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Impact of the EMA's new guideline on setting health based exposure limits for risk identification in the manufacture of different medical medicinal products in shared facilities

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This presentation addresses some potential regulatory changes as a result of the new EMA guidance relating to multiproduct facilities and how it aligns with ISPE's risk-MaPP guidance. The following are the major points of discussion:

1. The need for a risk assessment on a case by case basis scientifically showing that the compound can be safely made in the facility without cross contamination within the health-based limit set by a toxicologist
2. The routes of cross-contamination (mix-up, retention, airborne sedimentation and mechanical transfer)
3. The impact of guidance where segregation and dedication is not predicated by class (hormone, cytotoxic, mutagenic etc.) but by scientific evaluation

In this presentation, case studies will be discussed for illustration.

Biography

Julian Wilkins has over 30 years of professional experience in facility and containment solutions for the pharmaceutical industry. In 1991 he co-founded a pharmaceutical isolator company in the UK and in 1999 founded Pharma Consult US, a consulting company that is dedicated to controlling product and occupational exposure in the pharmaceutical and biotech industries. He is the founder of ISPE's containment, API and OSD CoP's. He is the co author ISPE Baseline guides "Risk-MaPP" (Guidance on Cross contamination) and OSD.

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