2-Day Video Conference Seminar

Raw Material Requirements (Health Canada/USP/EP) in a cGMP Environment - Issues and Solutions

By: Barry A. Friedman, Ph.D, Consultant in Biotechnology, Regulatory Compliance and Aseptic Processing Arena




SPEAKER

Barry A. Friedman, PhD LLC Consultant in Biotechnology, Regulatory Compliance and Aseptic Processing Arena

Barry A. Friedman, PhD, is a Consultant in the Biotechnology, Regulatory Compliance and Aseptic Processing Arena. Â Dr. Friedman possesses over 30 years of industrial managerial experience in various aspects of biopharmaceuticals and medical devices to include regulatory compliance, GLP/GMP, quality control, auditing, microbiology consulting, expert witness, sterility assurance, microbiological/analytical validations and fermentation technology.

LEARNING OBJECTIVES

Upon completing this course on raw material requirements in a cGMP environment participants will:

- Understand how various types of raw materials may impact the user.
- Learn of the impact of raw materials to include any bacterial and endotoxin issues in the timely production of a product.
- Determine the single most used raw material in large molecule production and what it means to the user.
- Find the sources of analyses assistance for raw materials.
- Appreciate the requirements for Phase 1 through commercial manufacturing—why safety is required as part of Phase 1
- Initiation of additional testing -- when?
- Examination of regulatory risk to include ICH Q7, Q9 and Q11.
- Why use compendial testing in lieu non-compendial testing.
- Testing requirements -- when is enough?
- Understand packaging and storage requirements and their impact on in-coming materials to include both raw materials and API.
- The impact of ASQ vs. square root of N+1 on sample size and attribute testing.

2-Day Video Conference Seminar

Raw Material Requirements (Health Canada/USP/EP) in a cGMP Environment - Issues and Solutions

COURSE DESCRIPTION

Raw material requirements in a cGMP environment are often overlooked as a Company develops new products. Depending upon the product being developed, e.g., tablets and capsules vs. biotechnology products to include recombinant microorganisms and gene therapy products, as few as fifteen to twenty or as many as sixty raw materials need to be sourced before the process can be moved from initiation through completion.

This highly interactive two day seminar on raw material requirements in a cGMP environment will:

- Compare and Contrast FDA, Health Canada, ICH, USP and EP requirements
- Review latest updates to include FDA, Health Canada, ICH, USP and EP requirements
- Examine a variety of the issues surrounding raw materials to include what materials should be tested and to what extent during Phase 1, 2, 3 and commercial production.
- Cover testing requirements during each Phase (Phase appropriate), to include microbial and endotoxin, and what may be optional (regulatory risk) until the product moves to its next Phase.
- Determine what options exist - even within a Phase 2 or Phase 3 testing framework.
- Discuss compendial vs. non-compendial testing and how to respond when no method is available.
- Discuss how a 90 percent vs. a 90.0 percent minimum purity analysis can delay initiation of testing.
- Explore the number of lots required for testing before reduced testing might occur and why some companies don't accept this route.
- Review the use of individual samples vs. composite samples for testing.
- Review packaging and storage requirements and their impact on in-coming materials to include both raw materials and API.
- Explore ASQ testing to include how to choose attributes and sample size.
- Determine when the ASQ vs. square root of N+1 is appropriate.

The objective of this FIVE HOUR/DAY, ON-LINE two day highly interactive WCS seminar is to explore raw materials and their requirements – issues and solutions. It will also explore how water impacts the final product since water is the single largest raw material that is used within most processes. Another objective is to assure that your organization is maintaining itself within a cGMP compliance framework to include ICH Q7, Q9 and Q11. Case studies to include Warning Letters will be discussed to illustrate regulatory raw material issues.

AGENDA

DAY 01

10.00 AM: Session Start

- Compare and Contrast FDA, Health Canada, ICH, USP and EP requirements.
- The various raw materials and the user impact
- Impact of raw materials in the timely production of a product
- The impact of the single most used raw material in large molecule production and its impact upon the user
- The regulatory requirements for Phase 1 through commercial manufacturing
- The use of additional testing – does one only review the C of A

DAY 02

10.00 AM: Session Start

- The use of compendial testing in lieu of non-compendial testing – pros and cons
- Regulatory risk (ICH Q9) with raw materials
- Testing requirements – how to sample
- Testing requirements – how to test
- The impact of ASQ and square root of N+1 on sample size and attribute testing
- Case Studies – Time to apply the previous two days
- Warning Letter examples

WHO WILL BENEFIT

- Quality professionals
- Regulatory professionals
- Compliance professionals
- Manufacturing engineers
- Quality engineers
- Quality auditors
- Quality Control
- Microbiology
- In-coming Materials
- Document control specialists
- R & D

2-Day Video Conference Seminar

Raw Material Requirements (Health Canada/USP/EP) in a cGMP Environment - Issues and Solutions

REGISTRATION FORM

Name **Email**

Organization **Department** **Position**

Phone **Mobile**

One Dial-in One Attendee - Live	Live Group-Max. 5 Attendees
$1495	**$3995**

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.