PEARA Global Education Institute
Catalog 2025-2026, Volume 4
Addendum, Effective April 8, 2026

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Page 24, PROGRAMS OF STUDY

Regulatory Affairs of Drugs and Medical Devices Training Program (USA & Europe)
Effective May 10, 2026, PEARA Global Education Institute is not enrolling new students in the program.

Regulatory Affairs of Drugs and Medical Devices Training Program (MENA Region)
Effective May 10, 2026, PEARA Global Education Institute is not enrolling new students in the program.

Effective May 10, 2026, PEARA Global Education Institute will accept new applications for the following program:

Global Regulatory Affairs of Drugs and Medical Devices
Credential awarded: Graduate Certificate
Program Length: 14 semester credits
Program Completion Time: 2 semesters
Method of delivery: Hybrid

Program Description
The certificate in Global Regulatory Affairs for Drugs and Medical Devices prepares students to become leaders in the regulatory field by helping them to become versed subject-matter collaborators in the U.S. and globally. Through participation in the program, students will develop and improve career-related skills in the highly regulated field of pharmaceutical and medical device manufacturing, marketing and sales. The curriculum covers regulatory environments in Europe, United States, MENA region (Jordan, Saudi Arabia, and United Arab Emirates), China, and Japan. Students will obtaining the necessary skills and knowledge to effectively navigate and manage regulatory affairs (RA) processes including operational RA, strategic RA, clinical RA, chemistry, manufacturing and controls (CMC) RA, and submission specialist RA.

Program Objectives
Upon completion of the program, students will:

- Understand the framework necessary to develop an integrated understanding of regulatory affairs in areas such as drug development and medical devices.
- Demonstrate knowledge of drug development and evaluation of global regulatory strategies that support biological product development.
- Understand topics such as protocol development, study design, post-marketing surveillance, evaluation, and assessment of regulatory submissions.
- Develop a regulatory strategy document for a medical product.
- Analyze the requirements of Good Manufacturing Practices regulations for medical products.

- Devise and implement global strategies for drug, biologic, and device development and evaluation.
- Differentiate USA and other regional requirements for drug product and biologics development and registration.
- Formulate critical elements of CMC to drug development.
- Relate principles of clinical research design to practices in clinical trial management.
- Explain and differentiate the regulations and regulatory affairs processes related to drugs, biologics, biosimilars, medical devices, combination products, and cosmetics to bring a medical product to market.

Program Outline

Course Number	Course Title	Credit Hours
	Program Core	
GRA500	Global Regulatory Affairs and Compliance	3
GRA510	Development and Manufacturing of Drug Products and Medical Devices	3
GRA520	Good Global Regulatory Practices	3
GRA600	Clinical Trail Design, Management and Protocols	3
	Electives [Must select one (1) course]	
GRA530	AI in the Regulatory Affairs Landscape	2
GRA540	Advertising and Promotion of Drugs and Medical Devices	2
GRA630	Practical Project	2
	Total Semester Credit Hours	**14**

Page 29, COURSE DESCRIPTIONS

GRA500 Global Regulatory Affairs and Compliance

This course explores international regulatory requirements for the development and approval of new pharmaceutical products and medical devices in the U.S., EU, MENA region (Jordan, Saudi Arabia, and United Arab Emirates), Japan and China. This 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. Roles in developing products, navigating

the regulatory review and approval process, and maintaining products on the market will be discussed. The course offers students an opportunity to be guided through compliance issues and to gain understanding of the relationship between compliance and CE marking. The course also covers the risks and rewards of CE marking and an overview of liability laws in each global region. **3 semester credits; Pre-requisite: None**

GRA510 Development and Manufacturing of Drug Products and Medical Devices
This course is designed to provide an understanding of the studies conducted in support of the development of drug product (formulation/dosage form) and medical devices necessary to seek regulatory approval. An emphasis will be placed on pre-formulation/formulation studies for optimizing lead compounds during early stages of drug development, current good manufacturing practices (cGMP), the regulatory frameworks, standards, and guidelines governing GCP, QA, and QC practices across different countries and regions, and FDA/ICH guidelines for formulation components, processes and equipment, stability testing programs and overall quality assurance. Special aspects of formulation of biologicals and medical devices will also be discussed. **3 semester credits; Pre-requisite: GRA500.**

GRA520 Good Global Regulatory Practices
This course examines global regulations on good laboratory practices (GLPs), good clinical practices (GCPs), and good manufacturing practices (GMPs). This includes the globalization of practices in the US, Europe, China, Japan, and the Middle East, and the roles and responsibilities of various professionals implementing these regulations locally and globally. This course incorporates case studies to explore the process for the assembly and submission of proposals for a new drug or medical device (IND or NDA); the function of the regulatory affairs department in a pharmaceutical company; and data quality issues required for regulatory decision-making. **3 semester credits; Pre-requisite: GRA500**

GRA600 Clinical Trial Design, Management and Protocols
This course examines the design and conduct of clinical trials from the perspectives of investigators, sponsors, and regulators. Basic principles of study design are reviewed and applied, and contemporary issues in study design and management are considered. Students gain experience in developing a clinical trial protocol within a team-based environment that will simulate project development in the pharmaceutical industry.
3 semester credits; Pre-requisite: GRA500

GRA530 AI in the Regulatory Affairs Landscape
As artificial intelligence (AI) and software play an increasingly critical role in biomedical science and healthcare, understanding their regulatory landscape is essential. Topics include the regulation of software as a medical device, model-informed drug discovery, AI-driven diagnostics and imaging, clinical trial technologies, and laboratory information management systems. Additionally, the course examines government privacy regulations, cybersecurity considerations, and evolving policies for AI in regulatory decision-making.
2 semester credit; Pre-requisite: None

GRA540 Advertising, Promotion of Drugs and Medical Devices
Exploration of globally regulated guidelines and protocols for the advertising and promotion of

pharmaceutical drugs and medical devices. The course focuses on pre- and post-market issues for prescription drugs and medical devices. Students will also learn about the management of risks and compliance surrounding medical and commercial communications in the healthcare industry. 2 **semester credit; Pre-requisite: None**

GRA630 Practical Project
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. **2 semester credits; Pre-requisite:** Completion of all program core courses.

Page 33, ACADEMIC CALENDAR
Effective August 31, 2025, the institution shall adhere to the following academic calendar:

August 31, 2025	Fall Term Begins
August 31, 2025 – September 27, 2025	Fall Mini-Term A
September 28, 2025 – October 25, 2025	Fall Mini- Term B
October 26, 2025 – November 22, 2025	Fall Mini-Term C
November 23, 2025 – December 20, 2025	Fall Mini-Term D
December 20, 2025	Fall Term Ends
December 21, 2025 – January 3, 2026	Winter Break, No Classes
January 4, 2026	Spring Term Begins
January 4, 2026 – January 31, 2026	Spring Mini-Term A
February 1, 2026 – February 28, 2026	Spring Mini-Term B
March 1, 2026 – March 28, 2026	Spring Mini-Term C
March 29, 2026 – April 25, 2026	Spring Mini-Term D
April 25, 2026	Spring Term Ends
April 25, 2026 – May 9, 2026	Spring Break, No Classes
May 10, 2026	Summer Term Begins
May 10, 2026 – June 6, 2026	Summer Mini-Term A
June 7, 2026 – July 5, 2026	Summer Mini-Term B
July 6, 2025 – August 2, 2026	Summer Mini-Term C
August 3, 2026 – August 30, 2026	Summer Mini-Term D
August 30, 2026	Summer Term Ends
August 30, 2026 – September 4, 2026	Summer Break, No Classes