TBM group

3RD ANNUAL

EXCELLENCE IN CLEANROOM OPERATIONS, QUALITY ASSURANCE & CONTROL

Best practice in process optimisation, technology utilisation, risk mitigation and regulatory compliance

30th–31st March 2023 – Milan, Italy

VENUE

Radisson BLU

FEATURED

- Challenges of EU GMP Annex 1 implementation considering the wide scope of application and international relevance
- Aseptic filling process management with regulatory view and observations
- ISO cleanroom standards
- Sterilisation Myths and Practices
- Deviation management with case studies and best practices: identifying, assessing, correcting and documenting deviations from approved instructions or established standards
- Cleanroom Environment Control and Monitoring with respect to implementation of the new Annex 1 with effective date on August 2023
- Cleanroom operator management and training
- Risk Considerations for aging pharmaceutical facility cleanrooms and their modernisation

SPEAKER PANEL

Koos Agricola
Secretary ICCCS
Chairman ICCCS Accredited Education
Convenor of ISO 14644-17
Secretary ISO TC209 WG 4
Expert in ISO TC209 WG 2, WG 5, WG11 and WG15
NEN Delegate ISO TC209 & CEN TC243
Scientific Committee ISCC2022
VCCN coordinator CTCB-I courses
ISO Standards, Netherlands

Lars Ravn Flodgaard
Associate Director
Environmental Monitoring & Cleanroom support
ALK, Denmark

Dr. Thomas Becker
Senior Director Quality Clinical Manufacturing
CureVac, Germany

Michele Cavalleri
GLP Test Facility Manager
Eurofins Biolab, Italy

Thomas Adam
Head of QA Chemical APIs
Bayer, Germany

María Dolors Rafart
Global API Quality Director
Esteve, Spain

Valentino Ducati
Management Consultant
Arcondis Group, Switzerland

James L Drinkwater
Head of GMP compliance and Aseptic Processing support
Franz Ziel GmbH
Head of PHSS Aseptic Processing and Containment Special Interest Group
PHSS-Pharmaceutical & Healthcare Sciences Society

Varadharaj Vijayakumar
Senior Subject Matter Expert-Aseptic Fill Finish
WuXi Biologics, Germany

Paweł Adamiak
Quality Project Lead, Validation Senior Specialist
Polpharma, Poland

Maria Paola Baini
QA Strategic Growth Investment & Engineering Associate Director
Lonza Biologics, Switzerland

Di Morris
Qualified Person/Quality Compliance Advisor
PNR Pharma

Marcel Moritz
Sales Director Germany
Trescal, Germany

Zahra Halvorsen
Senior Consultant
Arcondis Group, Switzerland

SILVER SPONSOR

Trescal

BRONZE SPONSOR

Arcondis

Thursday 30th March 2023

DAY ONE

08.20 Registration & morning coffee

08.50 Opening address from the Chair

09.00 Challenges of EU GMP Annex 1 implementation considering the wide scope of application and international relevance

- A paradigm shifts in GMP regulations with major revision of Annex 1 (EU and PICS versions) for Sterile medicinal product manufacturing, revision of ICH
- Q9 on Quality Risk Management (QRM) and introduction of ICH Q12 Product
- Life cycle strategies. Considering the challenges of implementing the Holistic, risk based and proactive methodologies following QRM principles.
- Considering the wider Scope of Annex 1 application for non-Sterile products and ingredients/ substances that require bioburden control plus ATMP therapies. Assessing managing the conflicts between GMP and ISO
- Standards and Annex 1 and EU GMP for ATMPs.
- Characterising Protective 'First air' Unidirectional Airflow (UDAF) considering the protection attributes, the possible compromises of First Air protection and managing the limitations of Environmental and Process monitoring: EM & PrM

James L Drinkwater
Head of GMP compliance and Aseptic Processing support
Franz Ziel GmbH
Head of PHSS Aseptic Processing and Containment Special Interest Group
PHSS-Pharmaceutical & Healthcare Sciences Society

09.40 Annex 1 & Digitalization: Changes & Chances

- Digitalization: (Regulatory) Trends & Work environment
- Environmental Monitoring – Use Cases
  *Use case 1: Water Monitoring
  *Use case 2: Air borne cfu's
- Vision or reality – Data focused processes
- Changes & Chances: Conclusion

Valentino Ducati
Management Consultant
Arcondis Group, Switzerland

Zahra Halvorsen
Senior Consultant
Arcondis Group, Switzerland

10.20 Coffee & networking break

10.50 HPAPI Handling from Lab Bench to Pilot Plant within Chemical Development (case studies)

- GMP-Compliance and Regulatory Environment
- Cleaning concepts in the Manufacturing of HPAPIs (HPAPI-plant and isolators)
- Prevention of Cross-Contamination in Shared Facilities

Thomas Adam
Head of QA Chemical APIs
Bayer, Germany

10.50 Smoke Studies

- how the smoke studies changed over the last years
- fog generation in cleanrooms
- needed equipment
- needed Know-how
- smoke study as a part of Cleanroom qualification

Marcel Moritz
Sales Director Germany
Trescal, Germany

12.10 Lunch

13.10 Aseptic filling process management with regulatory view and observations

- Media fills key considerations
- Examples of FDA findings for contaminations in aseptic production.
- Proper personnel behavior in a cleanroom with good attitudes in aseptic processing (based on regulatory observations of bad practices)
- Validation of critical equipment's like Glove integrity testing.
- Risk based approach for Environmental Monitoring locations in Isolators

Varadharaj Vijayakumar
Senior Subject Matter Expert-Aseptic Fill Finish
WuXi Biologics, Germany

13.50 Validation of effectiveness of treatment

- Strategy for cleaning validation: what do you need (which protocols, your master plan, risk assessments, etc?)
- Validating the sanitized product and its effectiveness for different surfaces, time of exposure, etc.
- Successful strategies for testing whether cleaning was performed reliably
- Overcoming issues relating to the validation of the effectiveness of the treatment
- Validation sterilization of equipment
- Effective strategies for microbiological monitoring

Michele Cavalleri
GLP Test Facility Manager
Eurofins Biolab, Italy

14.30 Coffee & networking break

15.00 Cleanroom operator management and training

- The contaminant source (sources, prevention, hazards of contamination materials)
- Cleanroom operator behaviour (position responsibilities and skills)
- Operator training and knowledge

María Dolors Rafart
Global API Quality Director
Esteve, Spain

15.40 How do you effectively overcome challenges of performing environmental monitoring in isolators?

- Isolator vs. conventional cleanroom: Examining differences
- Best practices for microbial monitoring in isolators
- Design considerations for your environmental monitoring
- Maximizing effectiveness and optimisation of sterilization process inside isolator
- How not to undermine the importance of monitoring in an isolator

Maria Paola Baini
QA Strategic Growth Investment & Engineering Associate Director
Lonza Biologics, Switzerland

PANEL DISCUSSION

16.20 Deviation management with case studies and best practices: identifying, assessing, correcting and documenting deviations from approved instructions or established standards

17.00 Chairman's closing remarks and end of day one

Friday 31st March 2023

DAY TWO

08.30 Morning coffee

09.00 Chairman's Opening Remarks

OPENING ADDRESS

09.10 **Sterilisation Myths and Practices**

- Issues regarding misconceptions of Autoclave Sterilisation
- What constitutes good sterilisation practices
- Issues with depyrogenation
- What the expectations are to achieve dry heat sterilisation and
- depyrogenation
- Other sterilisation concerns

Di Morris
Qualified Person/Quality Compliance Advisor
PNR Pharma

09.50 **Effective strategies for reaching inspection readiness for your cleanroom**

- Analysing inspector expectations and inspection trends
- Preparing for a successful EU/FDA inspection: What will the control inspector look for?
- Reaching readiness for the environmental monitoring program inspection
- Revalidating your cleanroom as a way to ensure constant standards' compliance
- The rise of a virtual inspection setting: What do you expect?

Dr. Thomas Becker
Senior Director Quality Clinical Manufacturing
CureVac, Germany

10.30 Coffee & networking break

11.00 **Risk Considerations for Aging Pharmaceutical Facility Cleanrooms and their modernisation**

- Extent of Aging Facilities and Regulatory Concerns
- Risk Factors
- Complexities of Risk Mitigation
- Modernisation Solutions

Lars Ravn Flodgaard
Associate Director Environmental Monitoring & Cleanroom support
ALK, Denmark

11.40 **Assessing the impact of automation and AI on the cleanroom maintenance**

- Examining fast-moving changes in the technology market
- Examining the potential for Artificial Intelligence integration
- Automating cleanroom processes as a way to optimize HVAC
- Keeping cleanrooms cleaner and better controlled via AI
- Innovative strategies of data collection and analysis via AI

12.20 Lunch

13.30 **Risk analysis; user requirement specification; design review of HVAC and clean rooms - aspects which are worth paying "extra" attention from user point of view. Case study.**

- Risk analysis as a tool to determine the appropriate requirements. Admission to defining the scope of qualifications.
- URS & Project. Which elements may have greater impact to the process than the other?
- Design Review - Is it needed? What is the purpose of this process and how to do it correctly.

Paweł Adamiak
Quality Project Lead, Validation Senior Specialist
Polpharma, Poland

14.10 **ISO cleanroom standards (Pre-recorded presentation)**

- Brief history on the development of ISO Cleanroom standards
- Structure of present ISO Cleanroom Standards
- Contaminants and cleanliness levels
- Setting requirements
- Establishing control
- Demonstrating control

Koos Agricola
Secretary ICCCS
Chairman ICCCS Accredited Education
Convenor of ISO 14644-17
Secretary ISO TC209 WG 4
Expert in ISO TC209 WG 2, WG 5, WG11 and WG15
NEN Delegate ISO TC209 & CEN TC243
Scientific Committee ISCC2022
VCCN coordinator CTCB-I courses
ISO Standards, Netherlands

14.50 Coffee & networking break

PANEL DISCUSSION

15.20 **Cleanroom Environment Control and Monitoring with respect to implementation of the new Annex 1 with effective date on August 2023**

Panelist 1:
James L Drinkwater
Head of GMP compliance and Aseptic Processing support
Franz Ziel GmbH
Head of PHSS Aseptic Processing and Containment Special Interest Group
PHSS-Pharmaceutical & Healthcare Sciences Society

Panelist 2:
Di Morris
Qualified Person/Quality Compliance Advisor
PNR Pharma

16.00 Closing word from the Chairman & close of conference

SPEAKER OPPORTUNITIES

Do you have expertise, current research, or a strategy that could benefit your peers in the industry? Would you like to lead a fruitful discussion on challenges and opportunities?

If so, speak with us about becoming a presenter or moderator at one of TBM's conferences.

For speaking opportunities,

please email yuliya@tbmgroup.eu

TBM GROUP

An experienced business event organizer, focused on bringing innovation and the latest information to relevant target industries. We specialize in organizing exclusive and the best in-class events, custom-made to address the most pressing topics of various industries.

It is well known that you can't manage what you don't measure – so we are here to equip you with the right business tools to measure, compare, evaluate, and proceed in the right direction. Our committed team of experienced business professionals, with solid backgrounds in multidisciplinary fields, are here to create an exclusive environment at each of our tailor-made events. We craft each of our agendas to provide you with an environment aimed at benchmarking, networking, and generating insights amongst peers of various industries.

At **TBM Group**, we believe in the power of exchanging information; only through the exchange of best practices, and lessons learned, can meaningful progress be made. We believe in business progress based on constant re-evaluation and reflection, as a path to sustainable business development.

We create each and every one of our events with this theory in mind. Curious about what we have planned next? Please visit us at **tbmgroup.eu.**

FOLLOW US ON SOCIAL MEDIA FOR LIVE UPDATES OF OUR EVENTS:

LinkedIn: TBM Group

Twitter: @TBM_Group

Instagram: @tbmgroup_events

#tbmconferences *#tbmgroup*