ISPE NORDIC is pleased to invite You to a conference

Critical Utilities
Commissioning, Qualification and Sampling
New Guides from ISPE

Date: **27 April 2015**
Venue: **Fyrislund, Uppsala**

Who should attend?
Process Engineers, Quality Engineers, Quality Assurance and Project Managers.

We hope that you will book your calendars now, and remember to register for the event soon as seats are limited.

For **seminar registration** please https://ispenordic.nemtilmeld.dk/1/

If You have any questions regarding the seminar or registration, please contact:
Anders Widov, +46 708 29 41 90, anders.widov@wiphe.se

Program:

8:00-8:30	Coffee, registration
8:30-8:50	Welcome (Anders Widov ï Vice Chair ISPE Nordic)
8:50-9:35	Sampling 1: Sampling of Water (Jeppe Kjems ï CU Engineering)
9:35-10:20	Sampling 2: Sampling of Pure Steam (Anders Widov ï Wiphe AB)
10:30- 11:00	Coffee
11:00-11:45	Sampling 3: Sampling of Pure Gases (Katrin Åkerlindh ï Linde Gas)
11:45-12:30	C&Q 1: Jens Peter Gundorf (Novo Nordisk A/S)
12:30-13:30	Lunch, with vendor stalls
13:30-14:15	C&Q 2: Nissan Cohen (Rohrback Cosasco Systems, Inc.)
14:15-14:45	Coffee and Networking break
14:45-15:30	C&Q 3: Nissan Cohen (Rohrback Cosasco Systems, Inc.)
15:30-16:15	Closing comments, Discussion, Questions on Critical Utilities

The Critical Utilities Conference on New Guides 2015 intends to bring together people running and managing Clean Utility Systems in Scandinavia. As the two new guides are on Commissioning and Qualification and Sampling, people working with Qualification and Sampling are especially welcome.

Program Content ï Details:

Sampling 1: **Sampling of Water**
(Jeppe Kjems, CU Engineering)

Effective sampling is critical to the success of any pharmaceutical water system. Improper sampling may introduce extrinsic sample contamination, generating out of specification (OOS) data when a system is actually producing suitable quality. On the other hand, improper sampling and data interpretation may also create the opposite scenario, where the water quality is OOS but the interpretation of results yields the incorrect conclusion that the water quality is suitable. In either case, there could be an enormous negative impact on company image, cost, productivity, ethics, and regulatory liability, stemming from something as simple (and unfortunately as common) as bad water system sampling. Eliminating the reasons for these negative consequences through proper sampling and data interpretation is the underlying basis for the ISPE Good Practice Guide on ñSampling.ò This talk will outline the regulatory expectations as well as inputs/considerations from a practical point of view.

Sampling 2: **Sampling of Pure Steam**
(Anders Widov, Wiphe AB)

Pure Steam is for some not the same as Clean Steam and for others it is. What types of steam are used in the pharma industry? What standards exist on steam and which of those do we have to follow? Are we talking about the same steam? How do we know the steam fulfils the criteria we need? What errors are there in sampling of steam? What errors do we have to live with and which can be avoided? Sampling of steam also means handling material at up to 150°C and what impact has that on sampling? Those are some of the questions that were asked when starting to write the upcoming guide on sampling.

Sampling 3: **Sampling of Pure Gases**
(Katrin Åkerlindh, Linde Gas AB)

There have not been any good guides on sampling of Pure Gases available earlier on. The gas companies have had their own internal ones and those have often also been the basis for the SOPs in the pharma industry. This is the first accessible guide on the market and as it is published worldwide it has the chance of becoming an international standard.

C&Q 1: **Validation based on Quality Risk Management**
(Jens Peter Gundorf, Novo Nordisk)

The basis of doing validation based on QRM is to validate where the risks are and not perfunctory. This saves time and money decreasing the start-up time and paper work. On the other end position that matters are more rigorously tested. There is therefore a higher confidence in the systems and less deviations.

C&Q 2: **ISPE Good Practice Guide: Approaches to Commissioning and Qualification of Pharmaceutical Water and Steam Systems (Second Edition) Part 1**
(Nissan Cohen, Rohrback-Cosasco Systems, Inc)

The first edition of this practice guide was in the first years of the 21st century wide spread as many focused on pharmaceutical water and steam. However after the publishing of the ICH Guidelines ICH Q9 (Quality Risk Management) and Q10 (Pharmaceutical Quality Systems) it was somewhat outdated. An update including risk management was started in 2012 and the guide was published in 2014.

C&Q 3: **ISPE Good Practice Guide: Approaches to Commissioning and Qualification of Pharmaceutical Water and Steam Systems (Second Edition) Part 2**
(Nissan Cohen, Rohrback-Cosasco Systems, Inc)

About the Speakers:

Jeppe Kjems
The CEO of CU Engineering and a Critical Utility Specialist within the Pharmaceutical industry. Jeppe Kjems, M.Sc. Dairy Engineering and Engineering Technology Management, has +25 years of international experience, of which +20 years are within the Pharmaceutical and Biotech industries. He possesses a broad experience ranging from Engineering and Project Management to the production floor and practical qualification (DQ, IQ, OQ & PQ). Jeppe Kjems has given lectures about Critical Utilities in various International fora.

Anders Widov
The owner of Wiphe AB and a Critical Utility Specialist specialized on design of water distribution systems. Anders started his career in the Pharmaceutical Industry in 1990 working as a Project Manager at a consultant company. Although at different companies he has remained responsible for several projects in Europe, Asia and North America as Project Manager and Sales Manager primarily with water systems. Anders is one of the authors of ISPE Baseline Guide volume 4 on Water and Steam Systems and has also been involved in several Good Practice Guides from ISPE. He is the secretary of ISPE Critical Utilities International Steering Committee and holds the vice chair of ISPE Nordic Affiliate. Anders has a M.Sc. in Chemical Engineering from Lund Institute of Technology, Sweden

Katrin Åkerlindh
Currently, Katrin is ValidatBusiness Operations Manager for Healthcare Region Europe North at AGA Gas AB, Linde Healthcare and have previous to this position been Global Product Manager for Specialty Gases and Specialty Equipment at Linde Gas. She has more than 10 years of experience of specialty gases, specialty equipment and pharmaceutical grade gases. Prior to her current responsibilities, she has worked in the Linde Group and previously AGA AB Sweden covering global business development, sales and marketing, and project management. In 1995 she joined the pharmaceutical industry for three years, working with quality control, method validations, and instrument qualifications. She has been Chairman of the ISPE Nordic affiliate board. She holds a degree of Master of Science in Chemical Engineering at Lund Institute of Technology and an Executive Master of Business Administration at Lund University School of Economics and Management. Specialties: Business operations, product management, sales management, change management, project management, business development, product development, pharmaceutical industry, specialty gases

Jens Peter Gundorf
Management of People & Budget. Covering responsibility for organisation, finance, clients and business including activities like recruitment, resource management, development of people and organisation, strategies and administration. Both management positions for line of business and projects have been possessed.
Automation Engineering: Automation & IT strategies and concepts, standards, and automation project planning and execution including quality aspects.
Key words: Design by S88, SattLine programming, commissioning, qualification, GMP and Methods & tools.
Engineering, general: Design and qualification of biotechnological and pharmaceutical API processes and experience with finished pharma manufacturing.
Specialties: Quality Risk Management (ICH Q9) Compliance project, project management, Periodic System Evaluation project ï system, setup & project management, GVP ï project: FRS ï Package, which comprehends instructions and guidance for specification, qualification & commissioning of functions to manufacturing processes. Engineering of Purification Plants: Functional specification, design, automation, quality and documentation.

Nissan Cohen

A worldwide expert, with 40 yearsô experience, in Total Organic Carbon (TOC), high purity, ultrapure, reclaim and recycle water systems, with profound expertise in instrumentation, automation, and organic contamination oxidation systems using ozone, UV, ion exchange and catalysts. Accomplished writer of over 35 technical articles published in Ultrapure Water, A2C2, Pharmaceutical Technology, Pharmaceutical Engineering, Semiconductor International, The Journal of the Institute of Environmental Sciences and Technology. Four times nominated and recipient of Pharmaceutical Engineeringôs ñArticle of the Yearòaward given to a single article out of over 100 published articles for any given year. Contributing author and Chapter Leader of ñBaseline Guide for Pharmaceutical Water and Steam Systemsò Co-chairman and Coordinating Author of the ñApproaches to Commissioning and Qualification of Pharmaceutical Water and Steam Systemsò Good Practice Guide, Contributing author to the Good Practice Guide on Ozone, member of ISPE (International Society for Pharmaceutical Engineering), Technical Editor of the Journal of the Institute of Environmental and Science Technology (IEST), Technical Reviewer of Pharmaceutical Engineering, Chairman of the Water and Steam Forum of ISPE, Founder/Chair of the Discussion Forums of ISPE, Former member of the Technical Advisory Board of A^2C^2 magazine. Education: University of Wisconsin and Ruppin Institute ï degree in Agriculture and Genetics. Bilingual in English and Hebrew. Working knowledge of 5 additional languages. Member of International Standards Committees: ASTM E-55, IEST (WG 14644 Contamination Control), ASTM D-19.03, ISPE (International Society for Pharmaceutical Engineering) Steering Committee member for Communities of Practice Standards: Critical Utilities

Former Chairman of ISPE Committees: Membership Services, Publications, Pharmaceutical Engineering and Website. Former Steering Committee member of COPs: HVAC and PAT

Registration:

Please register at: https://ispenordic.nemtilmeld.dk/1/

The number of participants is limited. Seats are allocated on a first come, first served principal.

Conference Fee:

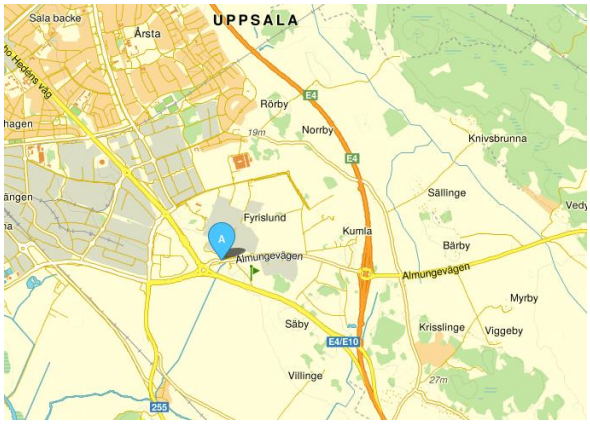
Category	Member	Non-member
Industry	ú 250	ú 450*)
Academia & Young Professionals	ú 100	ú 200*)
Students	ú 25	ú 45*)
Regulatory	ú 25	ú 25*)

**) 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 Biotechnology and Pharmaceutical Production. We can offer a limited number of table top exhibition possibilities for **only ú 500** (*excl. conference fee*). Contact us for further information.

Location: Uppsala Business Park (Virdings allé 32A, 754 50 Uppsala), Sweden



Questions regarding registration:

Nicolai Nymann, nicolainymann@gmail.com

Questions regarding the event:

Anders Widov (ISPE Nordic Clean Utilities COP Board Liaison), Anders.Widov@wiphe.se,

+46 708 29 41 90