



# Invitation to CLEANROOM SYMPOSIUM & EXHIBITION R3 Nordic

23<sup>rd</sup> - 24<sup>th</sup> May 2023 Kick-off event 22<sup>nd</sup> May 2023 at Marienlyst Strandhotel, Helsingør, Denmark.

# Authorities Expectations, EU GMP Annex 1 & 15 and the use of Standards

The Danish Medicines Agency's expectations for inspections and implementation of Annex 1

- Thomas Vestergaard Pedersen (DK) Danish Medicines Agency

Annex 1:2022 - Impact of revised Annex 1 on Design, Testing and Monitoring Cleanrooms and Clean Air Devices

- Gordon Farquharson, Critical Systems Ltd (UK)

CQV - The importance of Commissioning and Performance Verification as part of Q&V in Annex 15

- Conor Murray (IRL) 3dimension

The helpful standards

- Marianne Vidkjær (DK) Danish Standards

# Risk Assessment, Gap-analysis & Contamination Control Strategy

Management of Risks to Product Safety, Quality and Sustainability

- Roland Cocker (IRL) Cocker Consulting Ltd

Risk assessment in practice

- Kari Solem Aune (N) COWI

GAP-analysis according to Annex 1

- Ina Glamheden-Helle (S) Bavarian Nordic

Implementation of Contamination Control Strategy

- Kirsten Jorsal (DK) Ellab

Overview of PHSS published guidance on Contamination Control Strategy preparation and experience from application

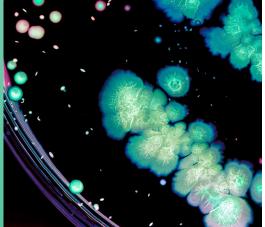
- James Drinkwater (UK) FranzZiehl



### **Environmental Monitoring**

Environmental microbial sampling

- Sabine Bessières Recasens (F) Merck



Microbiological impaction instruments - The importance of d50

- Berit Reinmüller (S) Chalmers

The challenge of microbiological contamination control and the role of the ISO 14644 family of "dashes"

- Conor Murray (IRL) 3dimension

#### **Hospitals & Healthcare sector**

Transmission of respiratory infections – clinical and theoretical knowledge post covid-19

- Elsebeth Tvenstrup Jensen (DK) Statens Serum Institut

Pandemic control strategies in built environment

- Piia Sormunen (FI) Granlund

Development of Ultraclean Air Operating Rooms

- Bengt Ljunqvist (S) & Berit Reinmüller (S) Chalmers

Healthcare sector – Lessons learned from new and existing sterilization units. -What's needed in order to be in control

- Jan Mottlau (DK) Niras / Michael Jensen (DK) Niras

Ensured cleanliness in healthcare premises. - Design process to achieve optimal local function regarding cleanliness

- Lennart Hultberg (S) ProcessHygien

Legionnaires' disease in Denmark: Legionellae - opportunistic pathogens present in most moist environments

- Søren Uldum (DK) Statens Serum Institut

#### **Cleaning & Disinfection**

Aseptic behavior - cleaning & disinfection

- Nadine Hoffmann (DK) Nadine Pharma Consulting

The importance of detecting and effectively removing disinfectant residues in the GMP environment

- Juliana Nassette (NL) Ecolab

Biocides and cleaning in cleanrooms

- Tor Hjelmer (S) Miclev

New Shade of Ultraviolet Light Disinfects Air and Surfaces Around Us With no Harm to Humans

- Peter Tønning (DK) UV Medico

Experiments in reducing surface microbial levels within Hospital Environments using Hydrogen peroxide vapor and blue led light

- Kim Hagström (FI) Halton

What is clean? -And when is clean, clean enough?

- Jette Holt (DK) Statens Serum Institut

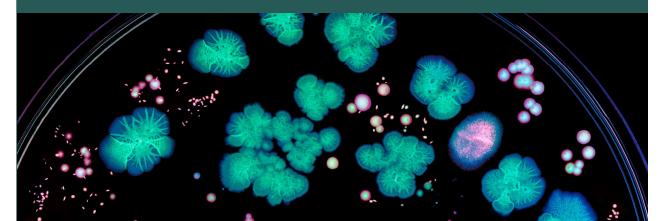
#### **Barrier technology**

Barrier technologies developments to meet Annex 1 requirements

- James Drinkwater (UK) Franz Ziehl

Contamination control of isolator

- Yuanzhong Wang (DK) Novo Nordisk



# Energy saving, HVAC, Waters systems & Cleanrooms

Energy efficient HVAC design for pharma

- Ulla Thomsen (DK) Novo Nordisk

Zero Carbon 2050 & Energy Reduction for Cleanrooms. Opportunities, standards/guidance and hazards

- Gordon Farquharson (UK) Critical Systems Ltd (UK)

Development of ultraclean air operating rooms -Bengt Ljungqvist (S)/Berit Reinmüller (S) Chalmers

Energy saving in water production

- Henrik Goldschmidt (DK) NNE

Cleanroom testing

- Svend Thygesen (DK) Bavarian Nordic

Vertical transportation through controlled environments lift prototype for multipurpose use

- Francesco Romano (I) Politecnico di Milano

Radiopharmaceuticals to be or not to be

- Anne-Mette Nielsen Wittekind (DK) Rigshospitalet

Water systems for pharmaceutical production

- Henrik Goldschmidt (DK) NNE

#### **Food**

Food safety of cobots

- Gun Wirtanen (FI) Seinäjoki University

Hygiene in food industry

- Kenth Kjærsgaard (DK) Niras



The symposium provides a fantastic opportunity to acquire high level knowledge in many disciplines. Furthermore, it offers an unique business opportunities by helping to grow your network with other participants' businesses, both as audience and as speakers or exhibitors.

The program and registration to the Symposium can be found on R3 Nordic homepage

https://r3nordic.org/produkt-kategori/courses/

The R3Nordic society is a non-profit association with activities in research, training, production, and product development in controlled environments.



**What:** The 52nd R3Nordic Symposium

When: 23rd & 24th of May 2023

Kick-off event on the evening the 22nd

**Where:** Marienlyst Strandhotel

Nordre Strandvej 2A

3000 Helsingør

Denmark

**Who:** The symposium will be of interest for you in the area of

pharma, life science, biotech, food and hospitals.