EFFICIENT BATCH RECORD DESIGN AND REVIEW

2 DAY VIRTUAL SEMINAR

OVERVIEW

This online training course provides a comprehensive and practical understanding of Batch Record Design, Documentation, and Review in compliance with FDA, EMA, and EU GMP requirements. Regulatory agencies require every manufacturer to maintain written procedures that document production and process controls — collectively known as batch records. Additionally, there must be formalized procedures for batch record review to ensure accuracy, traceability, and compliance with global quality standards.

WHO WILL BENEFIT

This online training is designed for professionals in the Pharmaceutical, Medical Device, and other life science industries. This Education Course is designed for all persons in Production and Quality Units who deal with the design and review of batch documentation in pharmaceutical, biopharmaceutical and API production. It is also addressed to Qualified Persons who want to improve their system of the batch record review
It will be especially valuable to the personnel and management, including senior management, in these areas:

- Quality Assurance
- Quality Control
- Facilities
- Manufacturing
- Validation Professions in GMPs and Pharmaceuticals

KNOW YOUR FACULTY

Kelly Thomas, Head Of Quality Assurance (USA)
Highly experienced Quality Assurance / Quality Control / Regulatory Compliance leader with experience in API, biologics / biotech, both aseptic and terminally sterilized manufacturing processes, medical devices, drug / device combination products, and all pharmaceutical dosages (Sterile Injectable, OSD, Controlled Substances, Aerosols).

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AGENDA

Regulatory Requirements applying to Batch Record Review, Pharmaceutical Documentation & the Quality System

- Global regulations and expectations
- Regulations Update and Latest Developments in Industry
- How documentation fits into the Quality System of recommendations and regulations
- Important data for Quality Assurance
- Risk Assessment and Continuous Improvement

The Design of the Master Batch Documentation

- Is there a need for re-design?
- Important aspects to consider
- How to gain efficiency

Efficiency in Batch Record Review

- Layout and handling
- How to reduce review time: examples
- How to handle and document deviations
- How to present review results to the QP
- Balanced Score Card
- KPIs

Risk Assessment/ Management Applications within the Batch Record Process

- How the risk lifecycle links with the BRR stages:
- Risks associated with paper and electronic records
- Risks associated with people checking documentation
- Relative risk factors
- Risks associated with the process
- Risks for QP 'discretion'
- Quality Risk Management
- Impact the effectiveness of deviations, OOS and

Change Controls

- Improvement of root cause investigations
- Using QRM to perform a SWOT analysis
- What does a good risk assessment look like?

QA Oversight on EBR validation activities

- Validation Life Cycle
- Qualification activities
- Maintenance
- Training

REGISTRATION FORM

Name **Email**

Organization **Department** **Position**

Phone **Mobile**

Register Online At www.worldcomplianceseminars.com

or by calling our offi ce : 844-267-7299

Terms And Condition

- Registration shall be reconfirmed only once payment has been made prior to the course.
- Cancellation of participant/s shall be submitted in writing to WCS ten days (10 days) before the course. There is a 50% liability on all bookings once made.
- WCS reserves the right to make alterations to the conference/executive briefing content, timing, speakers without notice. The event may be postponed or cancelled due to unforeseen events beyond the control of WCS. If such a situation arises, we will refund your registration fee or we will try to reschedule the event.