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Validation Fundamentals

*A Hands-on Two-Day Workshop Covering the
Basics for Conducting a Successful Validation Effort*

JUNE 10-11, 2009, SHERATON LA JOLLA HOTEL, LA JOLLA, CA

Key Learning Objectives:

- **Understand GMP and Validation Requirements**
- **ASTM E2500 Consensus Standard: Exploring New Thinking on Validation**
- **Master Planning for Validation Approaches**
- **Know the Critical Documents Needed for Successful Validation**
- **Validation Protocol Development and Defining Acceptance Criteria**
- **Protocol Execution Criteria and Addressing Deviations**
- **Learn Strategies for Ensuring the Operation Stays in a Validated State**

Including Multiple Interactive Exercises and Case Study Examples

Instructor:

Gamal Amer, Ph.D.

- *Experience includes over 25 years work in the pharmaceutical and related industries*
- *Has held senior management positions with leading pharmaceutical and consumer products companies*
- *Comprehensive process design experience in bulk pharmaceutical chemicals manufacturing, biotechnology manufacturing, pharmaceutical solid dosage manufacturing, and containment of potent and radioactive therapeutics*
- *A recognized expert in Risk Management Planning (RMP), Risk Based GMP Compliance, and validation.*
- *Has lectured and published extensively, including in peer reviewed publication on Risk, Validation and GMP compliance.*

Bring this workshop to your location:

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WORKSHOP AGENDA

DAY ONE

8:30

Introduction to GMP and Validation Requirements

The drug, food and cosmetics act gives the FDA the authority to ensure that such products are safe for human consumption. The Code of Federal Regulations (CFR) clearly stipulate that manufacturers of healthcare products, namely pharmaceuticals, biologics and medical devices are to insure that they are producing quality products and that they build the quality into rather than measuring it in the final product. To achieve such an objective the industry and the regulators expect that processes to manufacture such products would be validated.

- Review the GMP requirements for drug manufacture
- Review of CFR requirements of validation and process consistency
- Review of ISPE Guide Base Line guide on commissioning and validation.
- FDA's expectation as gleaned from 483 observations
- What is validation and how to approach it

9:30

ASTM E2500 Consensus Standard: New Thinking on Validation

The presentation will focus on providing an overview of the contents of this important standard. The impetus for developing the standard was to reduce the cost of validation, reduce the amount of paperwork and simplify the effort.

The standard sets scientific risk assessment as the basis for defining systems which must be verified as to their suitability for the intended use. It does recommend that Subject Matter Experts (SME) be utilized extensively in any verification effort and suggests that it is a good strategy to leverage information from your supplier and not repeat the work. Both industry and the regulators are still reviewing it and assessing its potential impact.

We will explore:

- The details of the standard and how to apply them
- What is meant by Verification of suitability for intended use
- How to use a science- and risk-based approach to ensure the proper verification is conducted
- The importance of User Requirement Specifications (URS), Good Engineering Practice (GEP), Quality by Design (QbD), and SME in support of the validation effort

10:30

Refreshment Break

11:00

Master Planning for Validation

Validation Master planning is an essential part of the overall validation effort for the production of pharmaceuticals and/or biological therapeutic agents. It is a scope document aimed at defining the extent of the validation effort and guiding it and the personnel involved with it. The plan defines which systems will be qualified, and how they will be qualified. In addition, the plan identifies the required resources to meet its objectives and the schedule to successfully implement the effort.

During the presentation you will learn:

- To define critical systems requiring qualification.
- The protocol requirements to complete the validation and meet the regulatory imperatives.
- How to define acceptance criteria and how to address/resolve deviations encountered during validation.
- How to prepare a VMP which will be approved and continue to be useful once it is approved.
- Define the schedule and priorities to insure successful validation effort.
- How to obtain commitment from the various organizations and stakeholders within your company to assist on making the validation effort a success.

12:00

Lunch

1:30

Critical Documents Needed for Successful Validation

Validation, which is confirmatory in nature, is a regulatory requirement. The regulation requires the preparation of many documents (VMP, Protocols, SOPs, etc.) in order to conduct the validation itself. Prior to preparing the required document you need to assemble, file and control certain documents associated with all of the equipment and each of the systems being validated. Collecting, filing and controlling of such documents is an integral and necessary part of any successful validation effort.

This session will discuss the following:

- Which documents you need?
- What are they needed for and how to use them?
- Where are the document and how to obtain them?
- How to file and control such documents

2:30 *Refreshment Break*

3:00 **Hands on Exercise**

Attendees will be asked to prepare a Standard Operating Procedure (SOP). A short introductory discussion will be moderated by the course instructors followed by a review of example SOPs. Once attendees are familiar with SOPs, they will be given a defined assignment to prepare a specific SOP following the guidelines presented. Upon completion of the assignment, an open discussion of the issues encountered by the attendees in the preparation of the document will ensue.

4:30 *End of Day One*

DAY TWO

8:30 **Validation Protocol Development and Defining Acceptance Criteria**

The current industry standard is to use Installation Qualification (IQ), Operation Qualification (OQ), and Performance Qualification (PQ) protocols to qualify equipment and systems. The Process Validation (PV) protocol is the ultimate protocol, which when successfully executed signifies the completion of the process validation effort. Protocols are a procedure to perform the appropriate tests to measure the performance of the system/equipment and represent a repository of all the data collected. It is important to recognize that each protocol is designed to accomplish specific objectives. Choosing the appropriate acceptance criteria to ensure the protocol achieves its objective is the most important part of preparing such protocols.

In this session you will learn:

- What the various protocols are designed to accomplish?
- How to prepare a flexible protocol that is easy to execute
- What are the appropriate acceptance criteria?
- How to develop the appropriate test to ensure the systems function as designed

9:30 *Refreshment Break*

10:00 **Hands-on Exercise**

In this session, the attendees will be given a description of a small system to be validated. Attendees will be divided into groups to work together on developing the appropriate protocols for validating the system. At the end of the session the class will review and discuss the issues

encountered while developing the protocols and attempt to identify hurdles to the execution of such protocols.

12:00 *Lunch*

1:30 **Protocol Execution and Addressing Deviations**

Once the protocols have been prepared and approved they must be executed. Execution has to be performed by trained personnel. Measurements and analysis have to take place using calibrated instruments and validated analytical methods. As the protocols are being executed, one will encounter many challenges associated with the as built conditions, which have to be properly and effectively addressed prior to pronouncing the equipment or system qualified or the process itself validated.

In this session you will learn:

- The appropriate methods to approach protocol execution
- Who should perform the protocol execution
- The importance of analytical methods validation and the use of calibrated instruments.
- How to effectively address deviations from pre-established acceptance criteria
- How to prepare summary reports for executed protocols that will be approved.

2:30 *Refreshment Break*

3:00 **Ensuring the Operation Stays in a Validated State**

Once the process and facility are validated it is important to ensure that they remain in validated state. Such an endeavor is achieved through monitoring and establishing a Change Control System. The concept of the validation life cycle will be discussed and ways of ensuring changes do not result in loss of control will be reviewed.

By attending this session you will learn:

- What is Change Control?
- What are the various types of changes one may encounter?
- When and where would validation be affected by change?
- How to prepare a Change Control SOP?
- When to apply change control in a simple manner?
- How to defend your actions to the regulators?

4:00 *End of Workshop*



PharmaEd Resources, Inc. • 2810 Robeson Park Drive • Champaign, IL 61822

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REGISTRATION INFORMATION

Register for the conference using one of four options:

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VALIDATION FUNDAMENTALS:

A Hands-on Two-Day Workshop Covering the Basics for Conducting a Successful Validation Effort
June 10-11, 2009, Sheraton La Jolla Hotel, La Jolla, CA

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To pay by check, please provide a purchase order below. Please note that all payments must be received five (5) days prior to the conference to ensure space. Attendees will not be admitted to the conference without full payment.

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PLEASE NOTE:

PharmaEd Resources does not offer refunds. However, if you cannot attend after registering, we are happy to apply your registration fee to another PharmaEd Resources event, or transfer your registration to a colleague. Notice of cancellation must be received at least 5 days prior to the event.

VENUE INFORMATION:

Dates: June 10-11, 2009
Hotel: Sheraton La Jolla Hotel
Hotel Address: 3299 Holiday Court
La Jolla, CA 92037
Reservations: (866) 716.8130 US
Hotel Telephone: (858) 452.4013
Fax: (858) 453.9909