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**Malaysia
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Managing the Risk of Cross Contamination

Managing the risk of cross contamination is important with multi-product facilities. The EMA has recently published draft guidance on Setting Health Based Exposure Limits and proposed updates to the GMPs which call for risk assessments to determine if products can be produced in shared facilities. Here how you can meet this requirement with ISPE's Risk-MaPP Baseline® Guide. This guide provides a scientific risk-based approach based on ICH Q9 to manage the risk of cross contamination in multi-product facilities.

Getting this assessment right can make a huge impact on a company's bottom line and can be the difference in the need for dedicated facilities or not. The assessment starts with getting the health-based limits correct – whether you use PDEs (permissible daily exposures), ADEs (allowable daily exposures) or something else, is it correct? What do you do with the limit once it is determined? How does the limit determine if there is a need for dedicated facilities? How will these limits benefit your operation?

Since many global regulatory requirements are based on the EU GMPs, how will these changes affect the global regulatory environment?

This two day session will be a combination of lecture, participant exercises, group discussion and question and answer sessions.

Proposed 2 Day Agenda for Risk-MaPP Session

1. Introduction
2. Brief History on how Risk-MaPP was developed
3. Regulatory Requirements
 - a. Review of EMA proposed guidance to compare and contrast to Risk-MaPP
 - b. Internal documentation
4. Risk Identification – Hazard Identification - Setting limits
5. Risk Analysis - Review modes of cross contamination
 - a. Mix-up
 - b. Retention
 - c. Mechanical Transfer
 - d. Airborne Transfer
6. Risk Analysis – What is needed
7. Risk Management Tools
8. Risk Evaluation – How to set acceptance limits
9. Risk Control – How to mitigate risk
10. Risk Communication
11. Q&A