ISPE® | Nordic Affiliate

CLEANING VALIDATION CONFERENCE

20th APRIL 2016

OTTILIAVEJ 8, 2500 VALBY, DENMARK
(H. LUNDBECK A/S)

Prerequisites for Cleaning Validation

How to Prepare for Cleaning Validation

This event is organized in collaboration with H. Lundbeck

Lundbeck

Prepare yourself for tomorrow's pharmaceutical production

Cleaning Validation has become the hottest topic in the pharmaceutical industry after the 2015 update of EU GMP volume 4, chapter 3 "Premise and Equipment" & 5 "Production" and Annex 15 "Qualification and Validation. The focus is on the risk of cross-contamination and toxicology evaluation of all components, not only product but also raw materials, solvents, detergents, etc.

How shall the industry interpret the regulations, rules and guidelines and how shall the cleaning validation and continuous cleaning verification be implemented?

This conference will focus on the regulatory requirements, the EMA guidelines on setting health-based exposure limits, how to conduct the toxicologic evaluations and do calculations of PDE and MACO, how to develop cleaning processes, how to work with multi-purpose equipment and how to implement cleaning and sterilization equipment.

Learning objectives

At the end of this conference, the participants will acquire the knowledge necessary for the rational and compliant implementation of a cleaning validation program for manufacturing equipment on pharmaceutical or chemical sites, from clinical to manufacturing batches.

Who should participate?

If you are working with design of equipment within the pharmaceutical industry, cleaning processes, process validation or quality assurance, you will benefit from this conference.

In addition to the learning session in the conference program, this event is an eminent opportunity to meet others from the pharmaceutical industry who are working with similar issues with cleaning validation.

During the conference the speakers will take us through the use of PDE and calculate MACO, trying to de-mysifiy the somewhat complex calculations. We will hear about toxicological evaluations, microbiological considerations, cleaning verification of production in a multipurpose facility, development of the cleaning process and implementation of cleaning equipment.

ISPE Nordic Affiliate is a nonprofit organisation with more than 700 members in the Nordic countries and the Nordic Affiliate is part of the international organisation ISPE with more than 20.000 members worldwide. As a member you will meet experts within most topics in the pharmaceutical industry. The members are a mix of professionals from production, consultants and vendors. The ability to network with these experts is of high value. Using the online debate forums you can present a problem and within few days you will get replies from many experts around the world. In addition, the Nordic Affiliate arranges networking meetings during the year, where ISPE members can participate for free.

So sign up today for this Cleaning Validation conference and make a difference for you and your workplace today, tomorrow and in the future to come.

Conference program 20 April 2016

08:00-08:30 | **Registration/coffee & bread/visit exhibition**

08:30-08:45 | Welcome - Introduction
Charlotte Krøyer, Cleaning Validation Specialist, Xellia Pharmaceutical ApS

08:45-09:30 | Challenges in the use of Permitted Daily Exposure for cleaning risk management
Carsten Baun Senholt, Toxicologist, Novo Nordisk A/S

09:30-10:15 | Defining limits and doing MACO calculations - part I
Pierre Devaux, ACM Pharma, France

10:15-10:30 | **Break**

10:30-11:15 | Defining limits and doing MACO calculations - part II
Pierre Devaux, ACM Pharma, France

11:15-12:00 | Cleaning Validation from a microbiologist's point of view
Lone Josefsen, QA Microbiologist, Novo Nordisk A/S

12:00-12:30 | **Lunch**

12:30-13:15 | ISPE's Guides and How They Apply to Cleaning and Cleaning Validation
Stephanie Wilkins, PE, PharmaConsult US

13:15-14:00 | Development of Cleaning Process
Luca Fumagalli, Cleaning Specialist, IWT SRL

14:00-14:45 | Cleaning Strategy of Multipurpose Equipment in GMP facilities
Evete Mawlad, Cleaning SME, CMC Biologics

14:45-15:00 | **Coffee break**

15:00-15:45 | Cycle Development for an Effective Cleaning Process
Beth Kroeger, Tech. Service Manager, STERIS Corporation, Life Sciences

15:45-16:30 | CPE (Closure Processor Equipment) and the complete life cycle from order to operation
Henrik Rentoft Larsen, Process Specialist, NNE Pharmaplan

16:30-17:00 | Sum up and planning Cleaning Validation CoP network meeting
Pernille Damkjær, Principal Scientist Cleaning Validation Specialist, Novo Nordisk A/S

17:00-18:00 | **Conference networking - incl. refreshments and snacks**

About the presentations

Challenges in the use of Permitted Daily Exposure for cleaning risk management

Carsten Baun Senholt, Toxicologist, Novo Nordisk A/S

Permitted Daily Exposure (PDE) has been established in the EMA/CHMP/ CVMP/ SWP/169430/2012 as the best practices for defining a health based exposure limit for potential carry-over in shared facilities.
This presentation will:

- introduce the general safety rationale behind health based exposure limits
- discuss the use of clinical versus non-clinical data
- outline the principles and methods behind the PDE model as defined in ICH guidelines
- discuss the relationship with other impurity guidelines such as the ICH M7 for mutagenic impurities
- some practical case studies will be presented

Defining limits and doing MACO calculations

Pierre Devaux, ACM Pharma, France

Historically, there have always been three approaches to establishing these limits. Firstly, the toxicological approach based on LD50, secondly the therapeutical approach based on minimal therapeutic doses and thirdly the 10 ppm approach. We retained the most critical of these three approaches to calculate the MACO value from the following equation and for the production of batch A after that of batch B.
After having reviewed the historical concept the new PDE approach is explained.
The method of calculation of the PDE concept especially the choice of the reference value and also the method to apply the different factors.
To finish, we'll relate the interrogations of the validation managers of the pharmaceutical companies in Europe to collect the data sources of the clinical and toxicological studies, the difficulties to interpret the ICH guidelines especially for F4 and the need to have or not have a toxicological expert who decides the reference studies.

Microbiology in Cleaning Validation

Lone Josefsen, Microbiologist, Novo Nordisk A/S

What are the microbiological requirements in cleaning validation? What microbiological methods are used and what does the results tells us (Bioburden, Swabs, ID and Endotoxin). What are the main problems around the cleaning process in relation to microbiologic tests? How do we quantify the level of cleanness? What about endotoxins and objectionable organisms

ISPE's Guides on Cleaning Validation

Stephanie Wilkins, Stephanie Wilkins, PE, PharmaConsult US

This presentation will discuss ISPE's Cleaning Guide; proposed content and schedule will be shared with the participants. In addition how ISPE's Risk-MaPP Guide set the stage for health-based limits for use in cleaning and cleaning validation and the current updates to this guide as a result of the new EU GMPs will be shared with the participants.

About the presentations

Cycle Development for an Effective Cleaning Process

Beth Kroeger, STERIS Corporation

This presentation will cover items to consider when designing an effective cleaning process, designing a process using laboratory studies and aspects that may impact the cleaning process once implemented. Factors extrinsic and intrinsic to the cleaning process will also be reviewed to ensure your cleaning process remains robust.

Cleaning Strategy of Multipurpose Equipment in GMP facilities

Evete Mawlad, Cleaning SME, CMC Biologics

In pharmaceutical industry, there is always the doubt related to when it is necessary to have dedicated or multiuse equipment and when is it possible to perform cleaning validation or verification in the same area yet different products? Concerned about carry-over and cleaning residues by usage of PDE?

Developing the cleaning process

Luca Fumagalli, Area Manager Pharmaceutical Cleaning Solutions IWT, Italy

Cleaning of critical contact parts with capillary orifices and crevices contaminated with product residues represent an important part of the routine cleaning operation with direct impact on the production down-time and the overall quality of the product.
In both manual and automatic cleaning processes, the target is to remove the contamination and the chemicals used involved in the process down to an acceptable level to ensure that residues of active pharmaceutical ingredients will not cross-contaminate the subsequent batch of product.
There are some key factors to consider such as temperature, coverage, mechanical and chemical action provided by the use of a suitable detergent and last but not least the time, to achieve an effective cleaning cycle.

CPE (Closure Processor Equipment) and the complete life cycle from order to operation

Henrik Rentoft Larsen, Process Specialist, NNE Pharmaplan A/S

The presentation will explain the process (Wash, Rinse, (silicone for Pistons)Sterilisation, Drying and cooling), followed by an aseptic unload of the PPM (Primary Packing Material). Furthermore the different challenges that did occur during the project will be explained.

About the speakers

Carsten Baun Senholt

Toxicologist, Novo Nordisk A/S

Has been employed as toxicological scientist in Novo Nordisk for more than 14 years. His main responsibility has been to identify, evaluate and control toxicological hazards from chemical impurities in parenteral pharmaceutical products. Carsten is associated as external expert in the ISO Technical Committee for biocompatibility of medical devices (TC194).

Pierre Devaux

ACM Pharma, France

Working with Contamination in Classified Areas, Cleaning Validation, Biocleaning of Classified areas, Good Manufacturing Practices. Microbiological Environmental Controls and trendings, Management of Media Fill Test and Management of aseptic deviations.Is certified trainer and speaker within cleaning validation for A3P.

Lone Josefsen

QA Microbiologist, Novo Nordisk A/S

Has worked with microbiology for more than 15 years and the last 5 years in API productions in the pharma industry. She has been working in QA and in QC Microbiology handling and evaluating cleaning validation samples. She has a MSc in Molecular Microbiology and PhD from University of Copenhagen.

Stephanie Wilkins

PE, Lean Six Sigma Green Belt, PharmaConsult US

Has over 30 years of professional experience in PM, eng., risk management and validation solutions for the pharma/biotech industry. She is president of PharmaConsult US, Inc., which provides cross contamination and containment consulting to the pharmaceutical industry. She is Co-Chair of the ISPE Risk-MaPP Baseline Guide Task Team, ISPE Trainer for Risk-MaPP and was a member of the ISPE International Board of Directors. Wilkins graduated from the Pennsylvania State University with a Bachelor of Architectural Engineering.

Beth Kroeger

Tech. Service Manager, STERIS Corporation, Life Sciences

Beth currently provides global technical support related to process research cleaners, cleaning validation and critical environments and frequently speaks on these topics for the Institute of Validation Technology (IVT), United States Pharmacopeia (USP) and the National Institute for Bioprocessing Research and Training. Beth has over 20 years industry experience in Biopharmaceutical and Oral Solid Dose manufacturing operations.

Luca Fumagalli

Area Manager, Area Manager, Pharmaceutical Cleaning Solutions, IWT SRL, Italy

Has 12 years' experience with cleaning and low-temperature decontamination.
Provides guidance to customers about the most suitable cleaning solutions according to the needs, starting from the analysis of the URS all the way through the FAT - SAT - IQ/OQ and PQ providing customers with technical support.

Evete Mawlad

Cleaning SME, CMC Biologics A/S

Has more than 9 years' of experience in validation and compliance within the pharmaceutical, biopharmaceutical and medical device industries. Prior joining CMC Biologics, she worked as Senior QA Associate at Biogen and as GMP Specialist at NNE Pharmaplan, where she assisted customers with challenging validation and compliance problems (including Cleaning Validation) and has successfully participated in GMP inspections by DHMA, EMA and FDA.

Henrik Rentoft Larsen

Process Specialist, NNE Pharmaplan A/S

Has more than 20 years' experience within the pharmaceutical industry. Started within automation and then moved to projects within W&S (Wash and sterilisation). Validation of Utensil Washer, Autoclaves, CIP/SIP and CPE. Has been working as PM and specialist.

Registration

Registation is done here:
https://ispenordic.nemtilmeld.dk/15/

Conference Fee

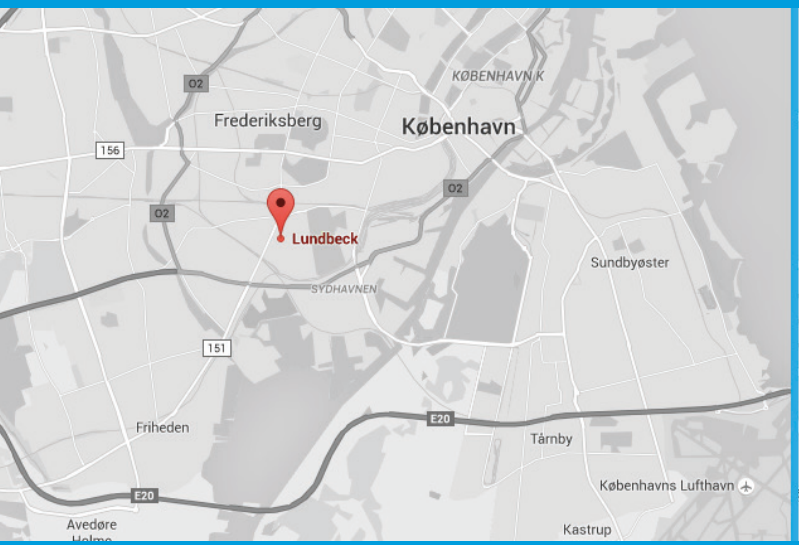
Category	ISPE Member	Non Member
Industry	€ 245	€ 485*
Academia (teachers)	€ 195	€ 435*
Young Professionals	€ 195	€ 435*
Regulatory	€ 150	€ 150*
Students	€ 100	€ 150*

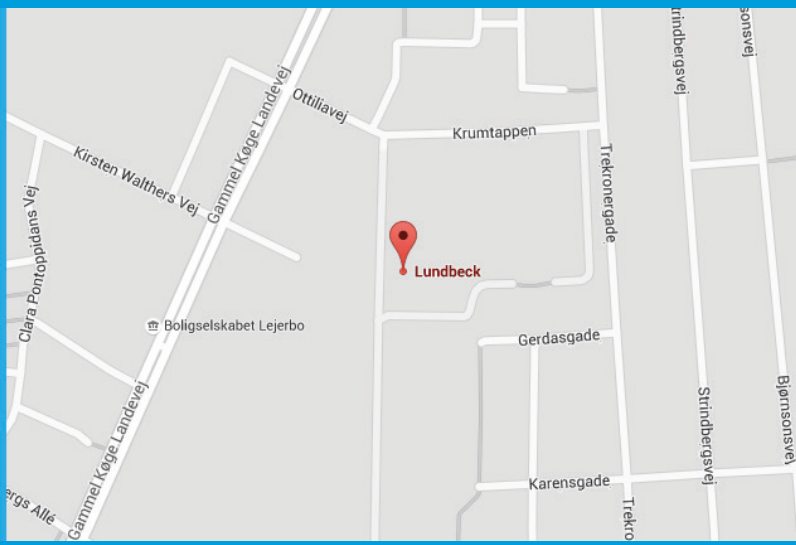
*) Includes one year ISPE membership

Tabletop Exhibition

This conference is an excellent opportunity to meet people working in all aspects of Cleaning Validation, from Design of Equipment for good cleanability, toxicological evaluations, cleaning equipment, analytical technology and Cleaning Validation performance. We can offer a limited number of tabletop exhibition possibilities for only € 600 (excl. conference fee). Contact us for further information.

Location





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