ISPE Nordic invites you to a conference on

**Advanced Aseptic Processing – including networking reception at Favrholm Campus**

7 October 2015
Favrholm Campus – Roskildevej 58, 3400 Hillerød, Denmark

The Advanced Aseptic Processing conference will give you the latest trends in processes and equipment for aseptic processing including discussions on Isolators/RABS, single-use equipment, containment, case studies and more. With the paradigm shift towards more and more aseptic processing the industry is changing and these market changes are forcing changes to the technical solutions needed.

**Program:**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.00 – 9.15</td>
<td>Welcome</td>
</tr>
<tr>
<td>9.15 – 10.00</td>
<td>Introduction to Advanced Aseptic Processing – Charlotte Enghave Fruergaard, NNE Pharmaplan</td>
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<tr>
<td>10.00 – 10.45</td>
<td>Risk of contamination through pinholes in gloves and how to prove the integrity – Yves Scholler, Skan AG</td>
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<tr>
<td>10.45 – 11.15</td>
<td>Break</td>
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<tr>
<td>11.15 – 11.45</td>
<td>Isolator Containment Technology for the Manufacture of Antibody Drug Conjugates (ADCs) – Michael McLoughlin, ProSys Containment &amp; Sampling Technology</td>
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<tr>
<td>11.45 – 12.30</td>
<td>Retrofitting RABS to existing aseptic filling lines – Clive Brading, Sanofi</td>
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<tr>
<td>12.30 – 13.30</td>
<td>Lunch</td>
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<tr>
<td>14.15 – 15.00</td>
<td>Implementation of single use bioreactors for large scale manufacturing of biologics (Case Study) – Andrew Lewin, CMC Biologics</td>
</tr>
<tr>
<td>15.00 – 15.30</td>
<td>Break</td>
</tr>
<tr>
<td>15.30 – 16.15</td>
<td>Closing the gap between bench and bedside: manufacturing individual multi-peptide vaccines for cancer immunotherapy with ready-to-fill closed vial technology – Monika Stieglbauer, Universität Tübingen</td>
</tr>
<tr>
<td>16.15 – 16.55</td>
<td>Flexible Isolator with interchangeable L-Shape flange for many pharmaceutical processes – Dr. Paul Ruffieux, Consultant</td>
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<tr>
<td>16.55 – 17.00</td>
<td>Wrap-up</td>
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<tr>
<td>17.00 – 18.00</td>
<td>Networking reception with a glass of wine</td>
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This conference intends to bring together people working with pharmaceutical aseptic processes, such as Process Engineers, Project Engineers, Quality Engineers, Quality Assurance and Project Managers. This is to include guests and speakers from Europe, including leading scientists, engineers and managers.

The conference is a perfect opportunity to meet, discuss and network with colleagues from the industry, authorities and consultants working with aseptic processing. There will be a networking reception with a glass of wine/beer/soda after the conference.

Program Content – Details:

Presentation 1:  Introduction to Advanced Aseptic Processing  
/Charlotte Enghave Fruergaard, NNE Pharmaplan

This presentation introduces the technology trends within aseptic and sterile processes, such as barrier systems and disposables. How do the current market changes force technology changes? And what are the Regulatory expectations?

Presentation 2:  Risk of contamination through pinholes in gloves and how to prove the integrity  
/Yves Scholler, Skan AG

Glove Leak Testing in Isolators and RABS – A foundation for reasonable testing and good practices for risk mitigation.
- Regulatory requirements
- Available testing methods
- Common Practices
- Requirements to a Modern Glove Testing Unit

Isolators provide a high degree of protection for the product and/or the environment and operators in pharmaceutical production and sterility testing. Gloves allow for performing testing and for easy access to the process. Due to their nature (thin and highly flexible) and their risk of rupture, they are regarded as one of the main potential sources of contamination. Glove integrity testing is therefore a main issue.
Presentation 3: Isolator Containment Technology for the Manufacture of Antibody Drug Conjugates (ADCs) /Michael McLoughlin, ProSys Containment & Sampling Technology

Rigid Isolator Technology employed for the Contained Manufacture of ADCs
- Parallel development of Isolator and process equipment
- Integration of 3rd party equipment
- Ergonomics
- Layout to provide logical process flow with minimum footprint
- Testing (FAT/SAT /Containment)
- Lessons learned

Presentation 4: Retrofitting RABS to existing aseptic filling lines /Clive Brading, Sanofi

A practical presentation on the possible approaches for retrofitting RABS to existing sterile product filling lines based on real life experience. Included in the presentation are case studies to highlight the challenges of retrofitting RABS and how these challenges can be overcome, some does and don'ts to ensure a successful transition to barrier systems and also some thoughts on when retrofitting RABS is not the best solution.


Low temperature surfaces terminal sterilization of heat and/or radiation sensitive biological drug products in pre-filled syringes, vials or other drug delivery devices can provide benefits to the aseptic manufacturing process. Validation of a vapor phase sterilization process, such as the VHP low temperature surfaces terminal sterilization, is recommended to follow ISO 14937 (Sterilization of health care products -- General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices) and recently published USP 1229.11 (Vapor Phase Sterilization) guidelines.

Main purpose of this presentation is to provide guidance on cycle development and validation of VHP Low Temperature Surfaces Terminal Sterilization process in vacuum conditions. This presentation also describes the sterilization process principle and typical applications for reference.

Presentation 6: Case Study: Implementation of single use bioreactors for large scale manufacturing of biologics /Andrew Lewin, CMC Biologics

During the last decade single use technologies have grown significantly in the biotechnology industry mainly due to the flexibility and cleaning benefits. However, scale has been one of the biggest limitations until now. This presentation is aiming to show an example of how CMC Biologics has successfully implemented 6x2000L SUB system in Seattle and also what are the future plans to generate similar capabilities in Copenhagen.
Presentation 7: Closing the gap between bench and bedside: manufacturing individual multi-peptide vaccines for cancer immunotherapy with ready-to-fill closed vial technology
/Monika Stieglbauer, Universität Tübingen

Current cancer research shows that more than ever new strategies for treatment of cancer patients are necessary; immunotherapy appears to be one very effective way and has witnessed a real breakthrough in the past few years. Additionally individualized patient treatments come to the fore. Consequently a way has to be found to translate the research results into patient treatment which includes the production of pharmaceuticals.

The Wirkstoffpeptidlabor at the University of Tübingen established both the production of GMP certified peptides as active pharmaceutical ingredients and a formulation process with ready-to-fill closed vial technology for vaccine peptide cocktails including different peptides. Multi-epitope peptide vaccines can be composed both specifically for distinct tumour entities and individually for each patient but nevertheless in a reproducible way yielding high quality products.

Presentation 8: Flexible Isolator with interchangeable L-Shape flange for many pharmaceutical processes
/Dr. Paul Ruffieux, Consultant

The modular Isolator system was developed for manufacturing small scale batches with various packaging formats. The floor and backside of the Isolator forms an interchangeable flange, called L-flange. There are many different machines available for different pharmaceutical processes. The customer can start with a small Isolator installation that can be extended for future purpose or other processes requiring more space.
About the Speakers:

Charlotte Enghave Fruergaard, PhD, NNE Pharmaplan, Denmark
Charlotte is Partner in Global Process Consulting at NNE Pharmaplan. Charlotte has over 21 years of broad experience within pharmaceutical manufacturing of sterile products and is a leading expert within isolator and barrier technology and associated sterilisation techniques. Charlotte holds an MSc in mechanical engineering and a PhD in metrology. Charlotte has been a Member of ISPE since 1995, and is a Past Chairman of the International Board of Directors. She is co-founder and past Chairman of ISPE Nordic Affiliate. She is a member of ISPE Sterile Products Processing Community of Practice steering committee. Furthermore she has been the co-chairman of the ISPE “Barrier Isolation Technology Conference” in Europe in several years.

Yves Scholler, Skan AG, Switzerland
Yves studied mechatronics at the Trinational Engineering School (FTI). He joined SKAN AG in 2007 and is now a Sales Manager in the Industrial Division for Isolator Technology, responsible for Germany, Austria, East Europe and Scandinavia.

Michael McLoughlin, ProSys Containment & Sampling Technology
Michael is a founding member of ProSys Containment and Sampling Technology. Michael holds a Mechanical Engineering degree and MBA from the University of Limerick. Michael also studied at Stanford University where he completed the Leadership for Growth programme, graduating from the school of Business Management in 2011. After graduating Michael worked in Design Engineering, Application Sales, Project management and Operations with a number of US multinationals. Michael has successfully managed numerous technical innovative projects for OEM customers. This is set to continue as the growth of ProSys continues to expand into international markets.

Clive Brading, Sanofi, UK
Clive is Associate Vice-President in Sanofi’s Global Manufacturing Quality Operations team, with operational quality responsibility for Sanofi’s major sterile production sites globally. Clive has more than 30 years’ experience in manufacturing quality systems and compliance in the pharmaceutical industry. He has held quality and manufacturing leadership roles in small and large pharmaceutical organizations and has experience with all major pharmaceutical dosage forms and Active Pharmaceutical Ingredients (API). He has also spent time in GMP consultancy. He is currently based in the UK, but leads a team located in Europe and USA.
Juha Mattila, Steris Finn-Aqua, Finland
Juha is Senior Product Manager for STERIS Finn-Aqua High Purity Water & Steam, VHP Sterilization and Effluent Decontamination systems. He joined Steris Finn-Aqua in 2000 as process/mechanical engineer and has broad experience in the design and manufacturing of pharmaceutical and research process equipment, with several years in Research and Development department, directly involved in the development & design of STERIS Finn-Aqua products and process systems. He has worked directly with several clients in the designs and installations in Europe, North America and Asia, presented in several events, and contributed as author/co-author for articles in professional journals. Juha is a member of ISPE Nordic Board of Directors, PDA, ABSA, EBSA and Finnish Biosafety Network.

Andrew Lewin, CMC Biologics
Andy is has been Vice President Business development at CMC Biologics for the past three years. He has spent almost 20 years in the Biopharmaceutical industry and, prior to joining CMC, has led business development and project management departments at a number of manufacturing companies including NextPharma, Cobra Biomanufacturing and SynCo Bio Partners. He has an MA in Biochemistry from Oxford University.

Monika Stieglbauer, Universität Tübingen, Germany
Monika is Quality Assurance Manager of the Wirkstoffpeptidlabor Universität Tübingen.
Previously she was conducting pharmaceutical studies at Ludwigs-Maximilians-University Munich/Germany (graduation as licensed pharmacists) and being engaged in a public pharmacy in Munich (supporting preparation and obtaining ISO-Certification). Since 2012 she is a Ph.D.-student at the University of Tübingen, additionally at the included “Wirkstoffpeptidlabor” she has the functions of:
• Quality Assurance Manager
• Establishment of GMP-certified API and DP production
• Assistant Head of Quality Control

Dr Paul Ruffieux, Consultant, Switzerland
After studying chemistry in Basle, Switzerland, Dr Ruffieux worked first for Sandoz AG and then for Robapharm AG. From 1992-2001, he was employed by Cilag AG, where he was in the end the responsible director for NPI/New Technologies. Since July 2001, he has been Vice President with SKAN AG until his retirement. Now he is still active to isolate pharmaceutical processes to enhance quality.
Registration:
The number of participants is limited. Seats are allocated on a first come, first served principle.

Conference Fee:

<table>
<thead>
<tr>
<th>Category</th>
<th>Member</th>
<th>Non-member</th>
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<tbody>
<tr>
<td>Industry</td>
<td>€ 400</td>
<td>€ 640 1</td>
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<tr>
<td>Academia &amp; Young Professionals</td>
<td>€ 150</td>
<td>€ 350 1</td>
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<tr>
<td>Regulatory</td>
<td>€ 150</td>
<td>€ 150 1</td>
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<tr>
<td>Students</td>
<td>€ 100</td>
<td>€ 150 1</td>
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</tbody>
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1) Includes a 1 year membership in ISPE

Table Top Exhibition:
This conference is an excellent opportunity to meet people working with all kinds of aspects within Aseptic Production. We can offer a limited number of table top exhibition possibilities for only € 550 (excl. conference fee). Contact us for further information.

Register at: https://ispenordic.nemtilmeld.dk/8/ and take an active role in shaping the future of our industry.

Location:
Favrholm Campus – Roskildevej 58, 3400 Hillerød, Denmark

If you have questions regarding registration, please contact:
ISPE Nordic event supplier: Nicolai Nymann, ISPE.eventsupplier@gmail.com, +45 31 45 85 40

If you have questions regarding the event, please contact:
Charlotte Enghave Fruergaard, cen@nnepharmaplan.com, +45 30 79 72 08