PRA
CONSULTANCY

جامعة دبي الطبية
DUBAI MEDICAL UNIVERSITY
COLLEGE OF PHARMACY

Professional Regulatory Affairs

GCC Certification

Online/Onsite

Overview

The GCC Regulatory Affairs (RA) Certification is a healthcare certification,which educates young science and pharmaceutical graduates about the latest regulatory affairs, legislation and documentation in the region.

This course is also aimed at industry professionals who will additionally learn about the complexities of regulatory submissions related to products such as pharmaceuticals,herbal and veterinary medicines, agrochemicals, medical devices, supplements and cosmetics.

Why to Join

Upon Completion of this course, participants should be able to:

- Build up a solid and comprehensive foundation in regulatory affairs
- Understand the procedures of company, manufacturer and product registration according to the product category
- Create a thorough understanding of important regulatory concepts
- Gain expertise in the held of regulatory affairs documentation and process
- Encourage continuous learning and development in regulatory affairs field
- Get certified from Dubai Medical University
- Add a qualified certification to their CVs
- Know more about GCC health authorities regulations

Who Should Attend

- Students who want to pursue their career in regulatory affairs
- Young regulatory professionals who need more knowledge in regulatory affairs
- Professionals who want to shift their career to regulatory affairs career
- Regulatory Affairs Professionals who need to be certified by a recognized university.
- Personal who needs RA certification for the purpose of relocation or immigration
- Regulatory affairs professionals starting new projects in the GCC
- Professionals who want to have an update on the recent healthcare regulations in the GCC market

Experience & Prerequisite

This course doesn't require previous experience in regulatory affairs; however, it requires a relevant experience/ knowledge and a bachelor's degree in the Pharmaceutical/Medical area which qualifies you to benefit from the training.

We consider applicants with different background on a case-by-case basis.

Course Methodology

Our course is designed to equip participants with the real-world skills and knowledge required to be effective Regulatory Affairs Professional. Our course relies on a variety of training and facilitation methodologies and techniques used whenever applicable; these methods aim to enhance participant interaction while maximizing the learning journey.

Some of these methods are:

- Interactive presentations
- Group discussions
- Case studies

Course Timings

Sessions will start promptly at:

10:00 am and end at 02:00 pm,Dubai time.

every Sunday morning.

Course Structure & Duration

- One or Two modules will be delivered by the speaker from industries and academia at the Dubai Medical University.
- The course is conducted twice a year, only on Sundays for 3 months
- Participants will be evaluated based on individual module assessments that will be conducted online

Educational Partner

Dubai Medical University, Collage of Pharmacy the first pharmacy education institution in the Gulf region was established in 1992 to meet the growing needs of healthcare professionals. The beginning of a long journey to excellence and continued development was set forth by the astute visionary Haj Saeed Bin Ahmed Al Lootah under the leadership of Prof. Sherief Khalifa.

The institution is committed to providing accredited pharmacy education for undergraduate and graduate-level female students, advancing pharmaceutical knowledge through research and community service in order to serve the pharmacy profession, the scientific community, and the public.

In 2005, it won the Dubai Quality Appreciation Programme award for education presented by Sheikh Mohammed bin Rashid Al Maktoum, Crown Prince of Dubai.

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Type of Companies Hiring RA Professionals in GCC

- Pharmaceutical Companies and Manufacturers
- Medical Device Companies and Manufacturers
- Biologics and Biotechnology related sectors
- Veterinary Products Companies and Manufacturers
- Cosmetic Companies and Manufacturers
- Health Authorities
- Pharmaceutical Consultancy Companies
- Scientific Offices
- Marketing Authorization Holder Offices
- Medical Stores
- Healthcare Logistic Companies
- Notified Bodies
- Herbal Companies and Manufacturers

RA Professional Positions

- Regulatory Affairs Associates
- Regulatory Affairs Assistance
- Regulatory Affairs Head / Director
- Medical Information Associates
- Drug Inspector / Drug Controller / Drug Safety
- Specialist/ Regulatory Food
- Safety Scientist
- Quality Operations / Quality Control / Quality
- Assurance
- Regulatory Affairs Consultants
- Labeling Professional
- Public Affairs
- Pricing Strategy Expert

Module 1:
Introduction to Regulatory Affairs

This module presents an introduction to the field of Regulatory Affairs (RA) in the GCC. It will explore the regulatory pathway of medical products. It also briefly outlines the critical events and their impact on each stage of the product life cycle for drugs, biologics, and medical devices. The module will also touch upon the evolution of the regulatory profession and discuss the roles and responsibilities of a RA professional.

Module 2:
Common Technical Document (CTD)

This module will train the student in working with the Common Technical Document (CTD), created by ICH. It is the globally accepted format used for submitting new drug applications, product renewals, and variations by pharma to governmental authorities all around the world. The CTD is an essential part of the RA professional work. This module will provide extensive training to understand and master the CTD and the specific rules and requirements, regarding the different GCC countries.

Module 3:
Electronic Common Technical Document (E-CTD)

This module will focus on enabling the students to prepare, publish and validate e-CTD submissions. It will prove a clear understanding of the global e-CTD guidelines and go more depth into the regional differences between the GCC countries. The technical basis of the e-CTD structure will be explained so that the students will have a clear overview and understanding of all the aspects of the e-CTD.

Module 4:
Pharma Registration in GCC

This module will provide a thorough understanding of the requirements for the registration of pharmaceuticals in different GCC countries. It will cover the registration process in Kuwait, Bahrain, Qatar, UAE, Oman, and Saudi Arabia. This module will guide you step-by-step through the guidelines necessary from new product registration to product renewal. It will also provide a thorough understanding of the above & will help to gain the needed skill to do registration-related roles in a more effective manner.

Module 5:
General Sales List Pharmaceutical in GCC - General Products (OTC)

This module will provide you with all the necessary information about the requirements for general sales list pharmaceuticals. These are the medicine that can be purchased without the supervision of a pharmacist. This module consists of two parts: part one will discuss the guidelines set by the governmental authorities. The second part will focus on the guidelines that are followed by the manufacturing site of the pharmaceutical company.

Module 6:
Overview on Food & Beverages Regulatory Affairs

This module will explore theory, regulations, tools and techniques practice in Regulatory Affairs. This module contains three section. First section includes the information about GCC Regulatory Framework, GSO Ways of Working, Legislative Bodies in the Region. It also covers about the National, Regional & International Standards of Food & Beverages. This module will make you understand about the basic Terminology and Product Registration & Registration Markets in GCC. Second section includes Regulatory Standards in GCC (Halal Standards) and last section consist of Shelf life and Regulatory Role in Food Industry

Module 7:
Good Manufacturing Practice (GMP)

GMP are guidelines that provide a system of processes, procedures, and documentation to assure the product has the identity, strength, composition, quality, and purity that it is represented to possess.
This module is an introduction to the principles and practices of GMP. Emphasis will be given to the foundations of the regulations that control the manufacturing and distribution of pharmaceutical, biologic, and medical devices in the UAE.

Module 8:
Stability Studies Related to GCC

his module will provide a clear understanding of the science and principles, regarding the stability of pharmaceuticals. Stability testing is a mandatory requirement for product registration. Stability studies will determine the quality of the product and analyze the variation that occurs with time under the effects of different environmental factors. This module will also cover the stability guidelines that are specific to the GCC countries.

Module 9:
Product Life Cycle Management

The purpose of this module is to provide a good understanding of the Product Life Cycle (LCM) of pharmaceuticals.

The LCM forms an essential part of the company and includes all the regulatory submission plans.

Therefore, it is an essential part of the regulatory affairs profession. The module will present an extensive step to step guideline for the creation, management, dissemination, and execution of LCM documentation.

Module 10:
Registration of Medical Device in GCC

The regulatory framework of medical devices differs substantially from the registration of pharmaceuticals. During this module, you will learn how medical devices are classified in the different GCC countries, based on their design complexity, use characteristics, and potential harm. This module will cover all the essentials to actively plan, manage and execute registration submission plans for medical devices in the GCC countries.

Module 11:
Labeling Guidelines

This module will explain the basics of labeling and artwork design of pharmaceutical packaging.
It will provide guidance in labeling requirement compliance for GCC countries. It will outline and discuss all the necessary information to adhere to the requirements of the governmental authorities for pharmaceutical registration. Labeling is an essential part of the RA professional and a critical aspect of compliance with regulatory agency compliance.

Module 12:
Pharmacoeconomics

This module will introduce you to the field of Pharmacoeconomics, by focusing on the economic evaluation of pharmaceuticals in healthcare systems. It is designed to help the RA professional to acquire the skills necessary for applying pharma economic analysis on pharmaceuticals and gain an understanding of the pharmaceutical concepts (e.g., pricing, competitors) that are involved in the pharmacoeconomic analysis. Furthermore, this module will go more into depth in the methodologies, perspectives, and different analyses used by the RA professional to evaluate the economics of pharmaceuticals.

Module 13:
Registration of Cosmetics In GCC

The cosmetic industry has seen relatively stable growth over the past ten years, which makes it one of the most challenging and demanding markets. The regulatory framework for submitting cosmetic products is country-specific, with the GCC countries having their own specific requirements for cosmetic claims, labeling, translation, etc. This module will present the guidelines for registration of cosmetic products in the GCC countries and discuss several strategic approaches that can be followed for registration. The module is also designed to give you a full idea of the market compliance requirements for the registration of cosmetic products in the GCC. It will focus on the GCC standards and registration processes for the different strategies to register the cosmetic product in the GCC.

Module 14:
Gulf Health Council Registration

This module will able to Promote strategies and health policies to improve the health services in Gulf States. This module will also enable you to work collectively to strengthen cooperative ties in health fields in the region.

This session will allow you to control and eliminate the endemic & chronic disease. This module will also discuss how to Protect Gulf states from infectious diseases. GHC Registration is an essential part of the RA professional and a critical aspect of compliance with regulatory agency compliance.

Form a unified system to serve the mutual interests in the international.

The Gulf Health Council is the technical, administrative and financial body, which supervises and executes resolutions, directives and recommendations of the Ministry council.

Module 15:
Pharmacovigilance

This module is designed to provide a dear overview and understanding of the legal regulations and guidelines for good pharmacovigilance practices. This module will also discuss the essential documentation that are mandatory for good pharmacovigilance practices, such as the system master file (PSMF) and Periodic Safety Update Report (PSUR).

At the end of this module, students will be able to explain the different aspects of pharmacovigilance systems by the industry and the different global and local governmental agencies for PV governance. They will also be able to outline the main PV practices and risk management systems that are required for regulatory submission in the GCC countries.

Module 16:
The reimbursement mechanism in Gulf region

The module explores the definition, types, and basic concepts of reimbursement. The module discusses the current status of health insurance in the Gulf, focusing on the UAE. The main characteristics, areas, and principles of pharmaceutical reimbursement are detailed and explained. The mechanisms, policies, and formularies for pharmaceutical coverage in UAE health insurance are discussed.

The module aspires to empower the trainees with the tools to efficiently manage the complexities of pharmaceutical reimbursement in the private health insurance industry.

Module 17:
Pricing

This module is developed to create better knowledge of "WHY Pricing of Drugs is Regulated and HOW?

This module will enable you to understand the requirements and procedures involved for Criteria/Concepts adopted worldwide in Pharma Industry. Mainly focusing on Pricing Concept Adopted in Middle East and Gulf.

The module aspires to empower the trainees with the tools to efficiently Deep Dive in Gulf Pricing System and Guidelines

Module 18:
VET Medicine Regulation In GCC

This module will enable you to understand the requirements and procedures involved for VET Medicine Regulation. It will give you an overview of the GCC Veterinary Medicinal Product Registration process. The RA is multidisciplinary field, therefore it will help you to highlight the importance of registration for veterinary medicinal products in the GCC.
The purpose of this module is to provide you with a thorough understanding of GCC Veterinary Registration Authorities (Saudi FDA – MOCCAE in UAE - Ministry of Health Kuwait) background

Module 19:
Communication Skills in Regulatory Affairs & RA Interview

This module will consist of two parts. The first part will teach the student everything they need to know about effective and successful communication in the field of regulatory affairs. The RA is a multidisciplinary field, where communication with different entities from both industry and government is established. Excellent communication skills are a basic requirement for working in the RA field. The second part of this module will advise the student on how to find a job in regulatory affairs, what companies are looking for in candidates, and how to prepare for a job interview as a regulatory affairs professional.