باوزير فارما للاستشارات

Bawazir Pharma Consulting

Basics of Drug Regulatory Affairs

SFDA Explained

Date of The Training

2_October_2023

Riyadh, Saudi Arabia

2023

OVERVIEW

Understanding drug regulatory affairs in the GCC region is very important for persons working in pharmaceutical sector in the region. This course is specifically designed for persons working in the regulatory affairs departments or related fields, who need knowledge of the SFDA and GCC regulatory processes. This training will also enhance understanding and be beneficial to persons who work in clinical research, data management, basic research, project management and marketing, etc.

LEARNING OBJECTIVES

At the conclusion of this training, participants will be able to:

- Define the key principles and processes used by the Saudi Food and Drug Authority (SFDA) in regulatory submission and approval.
- Define official regulatory policies and other issues pertinent to a successful SFDA and GCC regulatory strategy
- Describe key differences between National and the Gulf Cooperation Council Drug Registration (GCC_DR) regulatory requirements.
- Describe the requirements for marketing applications for drugs and biologics, New Drug Application (NDA), Biosimilares, Generic drugs, herbal and health products and document preparation.
- Recognise SFDA oversight and processes during the post-approval phase.
- Interact appropriately with the SFDA during all phases of drug registration
- Understand the regulatory requirements for prescription drug labelling and advertising/promotion.

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KEY TOPICS

- Principals of Regulatory Affairs (RA) and Legal Framework
- SFDA overview and pharmaceutical institutions licensing
- Principles of Products licensing and Evaluation
- GMP Inspection and Products Pricing
- Overview of the pharmacovigilance system
- Principles of Products Classifications and Listing
- Products Import, Release and Advertising
- Overview of the SFDA Electronic systems

WHO WILL ATTEND

Professionals working in:

- Pharma Regulatory Affairs
- Fresh Graduate
- Scientific Office Managers
- Regulatory Authorities.
- Dossier Management
- Pharmacist
- Compliance

Bawazir Pharma Approach

Bawazir Pharma approach is grounded in the belief that compliance and quality should be managed as any other critical business issue. Proper quality management and a state of regulatory compliance will result in a decrease in direct costs such as rejects, and indirect costs such as adverse events and recalls.

Bawazir Pharma offers professional services to complete all aspects of regulatory affairs. The depth of our experience and knowledge acquired from our work with the Regulatory authorities ,ICH, International Standards Organization is made available to our partners. Our team can guide your organization through compilation of an original submission, perform submission maintenance and step in to support your internal staff during workload peaks.

PROGRAM

08:45 – 09:00 REGESTRATION

09:00 – 11:00 SESSION 1

Principals of Regulatory Affairs (RA) and Legal Framework

- The history and evolution of the regulatory authorities and profession.
- Principles of Regulatory Affairs and regulatory professional
- Basic terms and definitions.
- Legal Framework for Pharmaceuticals regulations.
- SFDA Law.
- Pharmaceuticals Institutions and Preparations Law.
- Principles of pharmaceutical preparations registrations.
- International Council for Harmonization (ICH) guidelines.
- Narcotics and psychotropic law.

11:00 – 11:30: COFFEE BREAK

11:30 – 12:45 SESSION 2

Principles of Products licensing and Evaluation

- ABC for pharmaceutical products licensing.
- Regulatory Framework for Drug Approvals V_60.
- Guidance for Submission V_4 0.
- General requirements for pharmaceuticals preparations registration.
- Principles of pharmaceutical preparations registrations.
- Common Technical Document (CTD) and eCTD.
- Pharmaceutical preparations evaluation process.
- Registration Committees.
- Product Variations Guidance.

12:45 – 14:00 LUNCH

14:00 – 15:30 SESSION 3

Principles of Products Classifications and Regulatory Intelligence

- Overview of product classifications.
- Guidance for products classifications.
- Overview of the SFDA Electronic systems.
- Regulatory Intelligence

16:00 END OF TRAINING

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REGESTRATION

REGISTRATION FEES

Registration fee including refreshment breaks and lunches and training course material

FEES	SAUDI RIYAL
REGISTRATION FEES	SAR 3000.00
EARLY BIRDS REGISTRATION FEE PAY YOUR FEE BEFORE 29 September, 2023.	SAR 1700.00

Payment can be made through our Website Or by Bank Transfer

Name: Saleh Abdullah Bawazir Pharma Consulting Center
مركز صالح عبدالله باوزير للاستشارات المهنية

IBAN: SA6905000068202617255000

Swift Code: INMASARI

Bank Name: Inma Bank, SaudiArabia

To confirm your registration please send your payment receipt with your full name to info@bawazirpharma.com

For Registration please follow the link below

www.bawazirpharma.com

CANCELLATION POLICY

- All cancellations must be made in writing and be received at the Prof. Bawazir Pharma Consulting Center one week prior to the event start date. Cancellations are subject to an administrative fee:

- SAR 1000.00
- If you do not cancel one week prior to the event start date and do not attend, you will be responsible for the full registration fee.
- Prof. Bawazir Pharma Consulting Center reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, Prof. Bawazir Pharma Consulting Center is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

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- You may transfer your registration to a colleague prior to the start of the event. Please notify the Prof. Bawazir Pharma Consulting Center of any such substitutions as soon as possible.

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EXPERT TRAINER

Prof. Saleh A Bawazir
CEO, Bawazir Pharma Consulting Center
EX-Vice President for Drug Sector (SFDA)

Professor Bawazir worked for eight years as an advisor to the Minister of Health for pharmaceuticals. During his work, he chaired the committee that revised and updated the pharmacy law, updated drug registration procedures and established pharmaceuticals pricing guideline. He also represented the Ministry of health in the national committee that negotiate Saudi Arabia accession to the World Trade Organization (WTO) and the committee that establish the Saudi Food and Drug Authority (SFDA).

For the last nine years Professor Bawazir worked as vice president for drug affairs and advisor at the SFDA. During his work, he led the drug sector development through a strategic plan and managed to establish a state of the art drug regulatory system that ensure quality, safety and efficacy of the pharmaceutical products and contributed positively to overall public health. Under professor Bawazir supervision the SFDA built many electronic databases and regulatory framework that implement electronic Common Technical Document (eCTD) for drug submissions and established a strong regulatory framework for clinical trials and construct the Saudi Clinical Trial Registry (SCTR) Database. Under professor Bawazir leadership the drug sector at the SFDA is recognized as a leading drug authority in the region and worldwide. Furthermore, Professor Bawazir represented the GCC for the last eight years in the Global Cooperation Group under the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)

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