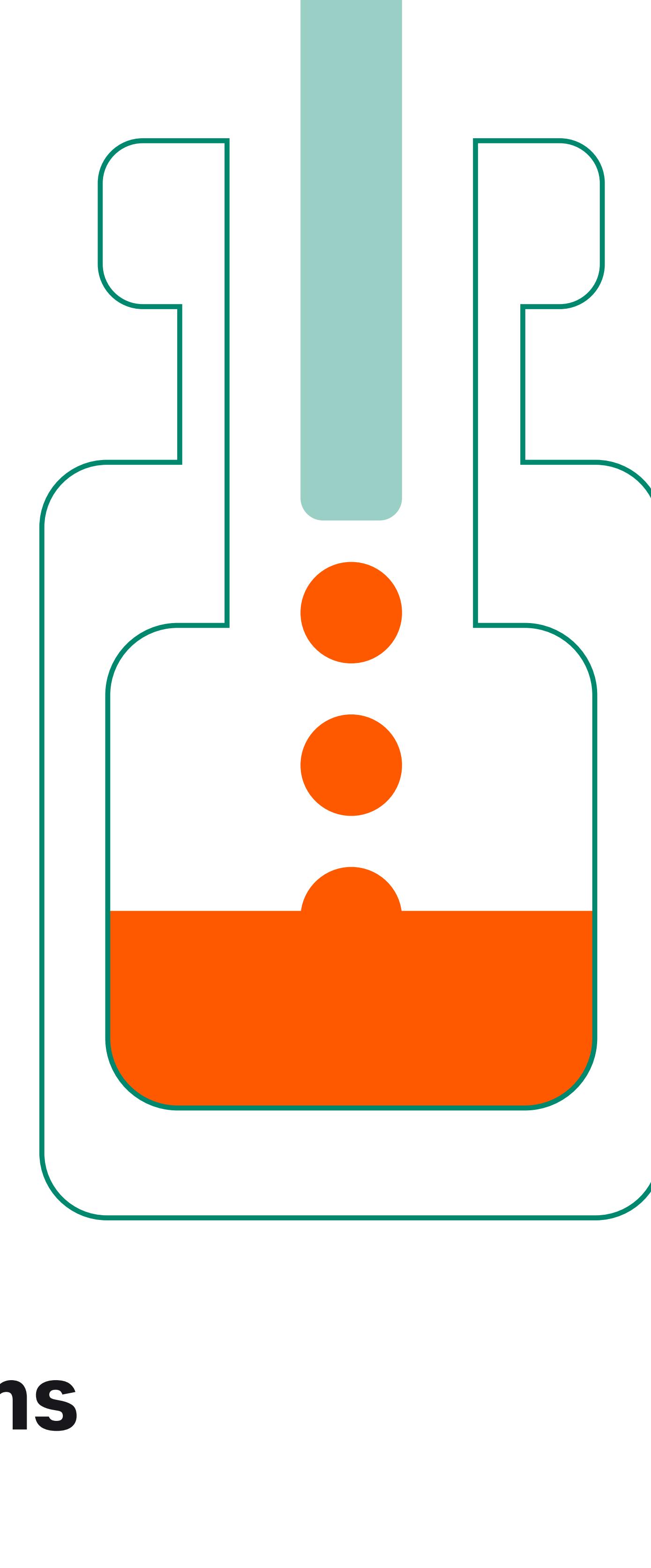


SA25 and Microcell™ workcells chart new territory in aseptic filling



Designed to meet EUDRALEX Annex 1 revisions

2023 revisions to Annex 1 guidelines for the GMP Manufacture of Sterile Medicinal Products include a new emphasis on developing and maintaining a comprehensive contamination control strategy for the entire manufacturing process to minimize microbial, particulate, and endotoxin contamination.

Annex 1 revisions include a greater focus on robotics, automation, and barrier technologies like isolators to reduce human intervention.

The Cytiva SA25 and Microcell™ workcells help companies meet stringent regulatory requirements while boosting capacity.

Two European CDMOs. Two successful Annex 1 GMP certifications. One proven strategy.

Swedish CDMO NorthX Biologics and Belgian CDMO White Raven were able to achieve certification in just 18 months or less. Here's how:

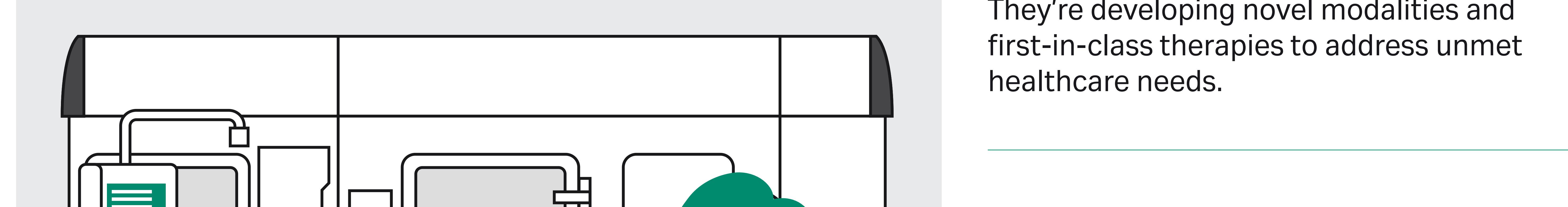
NorthX Biologics

(14 months, Microcell user)

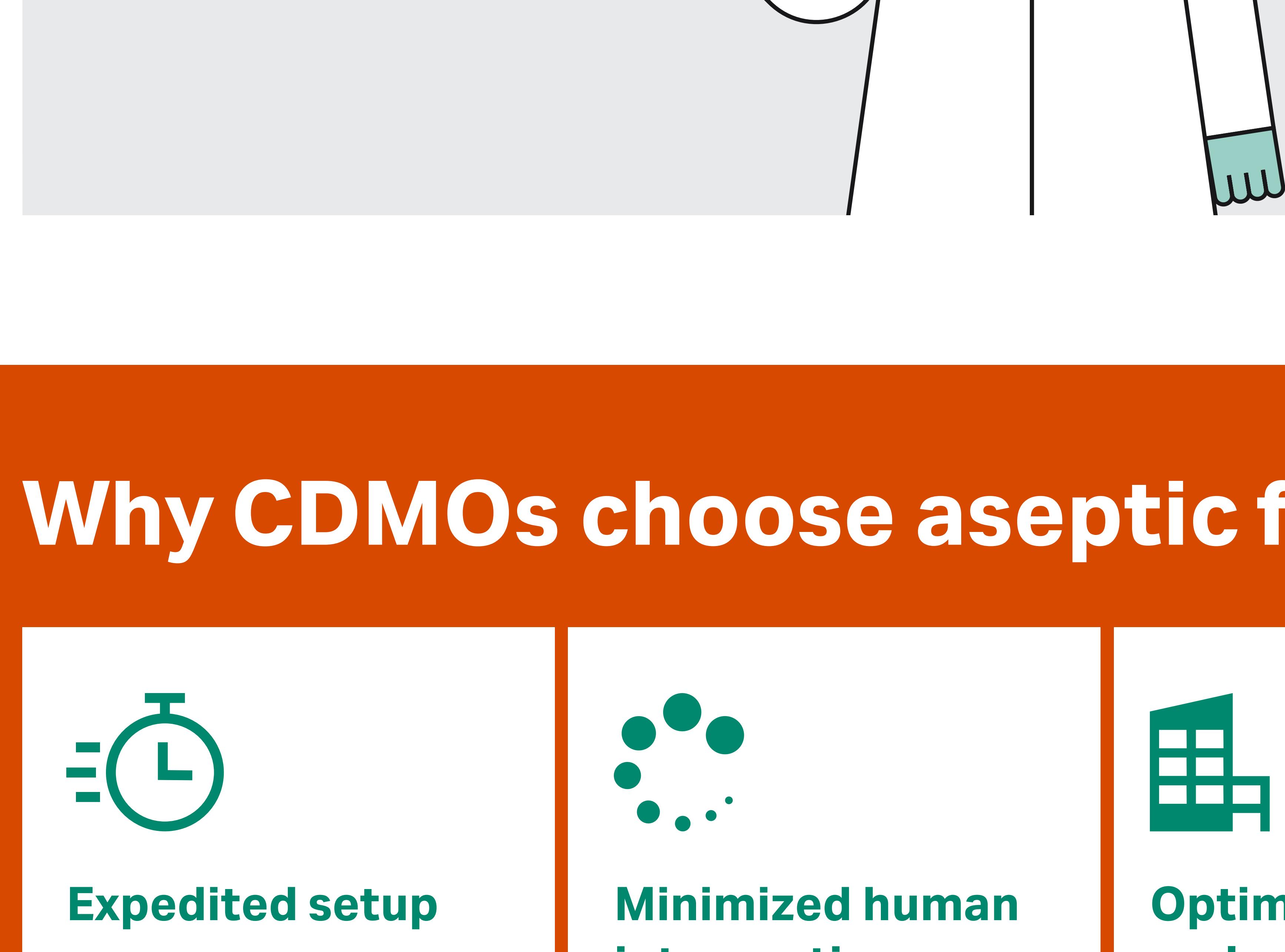


White Raven

(17 months, SA25 user)



Standardized robotic gloveless isolators enable faster access to breakthrough therapies



Small biotechs are driving innovation

They're developing novel modalities and first-in-class therapies to address unmet healthcare needs.

Time-to-market is critical

To succeed, these companies require rapid scale-up, regulatory alignment, and minimal operational delays.

CDMOs must be flexible and responsive

Supporting early-phase development means adapting to evolving requirements—without compromising GMP standards.

Why CDMOs choose aseptic filling workflows

 <p>Expedited setup Shortens tech transfer and installation timelines for faster project initiation</p>	 <p>Minimized human intervention Robotic gloveless aseptic filling reduces risk of microbial, particulate, and endotoxin contamination</p>	 <p>Optimized for early-phase manufacturing Supports small to mid-scale production, ideal for high-value low-volume clinical batches</p>	 <p>Annex 1 aligned Incorporates advanced isolation, automation, and environmental monitoring to meet the latest EU regulatory expectations</p>
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cytiva.com/aseptic-filling

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