

Biocontamination Control, Monitoring and Deviation Management - Best Practice for GMP Compliance



New training course!

August 26th 2014

in Malmö, Sweden at Scandic Hotel Triangeln

BioTekPro proudly present this unique one-day training course with Mr James L Drinkwater, on Biocontamination Control. The training course follows and presents the newly developed PHSS Bio-contamination Control Monograph 20.

Course overview

The PHSS- Pharmaceutical and Healthcare Sciences Society have developed a Bio-contamination monograph 20, the first of this type covering the complete life cycle for Bio-contamination with new initiatives and guidance on best practice for GMP compliance.

Each course attendee will be provided with a copy of the PHSS Bio-contamination monograph (over 200 pages) together with copies of the power point training slides as part of course material. This course applies to all those involved in GMP applications where controlled environments are used and is essential to keep up to date with regulatory expectations, current Life science sector thinking and best practice for GMP compliance.

The PHSS Monograph has had a full MHRA regulatory review before publication and specific section reviews from the IMB - Irish Medicines Board together with other peer review from Subject matter experts.

Training sessions

Sessions covering the four principle monograph sections:

Bio-contamination Characterisation and risk profiling

- Characterisation of microflora baselines and profiles
- New holistic initiative: Risk profiling and proactive response (RPPR) to risk escalation, avoiding critical zone contamination events

Bio-contamination Control

- Control strategies: an increasing regulatory requirement
- Contamination control attributes
- Bio-decontamination hierarchy
- Containment hierarchy as part of cross contamination control

Bio-contamination Monitoring with perspective on Rapid and Real Time Micro methods

- General principles of growth based Environmental monitoring
- New requirements for active air samplers and integration into Barrier Separation technology (Isolators and RABS)
- Risk based selection of sample locations
- Data trending, incidence rates and periodic reviews
- Perspective on Rapid and Real time Micro monitoring for environments (surfaces and airborne).

Bio-contamination deviation management

- Communicating Bio-contamination events
- Product and Process Impact assessments
- Flow of activities in response to contamination events or adverse trends
- Requirements (check list) for thorough root cause investigations
- CAPA - Corrective and Preventative Action plus efficacy check
- Response to failed Sterility Test

Date, Time and Course Fee

Date and time: August 26th 2014, 9.30 -16.30

Course fee: SEK 9.850:- (ex VAT). The course fee includes PHSS Bio-contamination monograph, copy of training slides, certificate, coffee and lunch



Trainer: James L Drinkwater

Chairman of the PHSS - Pharmaceutical & Healthcare Sciences Society

Leader of the PHSS Bio-contamination special interest group (including the MHRA)

Head of Aseptic processing technologies and GMP compliance: Franz Ziel GmbH

Member of the ISO 14698 WG02 UK mirror group re-writing the Bio-contamination standard

Registration and Questions

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