PRA CONSULTANCY

جامعة دبي الطبية
DUBAI MEDICAL UNIVERSITY
COLLAGE OF PHARMACY

Medical Device Regulation Masterclass - MENA

Online

Knowledge Partner:

mecomed

Course Overview

This course has been designed to help individuals build up a solid and a comprehensive framework in the medical device's regulatory affairs, and to provide a basic understanding of the medical devices including IVDs., addressing market information, technical documents, and guidelines of the related authorities in MENA region.

We are a leading provider of professional trainings for the medical and pharmaceutical industry. Relying on our extensive training portfolio with expert instructors and recognized certifications.

If you want to understand the rules that govern the Regulation of medical devices in the middle east Market place this course is perfect for you.

Course Outcome

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

1.Gain an extensive understanding about the important rules and regulations of the medical devices and the related authorities in the MENA region.

2.Get an overview of the EU medical device regulations.

3.Understand the need of the medical device regulations.

4.Gain a comprehensive knowledge about the medical devices' Market in the MENA region.

5.Learn the steps and procedures of the MD registration in each country separately.

6.Understand the technical dossier requirement and required certificates and how to obtain them (such as CE and ISO).

7.Get an overview of the importation procedures of the medical devices as per the competent authority.

8.Understand the medical devices quality standards for the MENA region.

Educational Partner

Dubai Pharmacy College, 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. Dr. Saeed Ahmed Khan.
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.

Supporting Organization

Mecomed is the Middle East and Africa trade association for medical devices diagnostics and imaging. They are the voice of the industry in the healthcare landscape and the patient is in the centre of all their activities, and their stakeholders are healthcare professionals providers, payers, patients advocacy groups, departments of health, regulators and others.

The content of the masterclass has not been checked by Mecomed for accuracy, and hence Mecomed is not responsible for the information shared during the masterclass and it is under the sole responsibility of the organizer and/or speaker and/or Dubai Pharmacy College.

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Course Methodology

Our course is designed to equip participants with the real-world skills and knowledge required to be effective Regulatory Affairs professional in the medical device field.

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
- Individual and team exercises
- One-to-one and group discussions
- Case studies

Course Structure & Duration

- One or Two taught modules will be delivered by the speaker from industries and academia at the Dubai Pharmacy College.
- The course is conducted once a year.
- Participants will be evaluated based on individual module assessments that will be conducted online.
- The certificate will be issued one month after the course end.
- Course is available online.

Who Should Attend

This course is ideal for medical or science bachelor degree holders who would like to start their RA career in medical devices and for newly joined employees to the RA departments in a medical device company, it can also be useful for the below: Course is available online.

- For a professional RA who will newly start working in MENA region and wants to know more about the MENA region's regulations and guidelines of MD sector.
- Fresh graduates with pharma, biomedical engineering, pharmaceutical science, or any medical background who wants to start their career in medical device industry.
- Regulatory Affairs Professionals who would like to enhance their knowledge in the Medical Device sector.
- Operation Managers within the medical device industry.
- Marketing & Business Development Professionals within the medical device industry.
- Internal and External audits of the medical device Industry.

Experience & Prerequisite Experience

This course doesn't require previous experience in regulatory affairs; however, it requires a relevant experience/ knowledge and/ or a bachelor's degree in the pharma, biomedical engineering, Pharmaceutical science, or any medical background which qualifies you to benefit from the training.
We also consider applicants with different background on a case-by-case basis.

Why to Join

- To network, and share experiences with other industry colleagues.
- To get certified from Dubai Pharmacy College as a RA specialist in medical devices for MENA.
- To get the know-how, regulations, and guidelines in Medical devices sector.
- To understand the certifications and technical documents that is usually medical device manufacturer prepare.
- A gate way for a new career opportunity.
- The attendees will be supported by a letter from the college to find an internship opportunity.
- PRA consultancy will guide the participants whenever needed.

Course Timings

Sessions will start promptly at 10:00 am and end at 2:00 pm every Saturday and Sunday.
There will be one short break for refreshment at 10:00 am.

Modules

1- Introduction to Medical Device (IVDs)

- Introduction
- Medical device definition
- Terminology
- Classification and Certification to comply with as per USA, EU and ME and
- Covering the GHTF

2- GCC Medical Device registration – UAE , Oman , Bahrain , Qatar, and Kuwait

- Market access
- Registration requirements
- Importation requirements
- Case studies

3- GCC Medical Device registration – KSA

- Market access
- Registration requirements
- Importation requirements
- Case studies

4- Medical Device Regulation - Egypt & Sudan

- Market access
- Registration requirements
- Importation requirements
- Case studies

5- Levant Medical device regulations
(Syria , Jordan , Palestine, Lebanon, and Iraq)

6- Materiovigilance in EU & and QSR in ME

7- EU Medical device regulations / (IVDs)(MDD and new MDR)

- Market access
- Registration requirements
- Importation requirements
- Case studies

8- Medical Device Regulations - Morocco, Algeria, Libya, & Tunisia

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