باوزير فارما للاستشارات

Bawazir Pharma Consulting

Understanding Biological Good Manufacturing Practice (GMP)

Date of The Training

22 May 2023

Riyadh, Saudi Arabia

Riyadh

KEY TOPICS

- Bio-Pharmaceutical Industry
- Quality Management
- Personnel
- Bioprocess Engineering
- Mammalian Bioprocess
- Cell Banking System

OVERVIEW

Understanding basics of Biological GMP are essential skills for people working in pharmaceutical industry. This course will provide an explanation to biological GMP guidelines and how to prepare for inspection. This training will also enhance understanding and be beneficial to persons who work in scientific offices, regulatory affairs, pharmaceutical manufacturers, data management, basic research, project management and marketing, etc.

WHO WILL ATTEND

Professionals working in:

- Production manager
- QA manager
- QC manager
- Pharma Regulatory Affairs
- Scientific Office Managers
- Regulatory Authorities.
- pharmaceutical manufacturers
- Pharmacist
- CRO staff

LEARNING OBJECTIVES

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

- Understand the principals of biological manufacturing.
- Describe the components for Bio-pharmaceutical industry.
- Understand Host systems
- Understand bioreactor systems & bioreactor modes
- Understand Bioprocess Engineering
- Understand Mammalian bioprocess
- Understand Cell Growth Curve & biological data and analysis
- Describe Cell banking system

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BC Approach

BC 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.

BC 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 22 May 2023

08:30 – 0900 REGISTRATION and COFFEE

09:00 – 10:00 SESSION 1

BIO-PHARMACEUTICAL INDUSTRY

- QUALITY RISK MANAGEMENT
- QUALITY MANAGEMENT
- PERSONNEL
- BIOPHARMACEUTICAL FACILITY
- PW & WFI System

10:00 – 11:00 SESSION 2 :

BIO-PHARMACEUTICAL INDUSTRY

- Host Systems
- rDNA TECHNOLOGY
- MAMMALIAN CELL SYSTEM
- BIOREACTOR SYSTEMS
- BIOREACTOR MODES
- CELL ENGINEERING

11:00 – 11:30: COFFEE BREAK

11:30 – 12:30 SESSION 3:

BIOPROCESS ENGINEERING

- BIOREACTOR SELECTION AND DESIGN
- BIOREACTOR PREPARATION FOR INDUSTRIAL SCALE
- BIOREACTOR MONITORING
- ASEPTIC OPERATION

12:30 -14:00 LUNCH

14:00 – 16:00 SESSION 4

MAMMALIAN BIOPROCESS

- **Upstream Processing (USP)**
- Cell Culture
- Growth Curve
- Biological Data And Analysis
- HARVESTING
- **Downstream Processing (DSP)**
- Capture, Purification strategies
- Biopharmaceutical Product & specifications

16:00 – 16:20: COFFEE BREAK

16:20 – 17:15 SESSION 5

CELL BANKING SYSTEM

17:30 END OF TRAINING

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REGESTRATION

Registration fee including refreshment breaks and lunches and training course material

FEES	SAUDI RIYAL
ADMISSION FEES	SAR 3000.00
EARLY BIRDS REGISTRATION FEE PAY YOUR FEE BEFORE 18 May 2023.	SAR 2000.00

Payment can be made by telex transfer or Bank Transfer

Name : Saleh A. Bawazir Pharma Consulting Center
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IBAN : SA6905000068202617255000
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To confirm your registration please send your payment receipt with your full name to info@bawazirpharma.com

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CANCELLATION POLICY

- All cancellations must be made in writing and be received at the Prof. Bawazir Pharma Consulting Center (BC) office 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 (BC) reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, Prof. Bawazir Pharma Consulting Center (BC) 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 (BCG) 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 (BC) 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 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)

Dr. ABDULAZIZ M. AL-SHOAIBI
BioPharmaceutical consultant

Abdu!Aziz M. Alshoaibi has over twenty years in the pharmaceutical, Biopharmaceutical, and regulatory affairs environment. He has been a key Biopharmaceutical GMP inspector and evaluator at SFDA. He led the GCC team to inspect Manufacturing Processes Of Biological Product at Chugai Pharmaceutical Company, Japan. He was a speaker to deliver the presentation of BJOSIMILAR at 2nd Saudi International Regulatory And Registration Conference.

Alshoaibi has been quality assurance supervisor monitoring biopharmaceutical API process validation, and Audit routine activities. He has been a Senior member of quality control department and a key member to establish Biopharmaceutical Quality control Laboratory including all required systems and associated SOPs at SPIMACO where he acquires extensive experience in Quality Assurance system. In additional to that he gave training to new employees at Quality control department. He is a Member at Saudi Society For Clinical Laboratory Science Since 2009 and Member at UCD Engineering Graduates' Association Since 2012.

Alshoaibi has been a key member of faculty staff and Educational committee at SRC. He constructed and delivered many courses such as Gene technology, Biochemistry, and Analytical chemistry, etc.
He holds BSc. in BIOCHEMISTRY, KSU, MSc. In BIOPHARMACEUTICAL ENGINEERING and PhD in BIOPROCESS ENGINEERING, UCD.

Eng. Sunil Nair FIE
Quality Operation Consultant,
Bawazir Pharma Consulting Center

Eng. Sunil Nair a pharmaceutical Engineer with Extensive Technical 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 was Head Validation at SPIMACO for more than 8 years before joining Bawazir Pharma Consulting Centre.

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