Annex 1 related to Barrier Technologies

Thursday 9 July 2020
Session start from 14.00 to 15.30 GMT

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Annex 1 related to Barrier Technologies.

Presenter
James Drinkwater: Head of GMP Compliance and aseptic process integration F Ziel GmbH and leader of the PHSS Aseptic processing and Bio-contamination special interest group. Co-lead of PHSS Annex 1 focus group.

Moderator
Di Morris: Senior GMP Compliance Advisor – Vaccines Audit and Risk Management at GSK and Co-Vice Chair of the PHSS. Co-Lead of PHSS Annex 1 focus group.

Abstract
The PHSS are one of the eleven Annex 1 commenting groups appointed by the European commission (EC) as part of the targeted consultation on version 12 of Annex 1. Within the current draft version of Annex 1 there is a section (combination of clauses) that covers barrier technology: Isolators and RABS. In review it is considered the current Annex 1 draft fails to differentiate Isolators and RABS and mixes requirements and as a result loses clarity and provides open interpretation.

The PHSS Annex 1 focus group have prepared alternative text to include the necessary differentiation and clarity on Isolators and RABS. This alternative text will form part of the commenting to the EC in the targeted consultation process.

This Webinar will focus on Annex 1 guidance on Barrier technology considering alternative text that adds clarity to Isolator and RABS definition, application and implementation for regulatory GMP Compliance.

- Introduction by moderator to Annex 1 revision and the targeted consultation process.
- The role of barrier technologies in contamination control and Contamination Control Strategy (CCS) as a principle new requirement in Annex 1.
- Insight the guidance from the PHSS on preparation of a Contamination Control Strategy (CCS) and Aseptic Containment Strategy (ACS) based on a case study.
- Proposed Annex 1 revision of clauses on Barrier technology and justification why further revision is considered necessary.
- Insight to associated Annex 1 PHSS text revisions on Qualification (including Classification) of Cleanroom and clean air devices that includes Barrier technology.
- Moderated Q&A session from incoming questions during the Webinar.