RISK MANAGEMENT OF RAW MATERIALS IN A GMP ENVIRONMENT

2 HALF DAY VIRTUAL WORKSHOP

Overview

Risk management of raw materials in a cGMP environment is an area that is often overlooked as a Company develops new products. Depending on the product being developed, e.g., tablets and capsules vs. biotechnology products, as few as fifteen to twenty raw materials or as many as sixty need to be sourced and accepted before the process can be moved from initiation through completion. This live, interactive presentation will extensively review this area. It will also delve into the renewed issue of microbial and endotoxin contamination of these raw materials and why the FDA, EMA and Health Canada have recently focused on them.

Training Agenda

- How to develop an overall strategy for testing raw materials in a Phase 1 through Phase 3 environment.
- What raw material testing is required during each Phase of clinical trials.
- What your Certificate of Analysis (COA) may and may not tell you.
- How to manage non-compendial testing.
- Issues with small vs. large molecules.
- Types of raw materials and their concerns to the user.
- Packaging and storage requirements and their impact on in-coming materials
- Impact of raw materials receipt in the timely production of a product.
- Review of validation criteria and recommendations for satisfying each as part of a microbiological validation.
- What is the single largest used raw material in large molecule production.
- Sources of analyses assistance for raw materials.
- Initiation of additional testing — when???
- Observe Warning Letters related to Raw Material issues.
- ASQ Testing square root of “n” plus 1 vs the ASQ methodology.

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Who Will Benefit

- QC and analytical methods scientists and managers
- QA directors, managers and personnel
- Compliance/Regulatory affairs professionals
- Managers of GMP facilities
- Supply chain managers
- Purchasing and Materials Control managers
- GMP site personnel
- Senior managers of companies using CMOs
- People investing in FDA-regulated product development projects.

Faculty Barry A. Friedman

Dr. Barry A. Friedman holds 30+ years of experience in aseptic processing, and regulatory compliance. Testing raw materials, environmental controls, microbiological factors, QC compliance, and analytical chemistry are his core expertise. Additionally, he has also worked on phases 1, 2, and 3, and commercially certified products obtained from bacteria, yeast, and mammalian cells. Since Dr. Friedman specializes in aseptic processing, internal audit, and regulatory compliance, you can discuss validation criteria and techniques to pass the FDA inspection.

REGISTRATION FORM

Name _____ **Email** _____

Organization _____ **Department** _____ **Position** _____

Phone _____ **Mobile** _____

Register Online At www.worldcomplianceseminars.com

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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.