INTERNATIONAL CLEANING FORUM 2015

Your training on cleaning validation: from theory to practice

P R O G R A M M E

The cleaning validation in pharmaceutical manufacturing has continued to receive a large amount of attention from customers, auditors and regulatory bodies that issued an updated release of Volume 4 of the EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use - Annex 15: Qualification and Validation - Chapter 9 Cleaning Validation.

Cleaning procedures routinely employed for equipment, containers and all other product contact parts are aimed to reduce to an acceptable level:

- The carryover of the previous product.
- The cleaning agent residues.
- The microbiological contamination.

The purpose of the cleaning validation is to give assurance that operations are properly performed in such a way that risks related to contamination of the product batches are well understood, assessed, mitigated as necessary and all the acceptance criteria duly met.

The cleaning of product contact pats is affected by several cross-linked factors:

- Type of cleaning process.
- Design and construction of the equipment.
- Types of residues, acceptance criteria, sampling and analytical methods.
- Maintenance of the validated state: critical parameters measurements, process alarms, training and periodic review.

It is the objective of this cleaning forum to provide a 360° overview on how to handle the cleaning challenges in the most efficient manner and in compliance with the regulatory and auditing bodies.

Main topics will be:

- Regulatory requirements.
- Technical aspects such as the design of the equipment.
- Quality assurance from chemical and toxicological to microbiological aspects.
- Live demos to allow the participants to work on real cases having a practical guidance on how to transfer theoretical knowledge into operation.

7 - 8 October 2015 • Casale Litta, Varese - IT

CLEANING EXCELLENCE

7 OCTOBER 2015

Registration ..... 11:00 - 12:00

Lunch buffet ..... 12:00 - 13:15

Welcome to the cleaning forum ..... 13:15 - 13:30

Cleaning validation:
approach, rules and guidelines as addressed by several regulatory bodies ..... 13:30 - 14:30

Establishing procedures, limits and acceptance criteria is essential in order to define when product contact parts are effectively clean for safe re-use in the production processes. Determination of the DHT (Dirty Hold Time) and CHT (Clean Hold Time) are also important aspects in ensuring that storage of parts does not affect the "clean" status by allowing for potential dust recontamination and microbial proliferation which subsequently may not be removed by the standard cleaning procedure. The documented procedures established for the quality management system shall include reference to the cleaning validation documents as part of the Validation Master Plan to comply with the requirements of the auditing authorities.

Quality by design:
operational and process risk mitigation and prevention ..... 14:30 - 15:30

The quality of construction of the equipment have a great impact on the final outcome of the process and its ability to get easily qualified, validated and traced. Quality is directly proportional to the criteria of selection of the materials in contact with the process, both stainless steels and polymers. The importance of the roughness of surfaces, welds and pipes to minimize adhesion of any substance and the impact of the quality of the components being used (fittings, valves and pumps) will be presented and discussed Last but not least, identification, monitoring, tracing and safe storage of the critical parameters as a guarantee for a safe process.

Coffee break ..... 15:30 - 16:00

Set-up and qualification of chemical and microbiological analytical methods ..... 16:00 - 17:00

Examples on how norms and guidelines affect the daily routine of the pharmaceutical industry. An overview on how to implement the most suitable method to set the amount of residues after cleaning. Values are determined by several different techniques in order to meet the acceptable limits such as NOEL (Non Observable Effects Level), MACO (Maximum Allowance Carryover) and ADI (Acceptable daily Intake). The final choice shall be taken considering the ratio between costs, efficiency, time consumption and reliability of the results.

Spot-light on the world of Detergents ..... 17:00 - 18:00

Detergents cover an important part of the cleaning process. GMP Detergents: production, certification and meaning of use.
How to select the most suitable detergent to achieve the desired cleaning results: general rules, identification and traceability of the residues during the cleaning validation.

Transfer to the Hotel 18:00

Dinner 20:00

8 OCTOBER 2015

Live demos ..... **08:30 - 10:30**

All participants, divided into two groups, will have the chance to perform typical cleaning related operations such as loading the parts, running a cycle after having set proper working parameters and assessing the final result of the process.

Session A - Product contact part washer

Washing of critical contact parts with capillary orifices and crevices contaminated with residues of semi-solid coloured product as part of the routine "end of batch" cleaning operation.

Group 1 ..... **08:30 - 09:30**
Group 2 ..... **09:30 - 10:30**

Session B - High pressure washing equipment

Washing of IBC internal surfaces with residue of sticky coloured ointment as it is routinely processed before being re-used.

Group 2 ..... **08:30 - 09:30**
Group 1 ..... **09:30 - 10:30**

Coffee break ..... 10:30 - 11:00

The cleaning validation in practice ..... **11:00 - 12:00**

In order to demonstrate that the parts are clean and meet the acceptance criteria, sampling and analysis should be performed according to the most appropriate verification technique, or a combination of different methods like swabbing and rinse samples, selected on a case by case basis.

The identification of the nature of the residues can either be performed by:

- Specific detection methods: chromatography and spectrophotometry.
- Non-specific detection methods: conductivity and TOC.

Pros & cons related to the different choice of detection methods will be presented and discussed.

Closing remarks ..... **12:00 - 12:30**

International Cleaning Forum 2015 - REGISTRATION FORM

Last Name | First Nome

Organization/Company | Title/Position

Address

Postcode | City | State

Phone | Fax | Mobile

E-mail address

Invoice Details

Organization/Company

Administration manager E-mail

Address

Phone | Fax | Mobile

VAT Registration Number

(if you are an individual please provide the National Identification Number)

Please provide all the information requested to avoid delays in processing the application.

Registration fee 250,00 Euro VAT included.

The Registration fee includes participation in the scientific programme, lunch, coffee breaks and shuttle buses hotel-venue-hotel.

We will help you with the reservation of the Hotel nearby the venue.

Date **Signature**

Please fill and send the registration form to:

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For any further information please contact your local agent or:

Phone +39 033296701