Raw Material Requirements (Health Canada/USP/EP) in a cGMP Environment
- Issues and Solutions: 2-day In-person Seminar

Description: Course Description:

Raw material requirements in a cGMP environment are 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 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:

- Consider Health Canada, FDA, 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 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.
- Explore ASQ testing to include how to choose attributes and sample size.

The objective of this two day 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. Case studies to include Warning Letters will be discussed to illustrate regulatory raw material issues.

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 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.
- Initiation of additional testing -when?
- Examination of regulatory risk (ICH Q9).
- Why use compendial testing in lieu non-compendial testing.
- Testing requirements -when is enough?
- The impact of ASQ on sample size and attribute testing.

Contents: Day Two (8:30 AM – 4:30 PM)

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 on sample size and attribute testing
Case Studies - Time to apply the previous two days
Warning Letter examples
Day One (8:30 AM - 4:30 PM)

Registration Process: 8:30 AM - 9:00 AM
Session Start Time: 9:00 AM

- 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 Two (8:30 AM - 4:30 PM)

- 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 on sample size and attribute testing
- Case Studies - Time to apply the previous two days
- Warning Letter examples

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