

Sneak Peek

*Aseptic Processing in Manufacture
of Sterile Products and ATMPs*



James L. Drinkwater

Franz Ziel GmbH,
Head of GMP Compliance



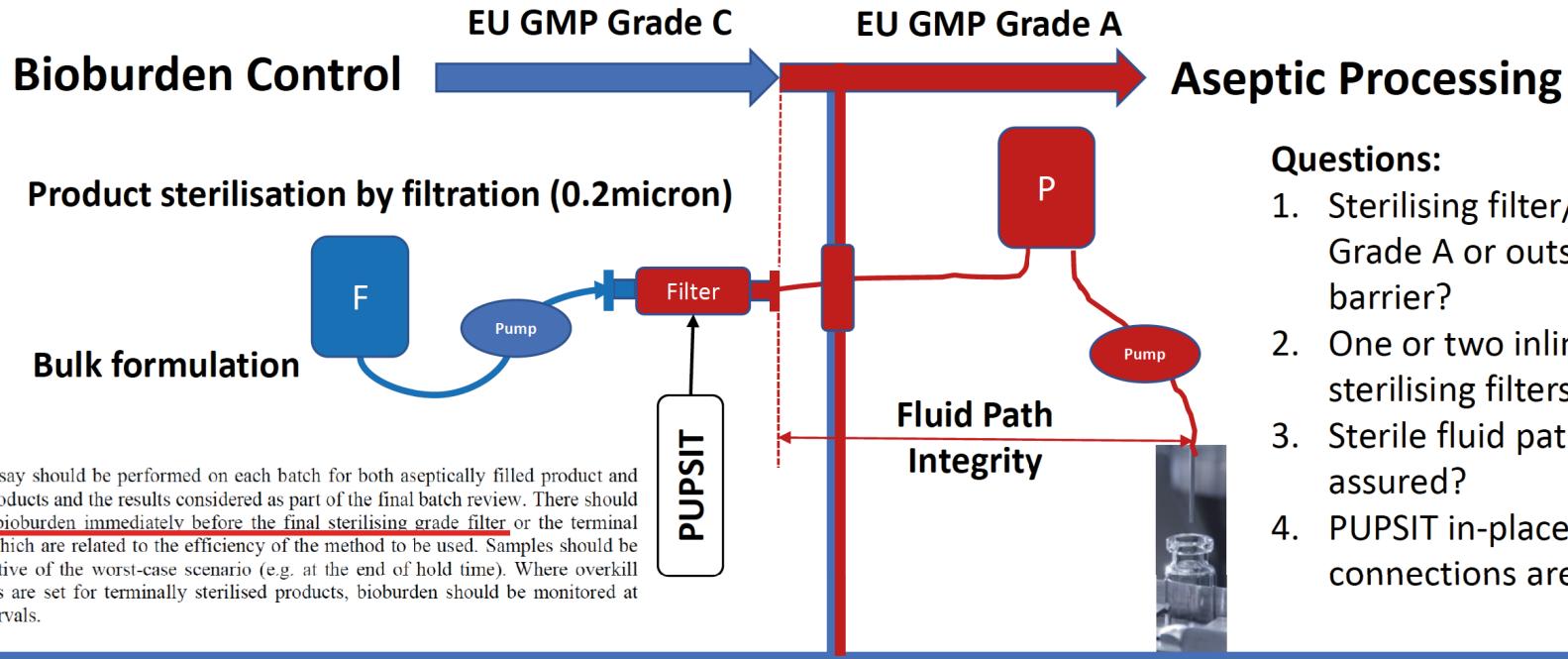
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SYMMETRIC

Aseptic processing Product pathway

01



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

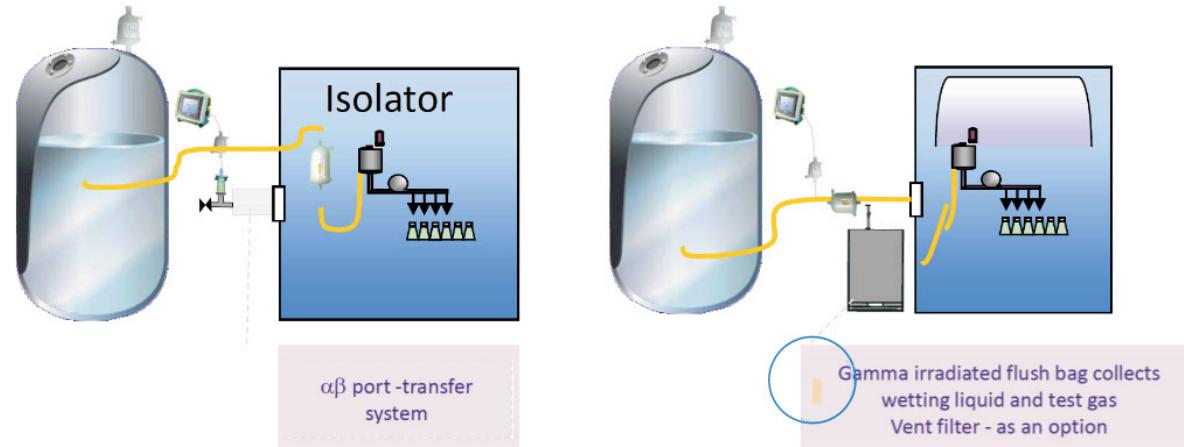
02

Annex 1 & PUPSIT: GMP Regulatory expectation & QRM

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

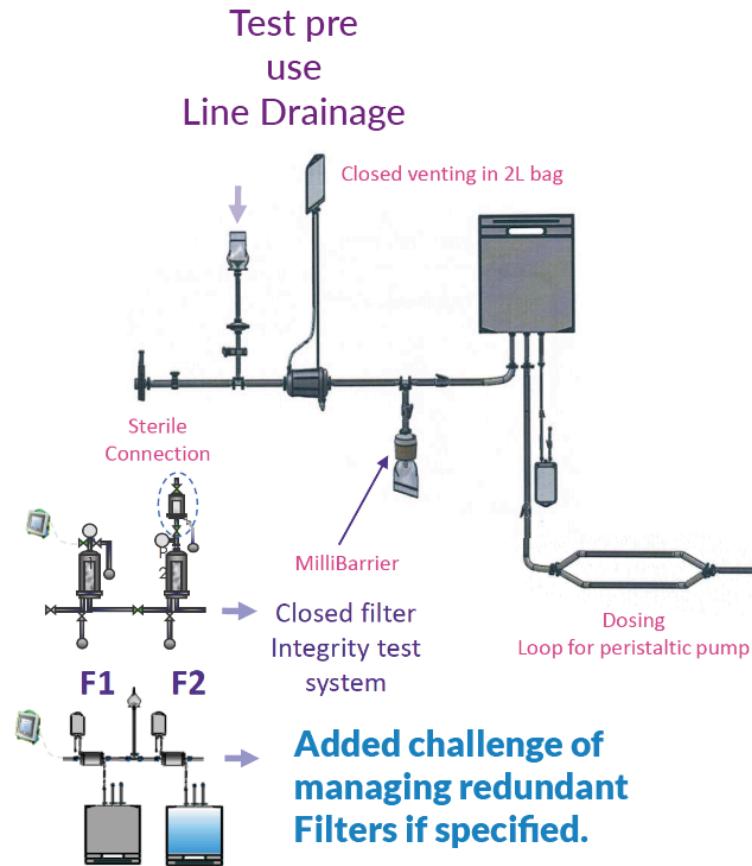


1. Product Filter Inside or Outside the Barrier Isolator?
2. SIP or Single use systems?

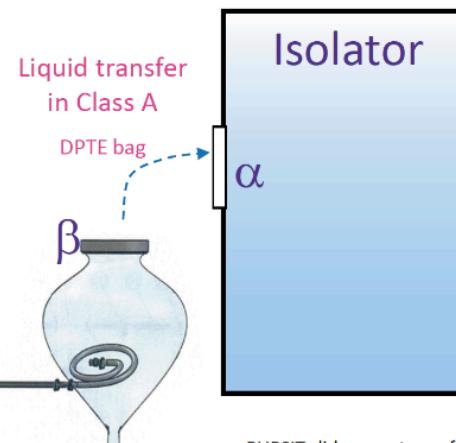


Images courtesy of Merck

A technical solution for PUPSIT integration in Isolator barrier



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



PUPSIT slides courtesy of Merck Life Sciences.

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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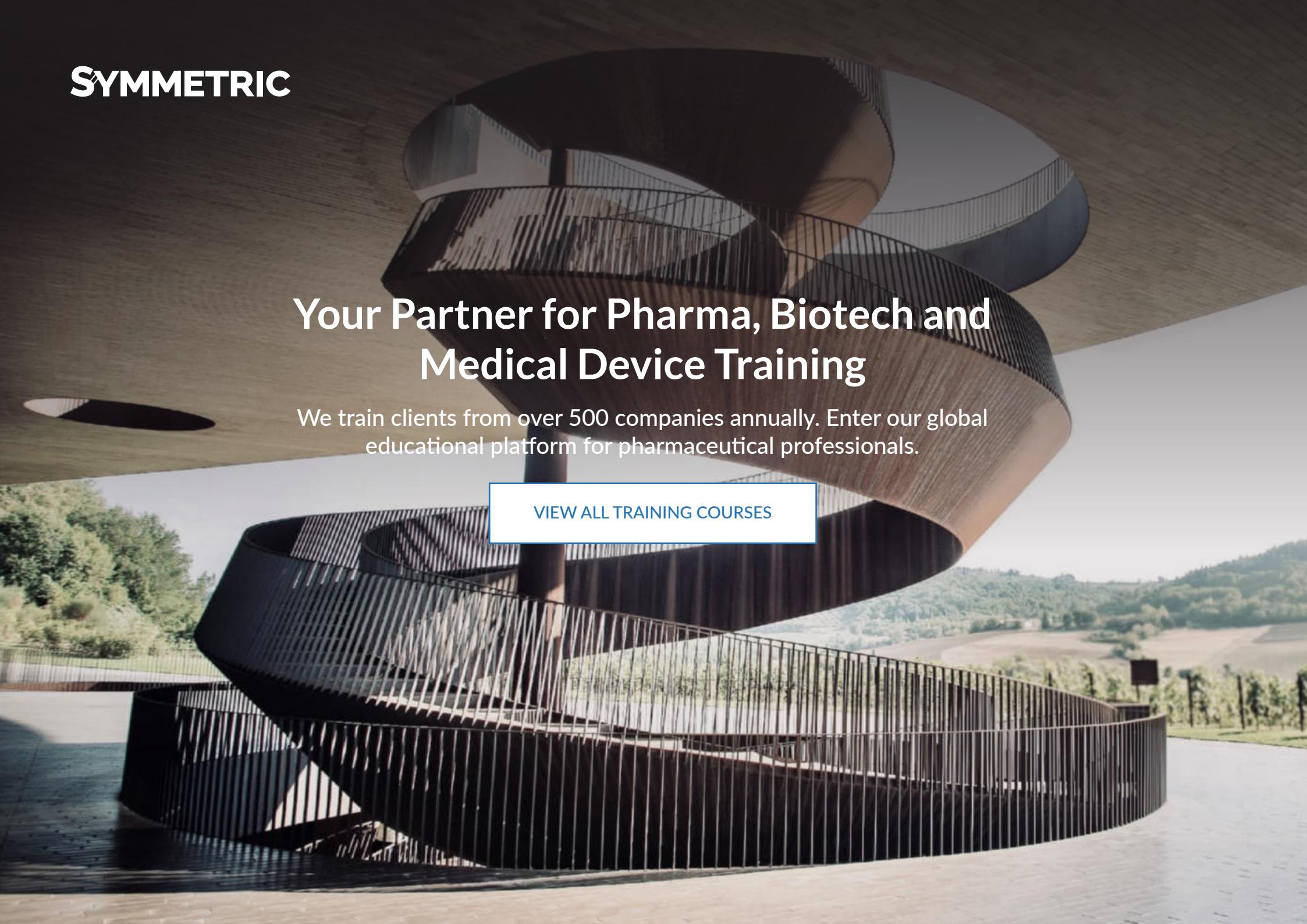


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Bratislava, Slovak Republic
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