

Sneak Peek

Aseptic Fill & Finish of Biologics



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SYMMETRIC

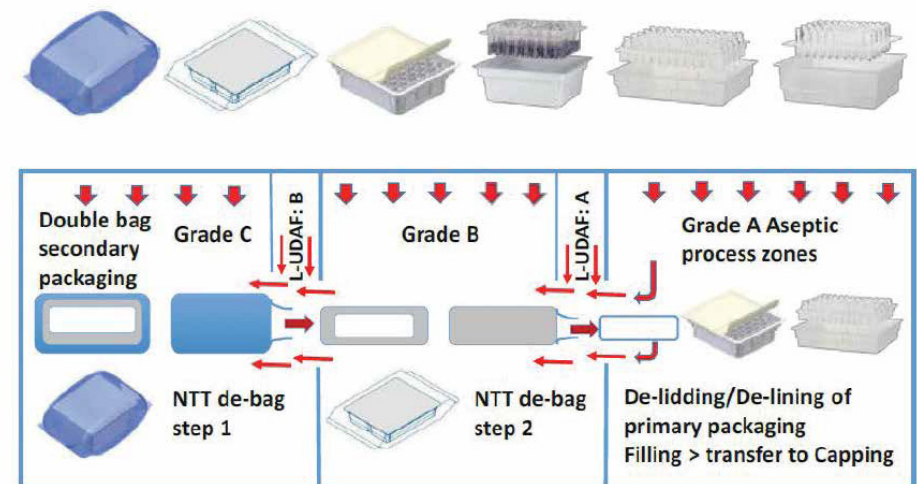
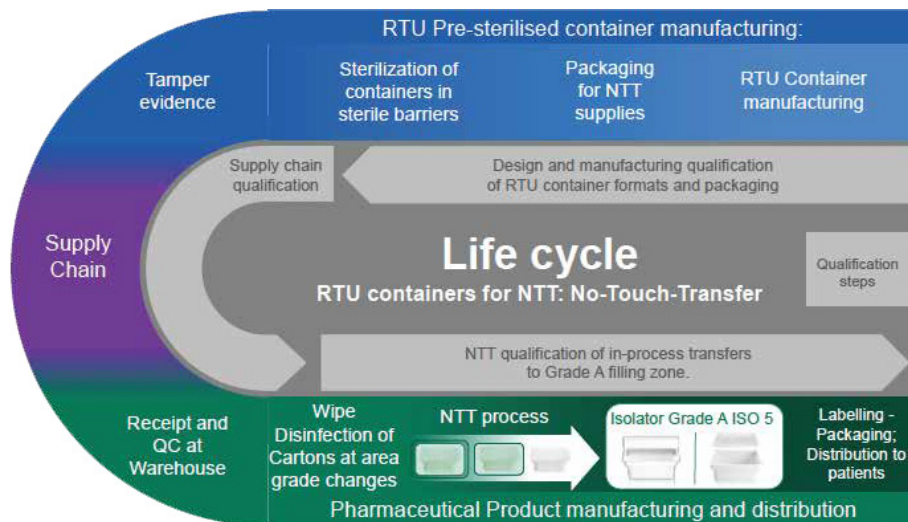
Session 1 learning objectives:

Life cycle strategies

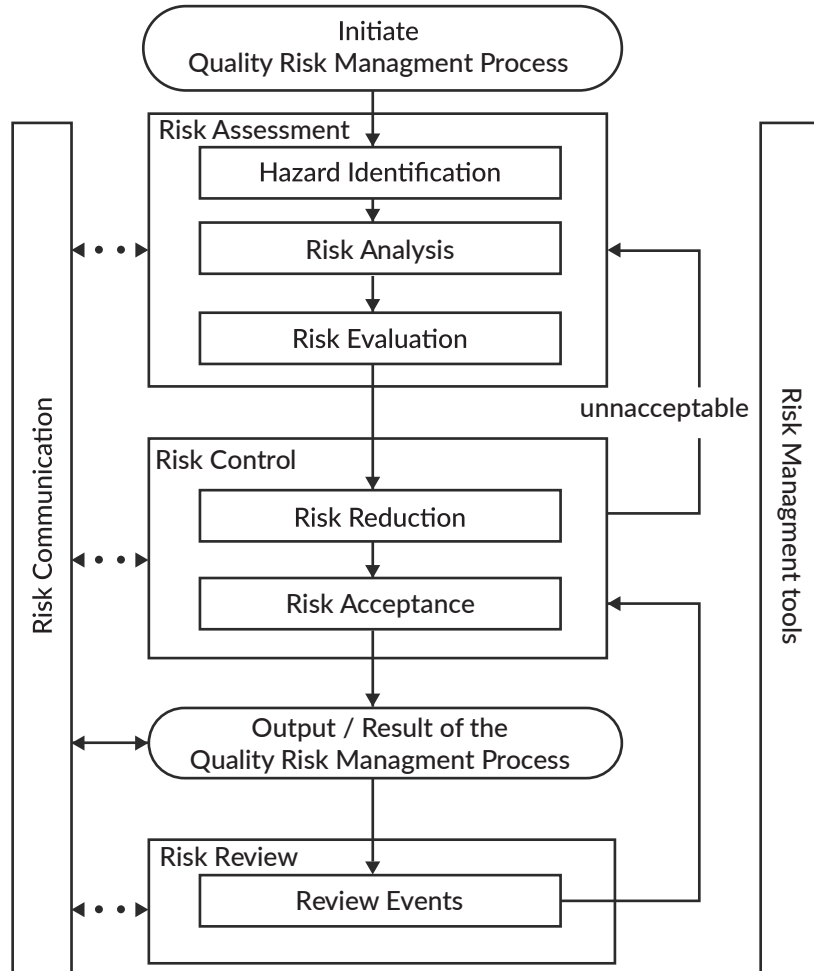
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Example of a Life cycle strategy applied to Ready to Use (RTU) pre-sterilised product containers with End to End Qualifications through design, supply change and in-process transfers to Point of Filling (in this case the NTT: No-Touch-Transfer process)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

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

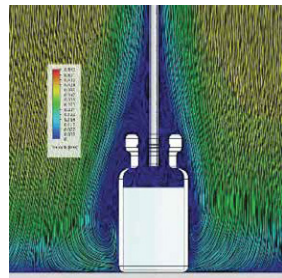
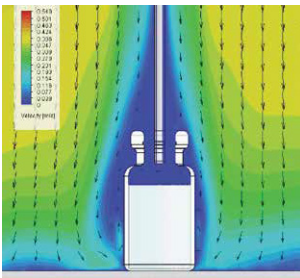


Session 2 learning objectives: QRM ICHQ9-revised



- 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



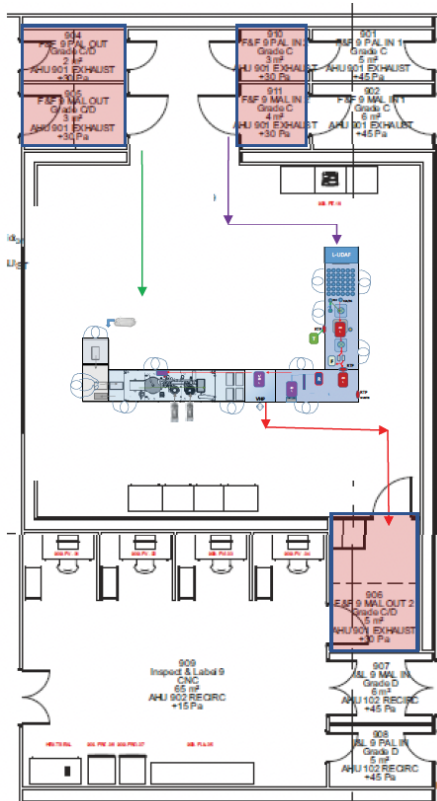
- **Computational Fluid Dynamic (CFD) models of the 'First air' protection at the point of fill indicate the a vial/ open container acts as an airflow dead leg causing air to form a 'shield' around the container but within the container there is very little (velocity) airflow protection –disrupt or break 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.**

Aseptic Containment levels of hazardous pharmaceutical – advanced therapy – ingredients / products				
Hazard levels	Health Based Exposure Limits		Aseptic Containment Levels (ACLs)	
Extremely hazardous Pharmaceutical product - API, Therapy ingredient or intermediate	OEB 6	100 ng / day	10 ng/m³	Containment solution based on HBELs ACL 6
Very highly hazardous	OEB 5	1000 ng/day	100 ng/m³	ACL 5
Highly hazardous	OEB 4	10 µg/day	1 µg/m³	ACL 4
Hazardous	OEB 3	100 µg / day	10 µg/m³	ACL 3
Moderate hazard	OEB 2	1000 µg / day	100 µg/m³	ACL 2
Low hazard	OEB 1	10 000 µg / day	1000 µg/m³	ACL 1
Banding	Permitted Daily Exposure (PDEs) - Health based exposure limits Human risks from exposure via inhalation, ingestion, skin contact		OEL (inhalation)	
Primary Containment Control measures	Closed processes	Single use systems	Health based Exposure Limits consider Toxicological effect levels NOEL, NOAEL for calculation of PDE, ADE	
Secondary Containment Control measures	Barrier technology (Isolated processing)	Airflow (direction, velocity, safety controls)	Process Cleanrooms – facilities (airflow + Pressure differential)	

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



**ATMP Viral vector
Formulation & Filling**



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

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

- **Overview of Oxford BiomedicaUK 'Oxbox' as a 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.**

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 Sneak Peek

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