

Register by
September 1st
and receive a
\$300 Discount!

PharmaED's

Cleaning Validation

A hands-on two day workshop covering the key components of cleaning validation planning, implementation and maintenance

OCTOBER 26-27, 2009, RADISSON-PLAZA WARWICK, PHILADELPHIA, PA

Key Learning Objectives:

- Understand the Regulatory Requirements for Cleaning Validation
- Review the Phases of the Cleaning Validation Lifecycle
- Develop an Effective Cleaning Validation Master Plan
- Effectively Develop and Define Acceptance Criteria
- Learn How to Appropriately Address Deviations
- Implement Strategies for Change Control, CAPA and Ongoing Monitoring
- Understand Steps Toward Continuous Improvement

About Your Trainer:

Instructor:

Gamal Amer, Ph.D.

- *Experience includes over 25 years experience 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:

For more information, contact PharmaEd Resources at (217) 721-5774.



PharmaED
RESOURCES, Inc.

WORKSHOP AGENDA

Day One

8:30

Cleaning and Cleaning Validation: The Regulatory Imperative

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 their equipment, facility and personnel are cleaned and maintained in a clean state. To achieve such an objective the industry and the regulators expect that manufacturers of such products will develop appropriate methods to clean and that the methods will be validate these methods. In this session we will:

- a. Review GMP cleaning requirements for drug manufacture
- b. Review CFR requirements to validate cleaning
- c. Review of FDA and Health Canada Guidance on Validating the Cleaning Process.
- d. Review ICH Q7 and Q9 requirements on Cleaning and Cleaning Validation
- e. Identify FDA's expectation as gleaned from 483 observations
- f. Applying the Risk Based Compliance approach to Cleaning and Cleaning Validation.

9:30

The Cleaning Lifecycle: A Holistic Approach to Compliance

The presentation will focus on advancing the principal of a cleaning and cleaning process validation lifecycle consisting of three phases. These are namely;

- a. The development and planning phase
- b. The execution phase
- c. The implementation and continuous improvement phase.

In order to ensure that cleaning is compliant with the regulatory requirements, one must spend time on

planning and developing the appropriate strategies of ensuring the equipment and facility can be cleaned through applying proper design strategies. The next step is to plan how to clean the equipment and facility and develop the cleaning procedures. The validation protocols are then developed and of course development of appropriate analytical methods as well as measuring techniques to be implemented as part of the validation and maintenance phases are identified.

The execution phase is where the cleaning procedure and techniques devised are tested and validated. This requires defining meaningful acceptance criteria and the appropriate approaches to address deviations from such criteria. Information gleaned from the execution phase is then fed back into the planning and development phase allowing for modification and continuous improvement.

Once the cleaning process is validated, then it is implemented according to plan. As time progresses, issues that arise are identified through implementation of a monitoring program and a robust CAPA program. The information resulting from both programs is also fed back into the planning and development phase to insure continuous improvement is achieved and that the knowledge is used for future development.

10:30 *Refreshment Break*

11:00 **Master Planning for Cleaning Validation**

The Cleaning Validation Master Planning (CVMP) is an essential part of the overall cleaning validation effort in the production of pharmaceuticals and/or biological therapeutic agents. It is a scope document aimed at defining the extent of the validation effort, defining the philosophy to be implemented, the general methodologies to be used, categorizing the major equipment and contaminants to be cleaned, and define the analytical methodology to address the objectives of the validation effort. The document also defines the resources, responsibilities and the time table required to implement the effort.

During the presentation you will learn:

- a. To define major equipment and contaminants groupings.
- b. The protocol requirements to complete the cleaning validation and meet the regulatory imperatives.
- c. How to define acceptance criteria and how to address/resolve deviations encountered during cleaning validation.
- d. How to prepare a CVMP which will be approved and continues to be useful once it is approved.
- e. Define the schedule and priorities to insure successful validation effort.
- f. How to obtain commitment from the various organizations and stakeholders within your company to assist on making the cleaning validation effort a success.

12:00 *Lunch*

1:30 **The Cleaning Procedure: What it Looks Like**

The cleaning procedure is a regulatory requirement and represents the basis for preventing contamination of the product. The procedure details the responsibilities for cleaning, the materials to be used in cleaning, how the equipment would be disassembled and re-assembled if necessary, how the various parts will be cleaned and what additional steps must be taken to ensure the item (whether equipment, facility, or container) is cleaned and would not cause contamination of the product. This session will focus on the contents that must be included in a successful cleaning procedure.

This session will discuss the following:

- a. What is the purpose of the cleaning procedure?
- b. How to define the frequency for cleaning?
- c. Who is responsible for the cleaning?
- d. How to define the procedure itself and ensure proper cleaning.
- e. What and where to clean?
- f. The documentation required for successful and compliant cleaning?

2:30 *Refreshment Break*

3:00

Hands on Exercise

Attendees will be asked to prepare a Cleaning Standard Operating Procedure (SOP). A short introductory discussion will be moderated by the course instructor. Once attendees are familiar with SOPs, they will be given a defined assignment to prepare a specific Cleaning 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

Cleaning Validation Protocol: Development and Defining Acceptance Criteria

The current industry standard is to use a Cleaning Validation (CV) Protocol to validate the cleaning procedure. Since the procedure is regarded as a cleaning process, CV itself could be considered a process validation exercise. If cleaning or washing equipment are used to achieve the cleaning, then such equipment must be qualified prior to performing the cleaning validation itself. The Cleaning Validation (CV) protocol when successfully executed signifies the completion of the validation effort and the acceptability of the cleaning procedure for the intended use.

It is important to recognize that the CV protocol is designed to accomplish a specific objective, namely to demonstrate that the cleaning procedure achieves the required results. 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:

- a. What the cleaning validation protocols is designed to accomplish?
- b. How to prepare a flexible protocol that is easy to execute?

- c. What are the appropriate acceptance criteria?
- d. How to sample and test for cleanliness?
- e. How to develop the appropriate test to ensure the cleaning procedure achieves the intended result.
- f. What analytical methods to use in executing the protocols?

9:30 *Refreshment Break*

10:00 **Hands on exercise**

In this session, the attendees will be given a description of a cleaning problem and an SOP to be validated. Attendees will be divided into groups to work together on developing the appropriate protocol for validating the cleaning procedure. At the end of the session the class will review and discuss the issues encountered while developing the protocol and attempt to identify hurdles to the execution of such protocol.

12:00 *Lunch*

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

Once the protocol has been prepared and approved it must be executed. Execution has to be performed by trained personnel. Measurements and analysis have to take place using calibrated instruments, accepted sampling techniques and validated analytical methods. As the protocol is being executed, one will encounter many challenges associated with execution of the procedure. These have to be properly and effectively addressed prior to pronouncing the cleaning process validated.

In this session you will learn:

- a. The appropriate methods to approach protocol execution.
- b. Who should perform the protocol execution
- c. The need to qualify cleaning equipment prior to validating the cleaning process.
- d. The importance of analytical methods validation and the use of calibrated instruments.
- e. Validating manual cleaning and how to ensure that it meets the regulatory requirements of consistency and effectiveness.

- f. How to effectively address deviations from pre-established acceptance criteria
- g. How to prepare summary reports for executed protocols that will be approved.

2:30 *Refreshment Break*

3:00 **Implementation, Change Control, CAPA, Monitoring and Continuous Improvement**

Once the cleaning procedure is validated, it is to be used consistently as intended. A logging mechanism to follow the history of the cleaning and provide a means to monitor the effectiveness of the procedure with time is used. Monitoring and Corrective Action Preventive Action (CAPA) programs are the basic tools ensuring continuous improvement of the cleaning procedure and its extension to new applications. Change Control is also used to ensure that any changes to the procedure are reviewed prior to implementation. It is also the means for ensuring that the procedure remains suitable for its intended use and continues to be in a validated state. 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.

In this session you will learn:

- a. The meaning of CAPA, Monitoring, and Change Control?
- b. What could cause problems with the existing cleaning procedure?
- c. How to establish alert and action levels and what to do when reached?
- d. When and where would validation be affected by change?
- e. When to use data collected from monitoring to plan your next cleaning procedure?
- f. How CAPA plays a role in the continuous improvement of the cleaning process?
- g. Why and when to revalidate? Is it revalidation or a new validation?
- h. How to defend your actions to the regulators?

4:00 *Close of Workshop*



About your conference destination:

The Radisson-Plaza Warwick is located in the heart of downtown Philadelphia, and adjacent to beautiful Rittenhouse Square. From the conference venue, you can access many points of interest in Philadelphia including Independence Hall, the Kimmel Center and the Avenue of the Arts and numerous shops, hotels and excellent restaurants!



REGISTRATION INFORMATION

Register for the conference using one of four options:

Online: www.pharmaedresources.com Phone: (217) 355-7322 Fax: (847) 589-0708

Mail: 2810 Robeson Park Drive, Champaign, IL 61822

PLEASE COMPLETE THE FOLLOWING:

FIRST NAME: _____

LAST NAME: _____

TITLE: _____

COMPANY: _____

ADDRESS: _____

ADDRESS: _____

CITY: _____ STATE: _____

ZIP: _____ COUNTRY CODE: _____

OFFICE PHONE: _____

MOBILE PHONE: _____

FAX: _____

E-MAIL: _____

Please register me for:

CLEANING VALIDATION:

A hands-on two day workshop covering the key components of cleaning validation planning, implementation, and maintenance

October 26-27, 2009, Radisson-Plaza Warwick, Philadelphia, PA

\$1,695 USD

REGISTER BY SEPTEMBER 1 AND TAKE \$300 OFF

PAYMENT METHOD

CREDIT CARD REGISTRATION:

CREDIT CARD VISA MASTERCARD AMEX

NAME: _____

CARD #: _____

EXPIRATION: ____ / ____

SIGNATURE: _____

BILLING ADDRESS: _____

CHECK REGISTRATION:

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.

PURCHASE ORDER #: _____

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: October 26-27, 2009
Hotel: Radisson Warwick Plaza Hotel
Hotel Address: 1701 Locust Street
Philadelphia, PA 19103
Reservations: (888) 201-1718 US
Hotel Telephone: (215) 735-6000
Fax: (215) 789-6105
Email: rhi_plph@radisson.com