Training course program
Bio-contamination control and monitoring of controlled areas.

Training course overview:

This one day training course presents best practice and new initiatives in the important area of Bio-contamination control and monitoring of controlled areas: Cleanrooms and Barrier Technology (Isolators and RABS; Restricted Access Barrier Systems). Reference information is taken from various PDA Technical Reports and the new PHSS – Pharmaceutical and Healthcare Sciences Society monograph 20 covering the life cycle of Bio-contamination.

The course is delivered in four sessions, two morning and two afternoon with interactive presentations and discussions covering the principle subjects of:

- **Bio-contamination definitions, charactererisation in controlled areas and risk profiling** in micro-flora groups to define expected, atypical microorganisms in controlled environments and objectionable and harmful microorganisms to products.

- **Bio-contamination control**: principles of environmental control in controlled areas, contamination control attributes of Cleanrooms and Barrier systems together with control targets in the process of establishing control to the formal state of control. Consideration is given to the developing requirements for Control strategies re: PHSS White paper on Control strategy for manufacture of Sterile Medicines, Drug products and substances plus the ISO 14698 standard on Bio-contamination that is currently under revision.

- **Environmental monitoring** including total particulate and microbiological monitoring - covering methods, tools and practice. Principle requirements for classification and monitoring of controlled areas are presented together with risk based setting of EM sampling locations and consideration to a full EM monitoring program for a Cleanroom and Filling Line with Barrier Isolator technology. A perspective is also provided on the current implementation of RMM –Real time fluorescence based monitoring technology for applications in bio-count monitoring including: training, investigations, risk characterization at control points in facilities and critical zone monitoring.

- **Bio-contamination deviation management** considering a process flow schematic of steps to take following events/ incidence of detection of atypical microbiological contamination in an EM program. Includes recommended check list of areas to cover in a root cause investigation to assure a thorough investigation and good basis for corrective and preventative action - CAPA.

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Registration and coffee/ refreshment from 8.30am

Training course start 9.0am: Welcome by Training course moderator.

Trainer: James Drinkwater – PHSS Chairman and F Ziel (Germany) Head of Aseptic processing technologies and GMP Compliance.

Session (1). 9.0am – 10.15am.

Bio-contamination definitions, characterisation in controlled areas and risk profiling

- Definitions: Bio-burden, Micro-flora, Bio-contamination.
- Controlled zones, classification and relationship between areas of different classification based on process: Conventional Cleanrooms, Use of: RABS Barrier technology, Isolator technology (with different pressure cascade regimes), Blow Fill Seal (BFS) technology.
- Characterization of Microflora in controlled areas; setting base lines defining reference library isolates.
- New initiative: Bio-contamination Risk Profiling and Proactive Response (RPPR). An initiative based on holistic profiling of EM data to determine risk escalation to contamination of critical Grade A zones facilitating proactive intervention for avoidance.

Coffee/ refreshment break 10.15am – 11.0am

Session (2). 11.0am – 12.15pm.

Bio-contamination Control.

- Contamination control principles and attributes of controlled areas: Airflow, pressure regimes, Material transfer control points (Hatches with disinfection steps), Personnel transfer control points (gowning and change rooms).
- Sanitization and Disinfection programs (qualification and regimes). Including Bio-decontamination hierarchy: Sterilization> Gaseous Disinfection Surface Sterilization> area/ surfaces Automated Gaseous Disinfection, Semi Automated Aerosol area/ surfaces disinfection> Manual Sanitization/ Disinfection process and Manual Sanitization/ Disinfection procedures.
- Progression through process of establishing control (implementing disinfection regimes and control measures) to formal state of control with monitoring to confirm control measures are effective.
- Control Strategies for Sterile product manufacture (terminally sterilized and Aseptic).

Lunch break 12.15pm – 1.30pm

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Session (3). 1.30pm – 2.30pm.

Bio-contamination Monitoring of environments: airborne and surfaces.

- Differentiation between requirements of environmental Classification and monitoring.
- Understanding the strengths and limitations of environmental monitoring. Perspective on USP<1116> guidance (not endorsed in the PHSS bio-contamination monograph).
- Classical Environmental tools, methods and techniques.
- Environmental sample incubation regimes and comparison of recovery.
- Perspective on RMM Real Time Bio-count fluorescence based monitoring technology and application in environmental monitoring of controlled areas.
- Combination technique monitoring to build picture of microbiological contamination control status of a controlled area.
- Environmental monitoring data trends, run charts, holistic profiles, incidence rates and reporting.
- Setting risk based EM sampling locations.
- Example of full environmental monitoring program for a Vial Filling Line for freeze dried products using Isolator Barrier technology.

Refreshment break 2.30pm – 2.45pm

Session (4). 2.45pm – 3.45pm.

Bio-contamination Deviation Management.

- Significance of microbiological deviations from target limits/levels in an environmental monitoring program for controlled areas.
- Microbiological deviation management – process flow schematic to follow in response to a contamination event or incidence.
- Check lists of areas to review in a Root cause investigation (or most probable root cause) following a contamination event and ahead of CAPA implementation and CAPA efficacy check.

Final discussions, thanks and close by 4pm.