باوزير فارما للاستشارات

Bawazir Pharma Consulting

Advance GMP II
Sterile Medicinal Products

03 November, 2022
Riyadh, Saudi Arabia

3 November 2022
Riyadh Saudi Arabia

OVERVIEW

Understanding the Pharmaceutical Quality System is an essential skills for people working in pharmaceutical manufacturing industry. This course will provide an overview of the pharmaceutical quality system for sterile medicinal product as specified in SFDA GMP guidelines and prepare for implementation. This one day course is designed to increase their knowledge in contamination control strategy, specific technologies and will provide a comprehensive, yet practical assessment of the regulations.

This training will also enhance understanding and beneficial to persons who work in product development and Technology transfer, regulatory compliance, pharmaceutical manufacturers, production engineering, site engineering, Quality Operations etc.

LEARNING OBJECTIVES

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

- Understand the principals of Production Technology for sterile medicinal products
- Understand the contamination control strategy
- Describe the premises for a clean area and clean area monitoring
- Understand the principles of specific technology for the sterile medicinal product manufacturing

KEY TOPICS

- Pharmaceutical Quality System (PQS)
- Personnel
- Equipment
- Premises clean area and monitoring
- Production Technology
- Specific Technologies
- Processing (Production-Sterilization)

WHO WILL ATTEND

Professionals Working in:

- Production – OSD
- Pharma Regulatory Affairs
- Product Development
- Production Engineers
- Quality Assurance
- Pharmacist
- Compliance

Bawazir Pharma Approach

Bawazir pharma consulting center 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 consulting centre 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.

TRAINING PROGRAM

08:45 – 09:00 REGESTRATION and COFFEE

09:00 – 09:30 SESSION 1:

Pharmaceutical Quality System (PQS)

- Introduction- Requirements of Mfg. of sterile products
- Contamination control strategy
- Pharmaceutical Quality System

09:00 – 09:30 SESSION 3:

Equipment

- Introduction- Design, Drawings & Qualification
- Maintenance and Cleaning
- Equipment- general
- Utilities- general, Water System, WFI, Steam, Compressed Air and Vacuum system

10:30 – 11:00: COFFEE BREAK

11:00 – 11:40 SESSION 4:

Premises- Clean Area

- Clean Area
- Grade A, B
- Clean Area- Cleaning, Drains
- Airlock
- Clean Area- Filtered Air, High potent material

12:45 -14:00 LUNCH

14:00 – 14:40 SESSION 6:

Production Technology

- Terminally sterilized products
- Aseptic preparation
- Finishing of sterile products

15:30 – 16:00: COFFEE BREAK

16:00 – 17:30 SESSION 8:

Processing (Production- Sterilization)

- Sterilization
- Sterilization- Moist Heat
- Sterilization- Dry Heat
- Sterilization- with ethylene oxide
- Filtration of Medicinal product which cannot be sterilized in their final container

PROGRAM OF DAY

09:45 – 10:30 SESSION 2:

Personnel

- Cleanroom
- Training
- Personnel monitoring and Process stimulation
- Hygiene and Cleanliness
- Restricted Access
- Clothing
- Laundry
- Aseptic technique

11:40 – 11:45 : BREAK

11:45 – 12:45 SESSION 5:

Premises- Clean Area monitoring

- Airflow pattern
- Facility Design
- Isolator
- Airborne particle, Viable particle
- Environment monitoring
- Clean Area- Environment, Contamination control

14:40 -14:45 BREAK

14:45 – 15:30 SESSION 7:

Specific Technologies

- Form-Fill-Seal (FFS) Technology
- Blow-Fill-Seal (BFS) Technology
- Lyophilization
- Closed System
- Single-use system (SUS)

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17:30 END OF TRAINING

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REGESTRATION

REGISTRATION FEES

Registration fee including refreshment breaks and lunches and training course material

FEES	SAUDI RIYAL
ADMISSION FEES	SAR 2000.00
EARLY BIRDS REGISTRATION FEE **PAY YOUR FEE BEFORE 21st October, 2022**	**SAR 1000.00**

Payment can be made by Card or Bank Transfer

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

IBAN : SA69-0500-0068-2026-1725-5000

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

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.

TRANSFER POLICY

- 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.

PHOTOGRAPHY POLICY

- By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by Prof. Bawazir Pharma Consulting Center in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership

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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 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. Furthermore, Professor Bawazir represented the GCC for eight years in the Global Cooperation Group under the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)

Eng. Sunil Nair FIE

Quality Operation Consultant,
Bawazir Pharma Consulting Center

Eng. Sunil Nair a Chemical Technologist, Pharmaceutical Engineer and fellow of the Institution of Engineers (India) - Royal charter-UK with Extensive Quality Operations and Knowledge Management experience of about 3 decades. Experience with Pharmaceutical, Cosmeceutical, Nutraceutical and Food industry.

He has been instrumental in setting up an independent quality and regulatory compliance framework meeting global GMP standards like USFDA,TGA and MHRA. He is Listed on the national Repository for open Educational Resources as content reviewer for MHRD, Govt of India and Training and development on ISTD.

He was Head Validation at SPIMACO for more than 8 years before joining Bawazir Pharma Consulting Centre.

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