

# Sneak Peek

*Aseptic Processing in Manufacture  
of Sterile Products and ATMPs*

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**James L. Drinkwater**

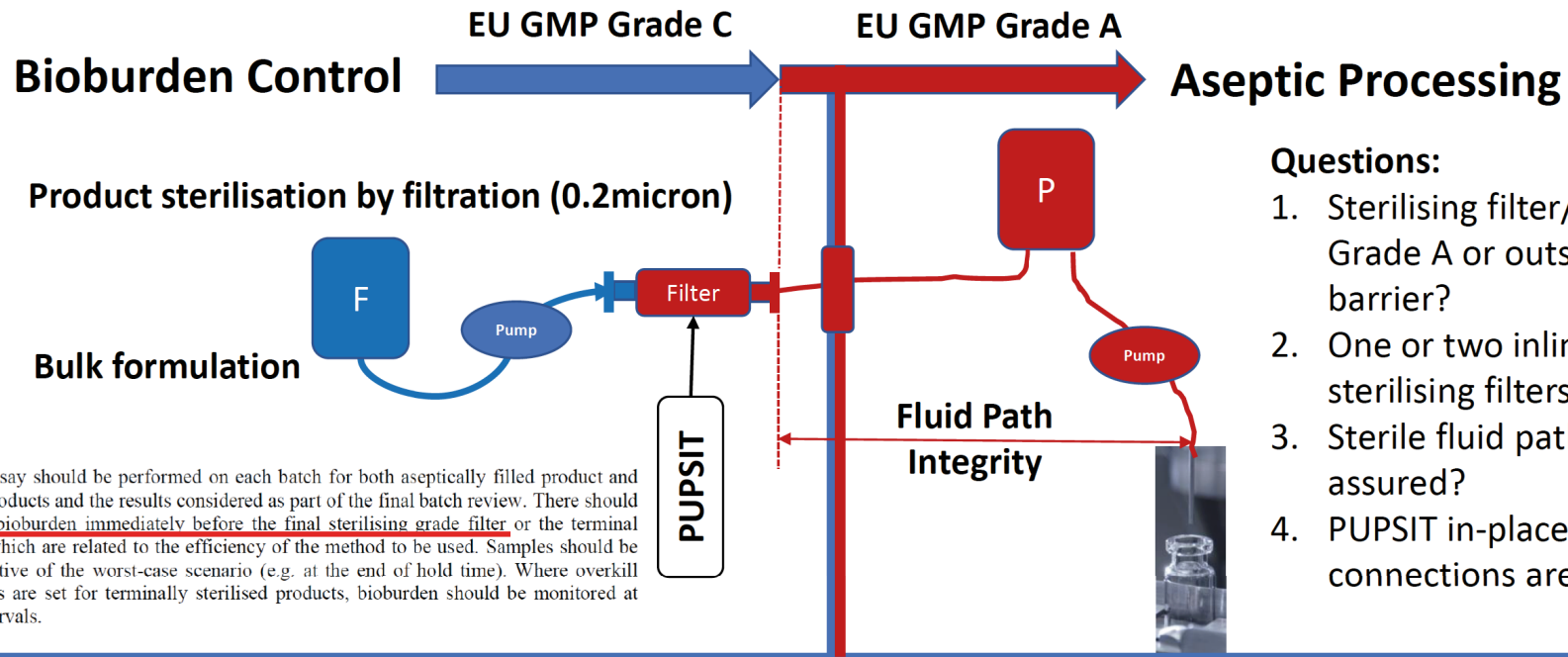
Franz Ziel GmbH,  
Head of GMP Compliance



**SYMMETRIC**

# Aseptic processing Product pathway

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10.3 The bioburden assay should be performed on each batch for both aseptically filled product and terminally sterilised products and the results considered as part of the final batch review. There should be defined limits for bioburden immediately before the final sterilising grade filter or the terminal sterilisation process, which are related to the efficiency of the method to be used. Samples should be taken to be representative of the worst-case scenario (e.g. at the end of hold time). Where overkill sterilisation parameters are set for terminally sterilised products, bioburden should be monitored at suitable scheduled intervals.

## Questions:

1. Sterilising filter/ PUPSIT inside Grade A or outside the barrier?
2. One or two inline Product sterilising filters?
3. Sterile fluid path integrity assured?
4. PUPSIT in-place test connections are present?

**The sterile Product pathway** must assure all connections and enter of the barrier technology do not compromise sterility.

**Not just integrity (in-place) of the sterilising filter is critical to assure sterility** but also the pathway from the filter to the Point of Fill (line integrity test methods are available).

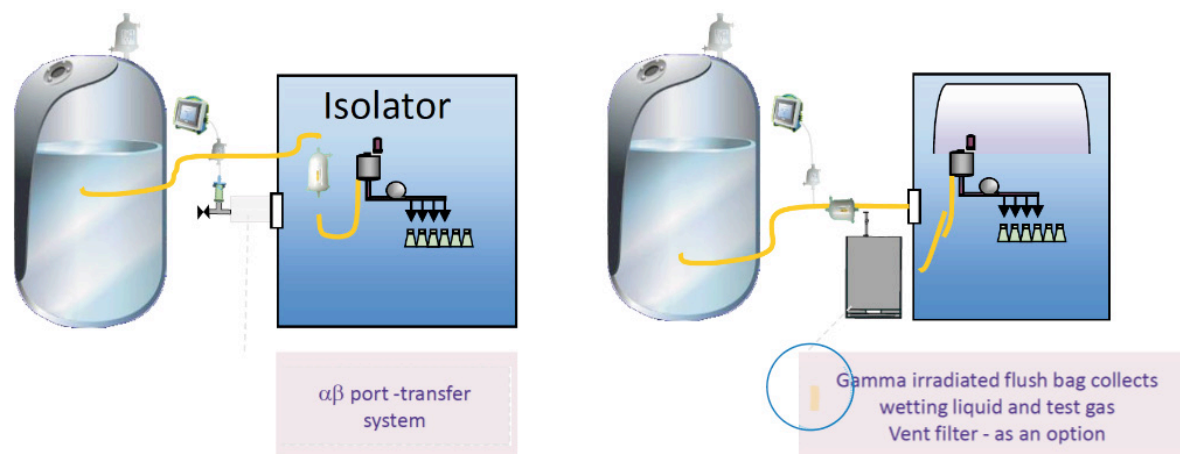
# Technical solution applied to PUPSIT for Isolator barrier



## Annex 1 & PUPSIT: GMP Regulatory expectation & QRM

Key decisions related to PUPSIT Barrier integration impact complexity of design and operations:

1. Product Filter Inside or Outside the Barrier Isolator?
2. SIP or Single use systems?



Images courtesy of Merck



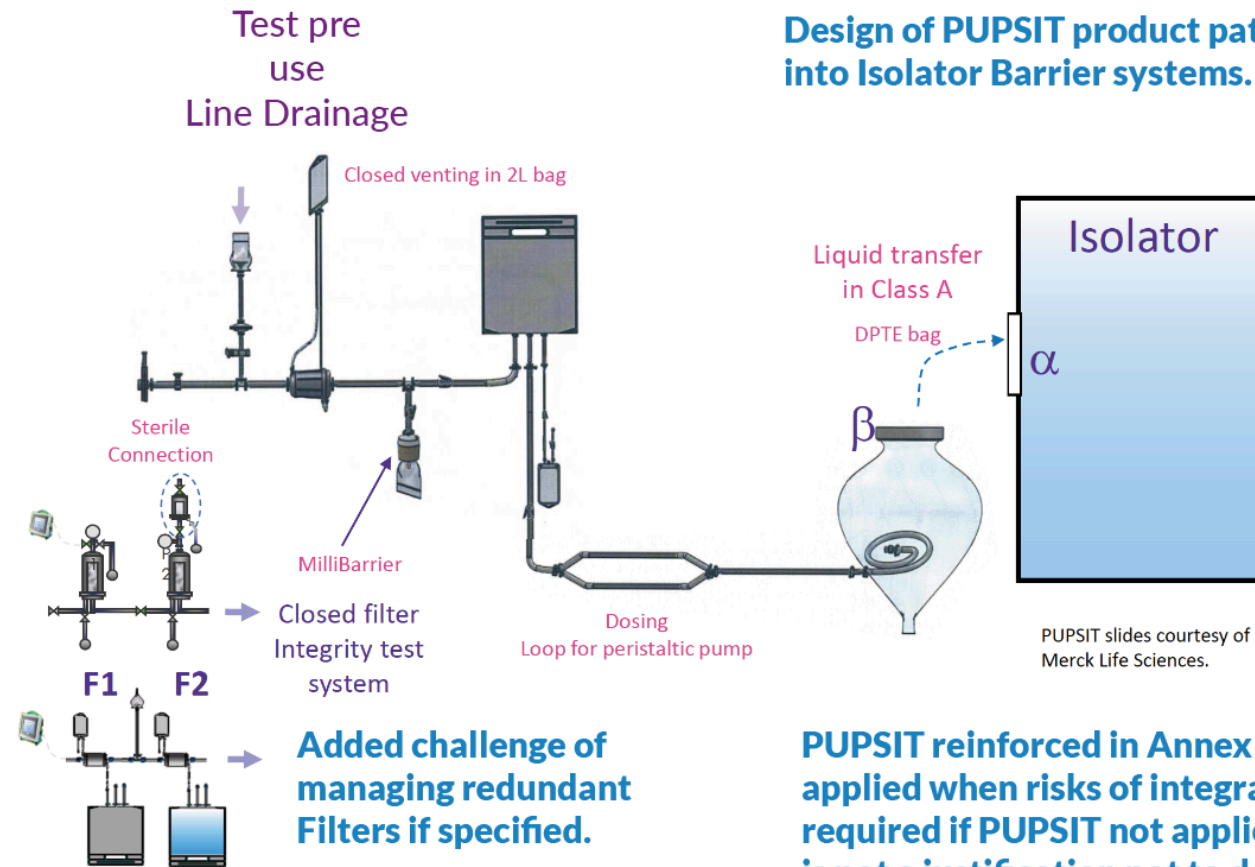
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Register

# A technical solution for PUPSIT integration in Isolator barrier



Design of PUPSIT product path test assemblies and integration into Isolator Barrier systems.

**PUPSIT reinforced in Annex 1 revision with QRM applied when risks of integration are high. Justification required if PUPSIT not applied.**  
**'its hard to do is not a justification not to do!'**

Images courtesy of Merck

# Registration

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