school. A student who is readmitted after dismissal for failure to meet this standard is readmitted on academic probation. The students are required to complete their program of study within 150% of the normal time frame allotted for completion of the program. The normal time frame is measured in credits hours attempted. A student who has been dismissed may reapply to Radex Institute Education after remaining out of school for one full semester. At that time, the student's academic records are evaluated to determine if it is possible for a 2.0 cumulative grade point average to be achieved and if the program can be completed within the maximum 150% timeframe.

Graduation and Awarding of Graduate Certificate

Students who fulfill all completion requirements will be awarded a "Graduate Certificate in Regulatory Affairs of Drugs and Medical Devices USA, Europe & MENA Region from Radex Institute Education.

Programs

Regulatory Affairs of Drugs and Medical Devices Training Program (USA &Europe).

Credential awarded: Graduate Certificate
Credits: 19 Credits
Method of delivery-Online

Program Description

This program is designed to assist the student with obtaining the necessary skills and knowledge to effectively navigate and manage regulatory affairs (RA) processes including operational RA, strategic RA, clinical RA, CMC RA, and submission specialist RA. The program includes critical thinking workshops and a project to allow students the opportunity to apply theoretical knowledge in a practical way.

Program Objective

The objective of our Regulatory Affairs of Drugs and Medical Devices Training Program (USA &Europe) is to prepare students to apply their learned knowledge about USFDA, SFDA and European regulations and regulatory affairs processes related to drugs, biologics, biosimilars, medical devices, combination products, and cosmetics to bring a medical product to market.

Regulatory Affairs of Drugs and Medical Devices Training Program

(USA &Europe) – Program Outline

Course No.	Course Name	Hours / Week	Duration	Credit
PRA01C1	Course 1: GCP, GMP, QA, and QC, International Perspective (USA &Europe)	3 Hours Lecture 3 Hours Weekly Critical Thinking Project	2 months (9 weeks)	3 Credit
PRA01C2	Course 2: Drug, Biologic, and Biosimilar Regulatory Process, International Perspective (USA &Europe)	3 Hours Lecture 3 Hours Weekly Critical Thinking Project	2 months (7 Weeks)	3 Credit
PRA01C3	Course 3: Medical Device Regulatory Process, International Perspective (USA &Europe)	3 Hours Lecture 3 Hours Weekly Critical Thinking Project	2 months (8 Weeks)	3 Credit
PRA01C4	Course 4: Cosmetics, Combination Products, & Pharmacovigilance, International Perspective (USA &Europe)	3 Hours Lecture 3 Hours Weekly Critical Thinking Project	2 months (8 Weeks)	3 Credit
PRA01C5	Course 5: Practical Project	Take home Self Project	1 month (4 weeks)	2 Credit
Total Credits				14 Credit

Regulatory Affairs of Drugs and Medical Devices Training Program

(MENA Region) Program Outline

Course No.	Course Name	Hours / Week	Duration	Credit Hour
PRA02C1		3 Hours	7 Weeks	2 Credit
	Course 1: Drug, Biologic, and Biosimilar Regulatory Process, International Perspective (MENA Region)	2 Hours Weekly Critical Thinking Project		
PRA02C2	Course 2: Medical Device, Combination Products, Cosmetics, & Pharmacovigilance, International Perspective (MENA Region)	3 Hours 2 Hours Weekly Critical Thinking Project	5 Weeks	2 Credit
PRA02C3	Course 3. Practical Project	Take home Self-project	2 Weeks	1 Credit
Total Credits				5 Credit

Course Descriptions

PRA01C1 – Course 1. GCP, GMP, QA, and QC, International Perspective (USA &Europe)

3 credits. Online delivery.

Course Description: This three-credit-hour course provides students with a comprehensive understanding of Good Clinical Practice (GCP), Good Manufacturing Practice (GMP), Quality Assurance (QA), and Quality Control (QC) in the context of pharmaceutical and healthcare industries from an international perspective.

The course will explore the regulatory frameworks, standards, and guidelines governing GCP, GMP, QA, and QC practices across different countries and regions. Emphasis will be placed on understanding the principles and requirements outlined by international regulatory bodies such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), the World Health Organization (WHO), and regulatory agencies like the Food and Drug Administration (FDA) in the United States, the European Medicines Agency (EMA), and others.

Topics covered in the course include:

1. Overview of GCP, GMP, QA, and QC principles
2. Regulatory frameworks and guidelines for pharmaceuticals and healthcare products
3. Key concepts and requirements of GCP, including ethical considerations, patient safety, and data integrity
4. Principles of GMP for pharmaceutical manufacturing, including facility design, equipment qualification, and process validation
5. Quality management systems and processes for ensuring product quality and compliance with regulatory standards
6. Role of QA in maintaining product quality throughout the product life cycle
7. Principles and practices of QC, including analytical methods, sampling plans, and testing procedures
8. International collaborations and initiatives for harmonizing regulatory requirements and standards

The course will utilize a variety of instructional methods, including lectures, case studies, group discussions, and guest speakers from industry and regulatory agencies. Students will have the opportunity to apply their knowledge through practical exercises, assignments, and projects that simulate real-world scenarios and challenges faced by

professionals working in the pharmaceutical and healthcare sectors.

By the end of the course, students will gain a solid foundation in GCP, GMP, QA, and QC principles with an international perspective, preparing them for careers in pharmaceutical regulation, quality assurance, compliance, and related fields in a global context.

PRA01C2 - Course 2. Drug, Biologic, and Biosimilar Regulatory Process, International Perspective (USA &Europe)
3 credits. Online delivery.

This course focuses on drug regulations and regulatory submissions in the USA and Europe. In addition, biologic and biosimilar regulations and regulatory submissions in these regions are introduced and discussed.

Course Description: This course, spanning three credit hours, offers students a comprehensive understanding of the regulatory processes governing drugs, biologics, and biosimilars in key regions including the United States, Europe, and the Middle East and North Africa (MENA) region. Students will explore the intricacies of regulatory requirements, approval pathways, and post-market surveillance systems for pharmaceutical products, biologics, and biosimilars within an international context.

The course will delve into the regulatory frameworks established by regulatory agencies such as the Food and Drug Administration (FDA) in the United States, the European Medicines Agency (EMA) in Europe, and regional regulatory authorities in the MENA region. Through comparative analysis, students will gain insights into the similarities and differences in regulatory processes across these regions, including key considerations for product development, submission, review, and approval.

Key topics covered in this course include:

1. Overview of drug, biologic, and biosimilar regulatory pathways
2. Regulatory requirements for preclinical and clinical development phases
3. Submission requirements and documentation for marketing authorization applications
4. Review and evaluation processes conducted by regulatory agencies
5. Post-market surveillance, pharmacovigilance, and risk management strategies
6. Impact of international harmonization initiatives on regulatory processes
7. Case studies highlighting regulatory challenges and considerations in drug, biologic, and biosimilar development
8. Emerging trends and future directions in global regulatory affairs

Utilizing a combination of lectures, case studies, guest presentations, and interactive discussions, this course will provide students with practical insights into navigating the complex landscape of international regulatory affairs for drugs, biologics, and biosimilars. Students will also have the opportunity to engage in hands-on exercises and projects aimed at applying regulatory concepts to real-world scenarios and challenges.

By the conclusion of the course, students will emerge with a deepened understanding of the global regulatory environment for pharmaceutical products, biologics, and biosimilars, equipped with the knowledge and skills necessary to pursue careers in regulatory affairs, drug development, compliance, and related fields on an international scale.

PRA01C3 -Course 3. Medical Device Regulatory Process, International Perspective (USA &Europe)3 credits. Online delivery.

The medical device regulatory environment is constantly evolving. Medical device regulations, medical device classifications, and regulatory submissions are the focus of this course.

Course Description:

This three-credit-hour course offers students a comprehensive examination of the regulatory processes governing medical devices in key regions, including the United States, Europe, and the Middle East and North Africa (MENA) region. Students will explore the regulatory frameworks, approval pathways, and post-market surveillance requirements for medical devices within an international context, gaining insights into the complexities of global regulatory compliance.The course will provide an in-depth analysis of the regulatory requirements established by regulatory agencies such as the Food and Drug Administration (FDA) in the United States, the European Commission and Notified Bodies in Europe, and regional regulatory authorities in the MENA region. Through comparative study, students will develop an understanding of the similarities and differences in regulatory processes across these regions, as well as the implications for medical device manufacturers seeking market approval.

Key topics covered in this course include:

1. Overview of medical device classification and regulatory pathways
2. Pre-market requirements for medical device development and approval
3. Submission and documentation requirements for regulatory filings
4. Regulatory review processes conducted by regulatory agencies and notified bodies
5. Post-market surveillance, adverse event reporting, and quality management systems
6. Harmonization efforts and international standards impacting medical device regulation
7. Case studies illustrating regulatory challenges and considerations in medical device development and approval
8. Emerging trends and future directions in global medical device regulation

Through a combination of lectures, case studies, guest presentations, and interactive discussions, students will gain practical insights into navigating the dynamic landscape of international medical device regulation. Hands-on exercises and projects will provide students with opportunities to apply regulatory concepts to real-world scenarios and challenges faced by medical device manufacturers operating on a global scale.

By the conclusion of the course, students will emerge with a comprehensive understanding of the global regulatory environment for medical devices, equipped with the knowledge and skills necessary to pursue careers in regulatory affairs, medical device development, compliance, and related fields across diverse international markets.

PRA01C4 -Course 4. Cosmetics, Combination Products, & Pharmacovigilance, International Perspective (USA &Europe) 3 credits. Online delivery.

This course covers cosmetic as well as combination products regulations and regulatory submissions. The course explores advertising and promotion regulatory framework and teaches concepts of pharmacovigilance regulations and regulatory process.

Course Description:

This three-credit-hour course provides students with an in-depth exploration of regulatory processes and pharmacovigilance considerations for cosmetics, combination products, and pharmaceuticals with a focus on the United States, Europe, and the Middle East and North Africa (MENA) region. Students will examine the regulatory frameworks, approval pathways, and post-market surveillance requirements for these products within an international context, gaining insights into the complexities of global regulatory compliance and pharmacovigilance.

The course will cover the regulatory requirements established by regulatory agencies such as the Food and Drug Administration (FDA) in the United States, the European Commission, and national regulatory authorities in the MENA region. Through comparative analysis, students will develop an understanding of the similarities and differences in regulatory processes across these regions, as well as the implications for manufacturers and regulatory professionals operating in the cosmetics, combination products, and pharmaceutical industries.

Key topics covered in this course include:

1. Overview of regulatory frameworks for cosmetics, combination products, and pharmaceuticals
2. Classification and regulatory pathways for different product types
3. Pre-market requirements for product development, registration, and approval
4. Submission and documentation requirements for regulatory filings
5. Regulatory review processes conducted by regulatory agencies and notified bodies
6. Post-market surveillance, adverse event reporting, and pharmacovigilance practices
7. Harmonization efforts and international standards impacting regulatory compliance
8. Case studies illustrating regulatory challenges and considerations in product development and

approval
9. Emerging trends and future directions in global regulatory affairs and pharmacovigilance

Through a combination of lectures, case studies, guest presentations, and interactive discussions, students will gain practical insights into navigating the complex regulatory landscape for cosmetics, combination products, and pharmaceuticals on an international scale. Hands-on exercises and projects will provide students with opportunities to apply regulatory concepts and pharmacovigilance principles to real-world scenarios and challenges faced by industry professionals.

By the conclusion of the course, students will emerge with a comprehensive understanding of the global regulatory environment for cosmetics, combination products, and pharmaceuticals, equipped with the knowledge and skills necessary to pursue careers in regulatory affairs, product development, pharmacovigilance, and related fields across diverse international markets.

PRA01C5 –Course 5. Practical Project 2 credits. Online delivery.

In this course, the students will be provided with a fictional drug Common Technical Document (E-CTD) regulatory submission. The students are required to extract assigned regulatory deficiencies, prepare the regulatory response, and prepare the complete E-CTD submission according to the USFDA regulations.

PRA02C1 – Course 1. Drug, Biologic, and Biosimilar Regulatory Process, International Perspective (MENA Region)
2 credits. Online delivery.

This course focuses on clinical trials, Good Clinical Practices (GCP), Good Manufacturing Practice (GMP), and drug regulations and regulatory submissions in the MENA Region. In addition, biologic and biosimilar regulations and regulatory submissions in these regions are introduced and discussed.

Course Description:

This three-credit-hour course offers students a specialized examination of the regulatory processes governing drugs, biologics, and biosimilars with a focus on the Middle East and North Africa (MENA) region. Students will explore the unique regulatory frameworks, approval pathways, and post-market surveillance requirements for pharmaceutical products within the diverse and evolving regulatory landscape of the MENA region.

The course will provide an in-depth analysis of the regulatory requirements established by regional regulatory authorities such as the Saudi Food and Drug Authority (SFDA), the UAE Ministry of Health and Prevention (MOHAP), and other regulatory agencies across the MENA region. Through case studies,

guest lectures, and interactive discussions, students will gain insights into the regulatory processes, challenges, and opportunities specific to the MENA region.

Key topics covered in this course include:

1. Overview of drug, biologic, and biosimilar regulatory pathways in the MENA region
2. Regional variations in regulatory requirements and approval processes
3. Pre-market requirements for product registration and marketing authorization
4. Submission and documentation requirements for regulatory filings
5. Review and evaluation processes conducted by regional regulatory authorities
6. Post-market surveillance, pharmacovigilance, and risk management strategies
7. Harmonization efforts and collaborations among MENA regulatory agencies
8. Case studies highlighting regulatory challenges and considerations in drug, biologic, and biosimilar development in the MENA region
9. Emerging trends and future directions in MENA regulatory affairs

Through a combination of lectures, case studies, and interactive activities, students will develop a nuanced understanding of the regulatory environment for pharmaceutical products in the MENA region. Practical exercises and assignments will provide students with opportunities to apply regulatory concepts to real-world scenarios and challenges faced by pharmaceutical companies operating in the MENA market.

By the conclusion of the course, students will emerge with a comprehensive understanding of the regulatory landscape for drugs, biologics, and biosimilars in the MENA region, equipped with the knowledge and skills necessary to navigate regulatory compliance and contribute to the development and commercialization of pharmaceutical products in this dynamic market.

PRA02C2 - Course 2: Medical Device, Combination Products, Cosmetics, & Pharmacovigilance, International Perspective (MENA Region)

2 credits. Online delivery.

Medical device regulations, medical device classifications, and regulatory submissions in the MENA region are the focus of this course. The course explores cosmetic as well as combination products regulatory processes and teaches concepts of pharmacovigilance regulations and regulatory framework.

Course Description:

This three-credit-hour course provides students with a comprehensive understanding of regulatory processes and pharmacovigilance considerations for medical devices, combination products, cosmetics, and pharmaceuticals within the context of the Middle East and North Africa (MENA) region. Students will explore the diverse regulatory frameworks, approval pathways, and post-market surveillance requirements for these products, gaining insights into the complexities of regulatory compliance and pharmacovigilance in the MENA region.

The course will cover regulatory requirements established by regional regulatory authorities such as the Saudi Food and Drug Authority (SFDA), the UAE Ministry of Health and Prevention (MOHAP), and other regulatory agencies across the MENA region. Through case studies, guest lectures, and interactive discussions, students will examine the regulatory processes, challenges, and opportunities specific to the MENA region for medical devices, combination products, cosmetics, and pharmaceuticals.

Key topics covered in this course include:

1. Overview of regulatory frameworks for medical devices, combination products, cosmetics, and pharmaceuticals in the MENA region
2. Classification and regulatory pathways for different product types
3. Pre-market requirements for product registration and marketing authorization
4. Submission and documentation requirements for regulatory filings
5. Regulatory review processes conducted by regional regulatory authorities
6. Post-market surveillance, adverse event reporting, and pharmacovigilance practices
7. Harmonization efforts and collaborations among MENA regulatory agencies
8. Case studies illustrating regulatory challenges and considerations in product development and approval in the MENA region
9. Emerging trends and future directions in MENA regulatory affairs and pharmacovigilance

Through a combination of lectures, case studies, and interactive activities, students will develop a comprehensive understanding of the regulatory environment for medical devices, combination products, cosmetics, and pharmaceuticals in the MENA region. Practical exercises and assignments will provide students with opportunities to apply regulatory concepts to real-world scenarios and challenges faced by industry professionals operating in this dynamic market.

By the conclusion of the course, students will emerge with the knowledge and skills necessary to navigate regulatory compliance, pharmacovigilance, and product development in the MENA region, contributing to the advancement of healthcare products and ensuring patient safety and efficacy across diverse international markets.

RAD02R3 – Course 3. Practical Project

2 credits. Online delivery.

In this course, the students will be provided with a fictional drug Common Technical Document (E-CTD) regulatory submission. The students are required to extract information from the E-CTD and fill the challenging regulatory forms that are required from the Saudi FDA, Jordan FDA, and the UAE Ministry of Health as a practice to register this fictitious drug in these countries.

Tuition and Fees

Application Fee (non-refundable)	**$ 100**
Regulatory Affairs of Drugs and Medical Devices Training Program (USA & Europe) **Total Program Cost**	**$ 4,900**
Regulatory Affairs of Drugs and Medical Devices Training Program (MENA Region) **Total Program Cost**	**$ 1,750**

Payment is due in full at the time of registration. If a student has a balance 30 days after the start of the program.

The program tuition fees could be paid in monthly installments per school year at the beginning of each academic term. The costs encompass all the program's virtual services. Textbooks are not included in the tuition costs

A hold and late fees will be placed on the account until the balance is paid in full.

Finance

Radex Institute Education Director or designee will answer any questions regarding payments and/or student accounts, as well as facilitate the processing of payments of tuition and fees and refunds.

Cancellation and Refund Policy

1. Cancellation may be requested in person, via email, or via postal services.

2. All fees are to be refunded if the student cancels within three (3) business days after signing the Enrollment Agreement and making an initial payment, with the exception of the application fee.

3. Cancellation after the third business day, but before the first class, will result in a refund of 80% of the total fees paid with the exception of the application fees.

4. Cancellation after attendance has begun, through 40% completion of the program, will result in a pro-rata refund computed on the number of hours completed to the total program hours. Cancellation after completing more than 40% of the program will result in no refund.

5. Termination date: the termination date for refund computation purposes is the last date of actual attendance by the student unless earlier written notice is received. Actual attendance is measured by the date of last communication between student and Radex Institute Education representative or the school's instructor(s).

6. Students who cancel their enrollment before having completed full payment for a course, will have their tuition recalculated and their pro-rata refund deducted from the full tuition price. Students will complete payment of tuition owed after the recalculation.

7. Refunds will be made within 30 days of receipt of cancellation notice.

8. Students who cancel their enrollment after paying in full, but are not eligible for a refund, are entitled to retain access to the online courses they paid for, as well as receive any applicable course materials.

9. A student can be dismissed, at the discretion of the Director, for insufficient progress, nonpayment of costs, or failure to comply with rules. Students who are dismissed will be refunded as per the Institute's refund schedule.

10. If the school terminates a program for any reason, and the school is unable to meet its commitments to teach-out students from the program, those who have paid will receive a 100% refund on fees paid to the school.

11. For a student who is on a leave of absence, the termination date is the date the student was scheduled to return from the leave of absence and failed to do so.

Leave Of Absence

Students may request a Leave of Absence (LOA) for up to one calendar year. To request a LOA, the student submits the Leave of Absence form to the Director. Included in the request is the expected date of return. The Director will maintain contact with the student during the LOA to monitor the student's plans to return to studies.

Facilities & Technology Requirements

Radex Institute Education is located at 150 South Pine Island Road, Suite 360, Plantation, FL 33324 near the intersection of South Pine Road and West Broward Blvd, with a separate entrance identified for students and visitors.

All programs and courses offered through Radex Institute Education are offered online. Computers used for the coursework must meet the following technology requirements:

- Microsoft Windows 10 Pro 64-bit or newer.
- High-Speed Internet Access.
- Intel® i5 or i7 Quad-Core or Xeon Ivy Bridge or newer processors.
- 3.0 GHz or greater processor speed.
- 8 GB Memory recommended; 4 GB minimum.
- 256 GB Hard Drive or greater.
- Wireless Network Adapter.
- Adobe Flash version 9 or above.
- Web camera.
- Microsoft Office 2016 or above, or a subscription to Microsoft Office 365.
- Adobe Reader version 7 or above.

Adequate access to tech resources is the key to student success in an online learning environment.

Online Learning Expectations

Radex Institute Education uses asynchronous learning through the MoodleCloud learning platform and live sessions. Students are scheduled for online live learning sessions each week. Students are responsible for all material taught in a course. This includes material taught via lecture, interactive class session, or discussion board. Assignments must be submitted on time. The instructor may reduce the grade for an assignment as a penalty for discussion posts or work submitted late. Graded work that receives below 80% will require a discussion with the instructor.

Instructor Interactions

Instructors interact with students via the LMS, during weekly Office Hours, and by email. Instructors offer up to two hours per week to meet with students live. The office hours are posted on the course homepage as well as in the syllabus. These sessions take place either via conference call or online via web conferencing. Additionally, students may email the instructor directly. Every instructor informs students of his/her email address and any other contact information of their choice, and responds within 24/48 hours, unless it is a holiday or weekend. Students may post general questions or comments in the appropriate venue within the course.

Assignment Submission Policy

All assigned coursework should be submitted in the format outlined unless the student has received prior approval. This includes but is not limited to forum postings, projects, and instructor emails. Each assignment must be submitted by its due date. Assignments submitted late may be subject to partial credit, or in some cases not accepted as determined by the course instructor. All assignments should be submitted prior to the end of the course date. Students who fail to submit all coursework by program end will be issued a Fail (F) for the course. If special circumstances require an extension for submitting coursework past the end of the program, students may request an extension and be issued an Incomplete grade.

Instructors have the option to modify the Assignment Submission policy. If an instructor chooses to modify it, the instructor is required to inform students of the policy during the first week of class. The default policy for late work is as follows:

Faculty and staff of Radex Institute Education realize that emergencies do occur. If a student knows that he/she will be unable to complete an assignment by the due date, he/she is to contact the instructor PRIOR to the due date. Early contact is best, as plans can be made to keep the student from falling behind, and ensure the highest possible grade.

Student Identity Verification Policy

Radex Institute Education takes measures to assure that students' identity is verified and only the individual who was accepted and is enrolled in the Institute has access to course materials, examinations, and grade reports.

Student identity is verified during the application process by submitting a copy of a valid government-issued photo identification document, such as a driver's license or passport. In addition, a phone or web-conferencing interview helps the Admissions personnel to confirm that personal identifying information is accurate, through informal discussion and verification of personal details.

When a student applies to Radex Institute Education he/she receives a unique login and password. Most of the course content and all online gradebooks can only be accessed when the student logs into the website with his/her individual username and password. Prior to sharing information with a student by email, the student is asked to provide identifying information.

Student Services and Career Services

Counseling is available to all students regarding their academic progress, placement opportunities and other related matters. Students must make an appointment with the Director of Education or Student Services Coordinator.

When the student successfully completes the program, Radex Institute Education will assist the graduate with job placement at no additional charge. Radex Institute Education does not guarantee employment to its graduates. The school, however, takes diligent efforts to assist its graduates in finding employment.

The Director and Student Services Coordinator will meet with students during their program and are available to answer questions and assist students/graduates during their job search. Students are assisted with additional activities such as writing/revising resumes, contacting potential employers, follow up on job leads, and scheduling of actual interviews. No fee is charged to graduates or employers for use of this service.

Privacy of Educational Records

The Family Educational Rights and Privacy Act (FERPA) gives students the right to inspect their educational records upon reasonable notice within 45 days after the day Radex Institute Education receives

an access request. A student should submit to the school Director a written request that identifies the record(s) the student wishes to inspect. The school Director will make access arrangements. Students have the right to request the amendment of the student's education records that the student believes is inaccurate, misleading, or otherwise in violation of the student's privacy rights under FERPA. A student who wishes to ask the school to amend a record should write to the school's Director and identify the part of the record the student wants changed, and specify why it should be changed. If the school decides not to amend the record as requested, the school will notify the student in writing of the decision and the student's right to a hearing regarding the request for amendment. Additional information regarding the hearing procedures will be provided to the student when notified of the right to a hearing.

The Act also guarantees the privacy of student educational records and sets forth the conditions and circumstances under which a student's educational records may be shown to others. Generally, Radex Institute Education must have written permission from the parent or eligible student in order to release any information from a student's education record. However, FERPA (34 CFR §99.31) allows schools to release student information without the student's written consent if the disclosure is to:

- Other schools to which a student is transferring;
- Specified officials for audit or evaluation purposes;
- Organizations conducting certain studies for or on behalf of the school;
- Accrediting organizations;
- To comply with a judicial order or lawfully issued subpoena;
- Appropriate officials in cases of health and safety emergencies; and
- State and local authorities, within a juvenile justice system, pursuant to specific State law.

Schools may disclose, without consent, "directory" information such as a student's name, address, telephone number, date and place of birth, honors and awards, diplomas/degrees, enrollment status, and dates of attendance. However, the student may specifically request in writing that such directory information not be disclosed, in which case the information should not be released. Students who feel that their rights under the Act have been violated are entitled to request a hearing before a school official who has no direct interest in the outcome of such hearing in an effort to resolve the problem.

Student Code of Conduct and Sanctions

Radex Institute Education expects mature behavior. Regulations governing student conduct and activities are based on the premise that attending class in an environment conducive to learning is the right of each student. A student is subject to suspension or termination for conduct that disrupts the teaching or administrative activities of the Institute or interferes with the rights of the student community. Examples of conduct considered unsatisfactory under these standards include but not limited to dishonesty, failure to comply with the school's policies, procedures and regulations, or with the directions of school's officials acting in the performance of their duties, harassment, and verbal abuse.

The school reserves the right to terminate any student for one or more of the following:

- Non-compliance, or failure, to abide by school rules.
- Unbecoming conduct.
- Excessive absences.
- Failure to pay school fees/tuition.
- Cheating, stealing, plagiarism.
- Sexual harassment of another student, or of school personnel.
- Harassment of any kind (Intimidation/Discrimination).
- Verbal or physical violence.
- Use of abusive language, or profanity.
- Failure to maintain required academic progress.
- Insubordination to faculty or staff.

Appeals

A student will have 10 business days following the issuance of a grievance decision to file an appeal. Appeals must be in writing. Appeals may be made on the following grounds:

Unsupported Findings: The findings made by the Director or her/his designee are not supported by the reasons offered in the written decision.

New Information: There is new information available that wasn't available at the time the grievance was originally filed and that is sufficient to alter the original decision.

All appeals will be reviewed and decided upon within 7 business days after the receipt of such appeal.

Student Grievance Policy

- Any student who has a grievance with the University or an instructor should first discuss the problem with the instructor or pertinent staff member. When possible, student complaints should be resolved during this initial and informal stage without the need to resort to formal proceedings.

  If a resolution is not reached, the student should make a written complaint and submit it to the school Director asking for a written response. The school Director will either personally investigate the complaint or formally appoint a designee with no prior involvement in the matter to undertake the investigation. The Director or designee will undertake the investigation with the intention of arriving at a solution that is acceptable to all parties involved. He/she may consult with the student or other persons as appropriate. The student will be advised in writing within 30 days of the receipt of the student complaint of the outcome of their complaint and of any consequential action to be taken. This will include a summary of the reasons for the decision.

- If a satisfactory resolution of the problem is not obtained, the student may contact:

  Florida Commission for Independent Education

  325 West Gaines Street, Suite 1414 Tallahassee, Florida 32399-0400

  Email: cieinfo@fldoe.org

  Fax: 850-245-3238

  http://www.fldoe.org/policy/cie/file-a-complaint.stml