SLOVENSKO FARMACEVTSKO DRUŠTVO
SLOVENIAN PHARMACEUTICAL SOCIETY

Slovensko farmacevtsko društvo v okviru Sekcije farmacevtskih tehnologov s pomočjo strokovnjakov na področju čistih prostorov in v sodelovanju s Sanolaborjem organizira

2024 GMP SIMPOZIJ

Novi EU GMP Annex 1 – zahteve, izzivi, primeri iz prakse

2024 GMP Conference Adriatic Region

Contamination control strategy - CCS (EU GMP Annex 1) – requirements, challenges, practical examples

11. junij 2024, Hotel Šport (Grajska cesta 2), Otočec

PROGRAM: https://www.sfd.si/dogodek/gmp-simpozij/

PRIJAVE: cleanroom@sanol-h.com

M: +386 (0)31 437 308

M: +385 (0)99 5050 265

Conference Programme

7.30-8.15 REGISTRATION

I. Contamination Control Strategy, GMP Annex 1: »Requirements, Strategies, Guidelines" – regulatory framework and requirements

Regulatory Requirements in GMP
- The revised Annex 1, highlights and new requirements
- CCS

Current status and challenges in Annex 1 compliance (regulators view)
- Expectations, interpretations

Contamination Control Strategy – a Dynamic System, holistic approach
- CCS and QRM
- aspects on how to develop the strategy and documentation

Sources of Contamination and Preventive Measures

Risk Assessment and QRM
- EM (strengths, limitations, challenges)
- Trending, detecting changes and managing deviations

Risk management and challenges in Advanced Therapy Medicinal Products
Perspectives in Regenerative Medicine

10.20-10.50 COFFEE BREAK

II. Contamination Control Strategies, GMP Annex 1: »Requirements, Strategies, Guidelines" – highlights and challenges

Contamination Control Strategy for cleanroom garments
- Cleanroom garments - what needs to be considered?
- (New) requirements on a CR garment system as an essential element of the CCS
- CR Garments - disposable or reusable, in the context of risk?

Disinfectants: Selection and Qualification
Special focus on new Annex 1 requirements (transfer disinfection, use of sporocide, residue management)
- Validation of Disinfectants
- Cleaning validation as a part of safety of the medicinal product

Principles of Hygiene, Health and Microbiology
- Requirements for personnel in the new Annex 1
- Behaviour and Access into Cleanrooms

- Personal Hygiene, hygiene of processes, hygiene of responsibilities within the frame of GMP
- Visitors and unqualified persons
- Training, Qualification and Validation of Operators

Microbiological Control for Non-Sterile Pharmaceuticals

Summary of requirements of the new Annex 1
- Inspectors view

13.00–14.00 LUNCH BREAK

III. Case Studies and best practices

Consumables and disposables as a potential source of contamination
- Gowning qualification & Validation to comply with new Annex 1
  - Body Box
  - Particle monitoring (Annex 1 vs ISO14644-1)
- Risk evaluation and risk management with cleanroom consumables and disposables
  - Wipes, gloves, disposables

Case study: Validation and decontamination process of Cleanroom garments
- Challenges and Solutions in practice

»The transfer of equipment and materials into and out of the cleanrooms and critical zones is one of the greatest potential sources of contamination«
- Best practices in Material transfer

Assessing integrity of isolator gloves
- Case study from pharmaceutical industry

Glove selection in compliance to GMP Annex 1
- Gloves to protect operators and processes

ATMP: accreditation for JACIE/GMP inspection

16.00-16.45 ROUND TABLE DISCUSSION WITH LECTURERS

16.45-17.00 CLOSURE OF THE SYMPOSIUM & FAREWELL COFFEE BREAK

Thank you!