Sneak Peek

Aseptic Fill & Finish of Biologics

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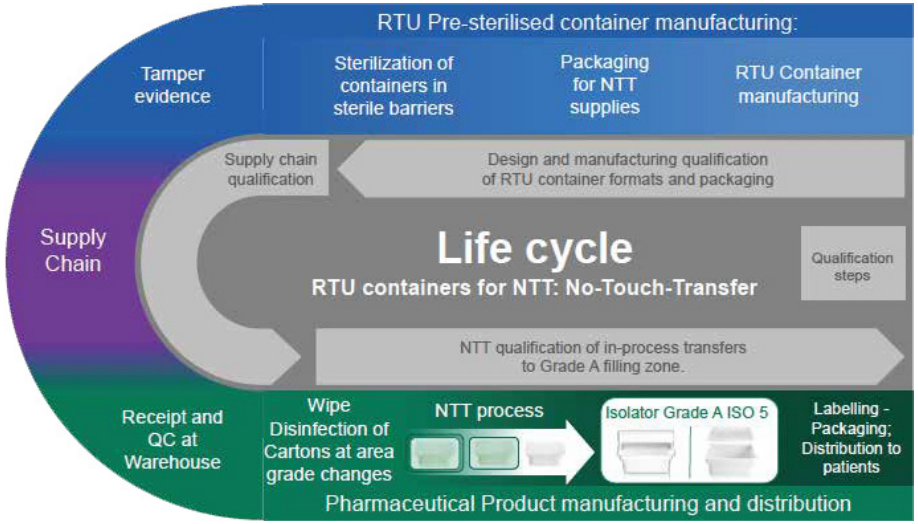
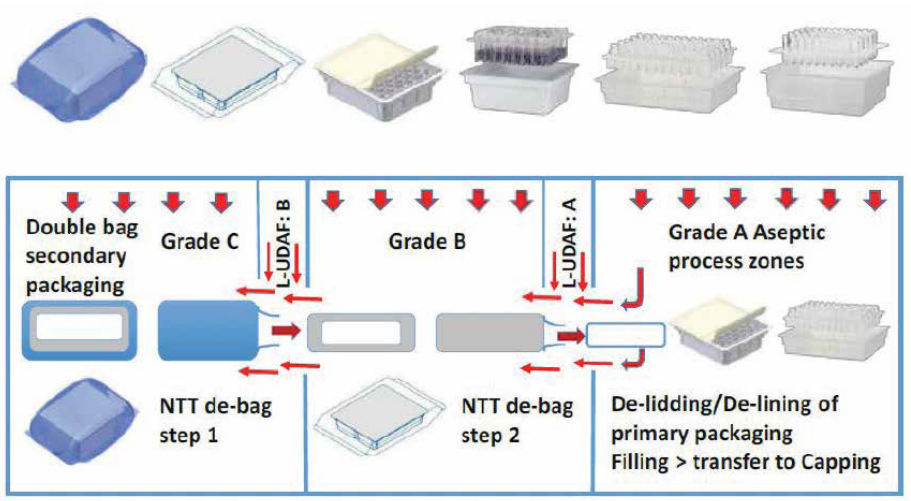
Session 1 learning objectives: Life cycle strategies

01

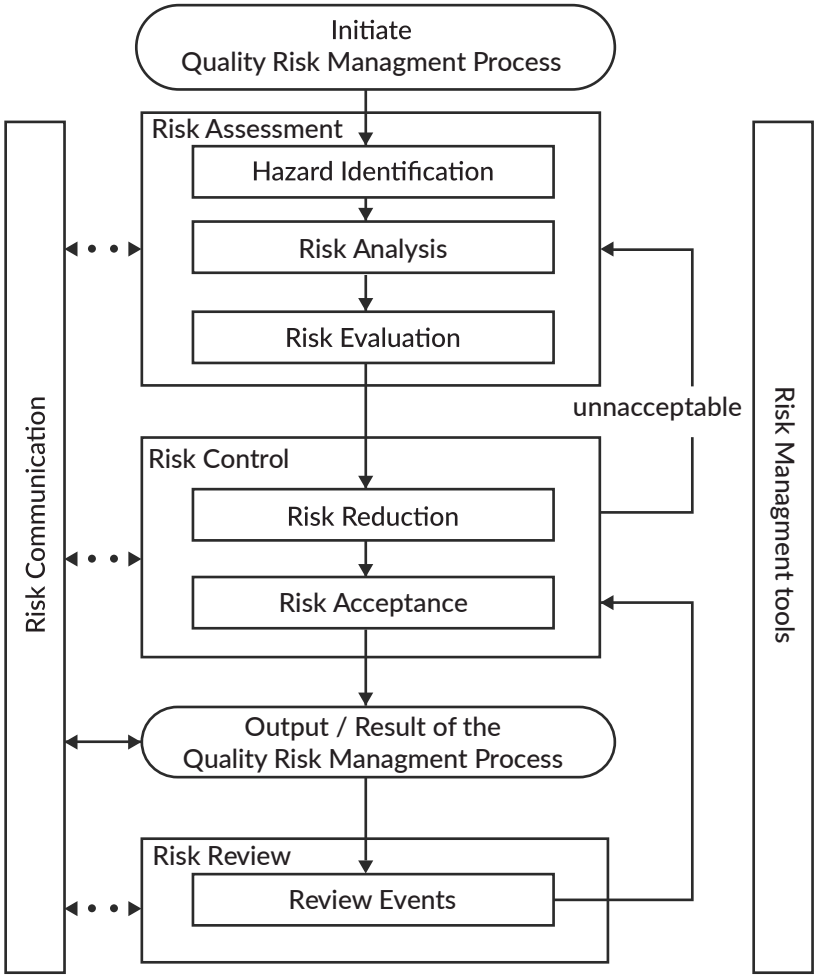
Example of a Life cycle strategy applied to Ready to Use (RTU) pre-sterilised product containers with End to End Qualifications through design, supply change and in-process transfers to Point of Filling (in this case the NTT: No-Touch-Transfer process) with applied EM and PM.



Pre-Sterilised container NTT: No-Touch-transfer
Process flow schematic

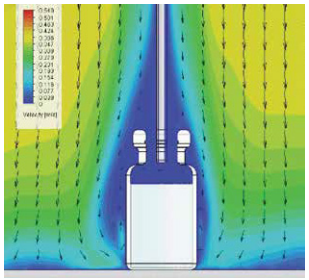


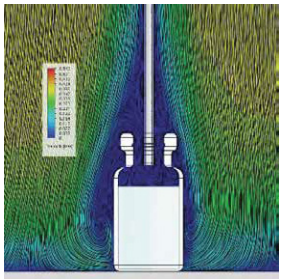
Session 2 learning objectives: QRM ICHQ9-revised

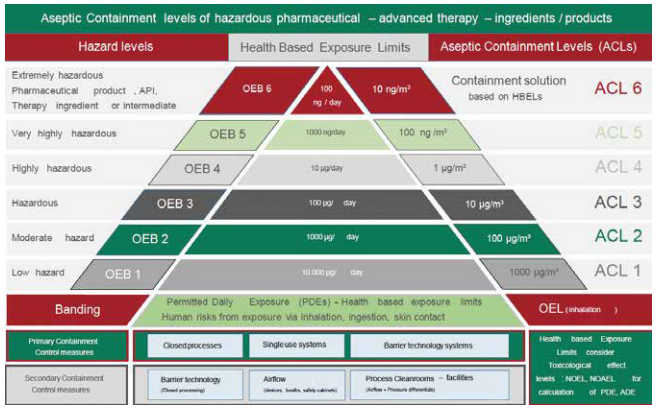


- **The QRM model has been revised in ICHQ9, learn why and what the impact is of the changes.**
- **Learn how QRM is applied when consider ingalternative, technologies, methods and practices to that defined in regulatory guidance.**

Session 3 learning objectives: Risks at Point of Fill







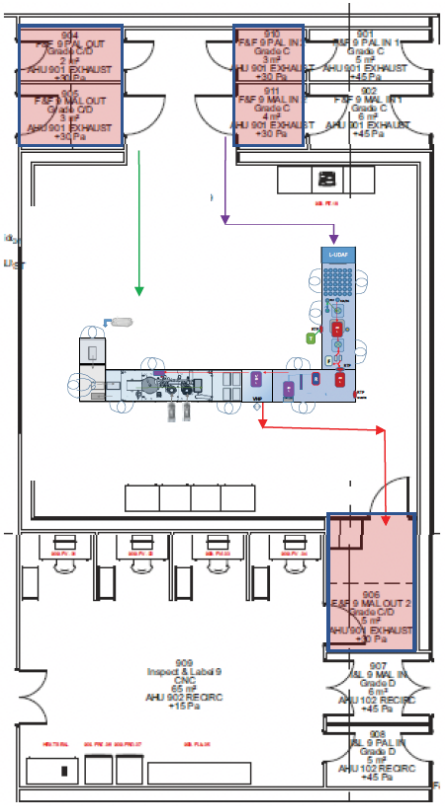
- **Computational Fluid Dynamic (CFD) models of the 'First air' protection at the point of fill indicate the a vial/ open container acts as an airflow dead leg** causing air to form a 'shield' around the container but within the container there is very little (velocity) airflow protection –disrupt of break the protective air shield and product contamination is likely. How are such risks mitigated?

- **Also CFD models demonstrate without significant down flow air inside the vial aerosols from product filling can spill out and contaminate the outer surfaces of the vial and surround.**

  This 'product aerosol' risk is a particular concern if products are toxic,biohazard and/or cross contamination control (between products/ batches) is required. **Learn what Aseptic-Containment strategies are applied based on Health based Exposure Levels (HBELs) at different levels** of potency/ hazard. Learn about filling aerosol distribution studies to characterise the contamination spread and risks.

Session 4 learning objectives:
Facility and Process Design with applied EM & PM

04



ATMP Viral vector Formulation & Filling

Combined processing platform of formulation 'Vector Pooling, HFF: Hollow fibre filtration, Concentration adjustments and automated Filling in Isolator technology.

- **Overview of Oxford BiomedicaUK 'Oxbox' asa case study from PHSS CCS Contamination Control Strategy guidance initiative.**
- **Aseptic process filling of a Lentiviral vector used in a CarTcell cancer therapy (ATMP).**
- **Aseptic–Containment:Aseptic process filling with viral containment control measures of a GMO (Genetically modified organism).**
- **Consideration of EM and PM (Environmental and Process Monitoring) applied at Set-up, in process filling operations and at end of batch to provide data based evidence of full GMP compliance.**

Case study of ATMP (CarTcell) viral vector filling into RTU pre-sterilised vials connected to formulation with extensive use of single use systems.

Session 8 learning objectives: Good Cleanroom behaviour/ Good Aseptic technique

- **Good aseptic technique is required in barrier systems** at set-up of both manual and automated processes in barrier systems and through process operations if processes are highly manual.
- **Good Cleanroom behaviour is required to reduce the risk escalation of contamination** if the surrounding environment to the barrier system exceeds specified and adverse levels of bioburden.

Registration

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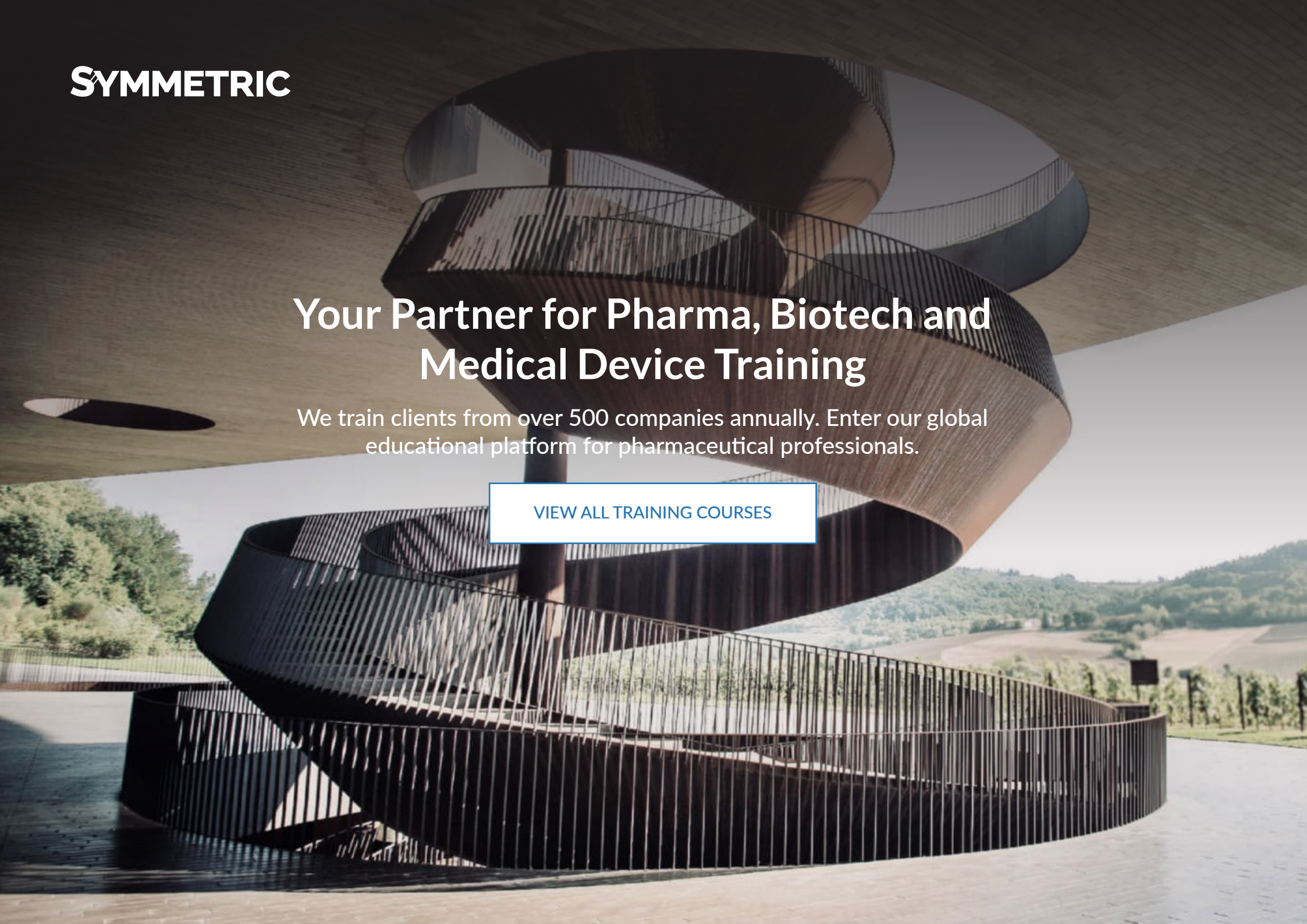
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