Cytiva aseptic filling

INSPECTION SUPPORT SERVICE

Gloveless isolators such as the SA25 aseptic filling workcell and Microcell™ vial filler are gaining traction in the biopharmaceutical space. However, innovation comes with complexity. That's why we offer support before your first GMP audit – to help you handle the novel regulatory considerations. The Cytiva™ aseptic filling inspection support service reduces compliance burdens, aligns with current standards, and empowers your team to step into inspections with clarity and confidence. We also help you during and after your inspection, depending on the package you choose.

This aseptic filling inspection support service compliments our qualification solutions by addressing the regulatory strategy and inspection readiness needs specific to gloveless isolator systems. It includes:

- Quality by design and integration with your contamination control strategies.
- Creation and review of regulator-facing documentation aligned with current expectations.
- Delivery of customized coaching to build internal regulatory expertise.
- Ongoing consultation to prepare for and respond to regulatory inspections.

Fig 1. SA25 aseptic filling workcell.

The scope covers the full journey from pre-inspection planning through post-inspection follow-up, delivering a consistent, robust approach to regulatory engagement across global markets.

To meet different needs, we offer two options – standard (Fig 2) and premium (Fig 3). Table 1 compares the features of each package.

Standard inspection support service package

Discovery workshops with Cytiva SMEs

Documentation review

Pre-inspection checklists and regulatory FAQs

Internal storyboards to prepare for inspection

GMP inspection readiness

Post-inspection support (if required)
Consulting support to prepare a response

Fig 2. Overview of what's included in the standard inspection support service package. SME is subject matter expert.

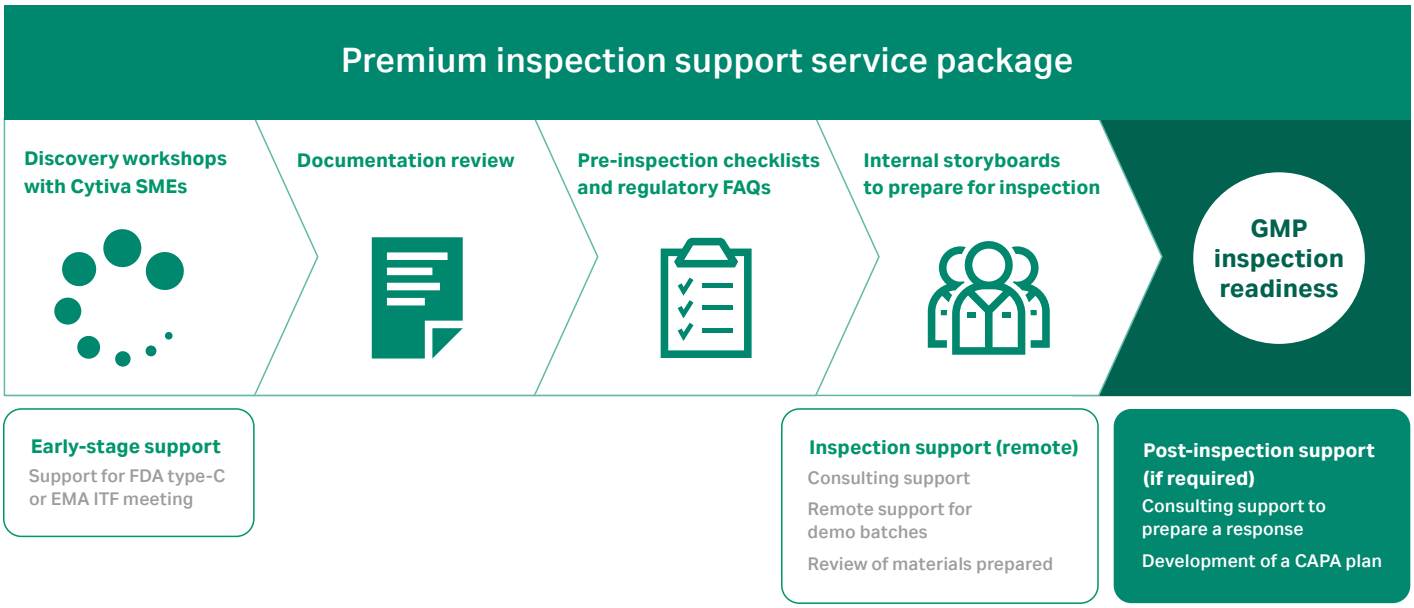

Fig 3. Overview of what's included in the premium inspection support service package. EMA is European Medicines Agency. ITF is Innovation Task Force. CAPA is corrective and preventative action.

What's included?

Description		Standard package	Premium package
Discovery workshops	During a collaborative discovery workshop subject matter experts (SMEs) from Cytiva review your qualification strategy, assess existing data and documentation generated, and identify potential gaps and opportunities to strengthen the regulatory position. They work closely with your team to develop a strategy to address any potential gaps.	✓	✓
Documentation review	SMEs from Cytiva review documentation that you generate and provide or data related to the qualification, validation, routine monitoring, or good operating practices of the aseptic filling equipment. They give actionable feedback to enhance your inspection readiness.	✓	✓
Cytiva supporting documents	SMEs from Cytiva have produced a suite of ready-to-use resources to streamline your inspection preparedness including: • Internal storyboards for inspection preparation. • Regulatory-facing presentations on the SA25 aseptic filling workcell or Microcell vial filler technology with placeholders for your data. • Pre-inspection checklist. • Frequently asked questions and associated answers that have been documented as part of ongoing service delivery and industry experience.	✓	✓
Inspection support (remote)	• Up to four hours of remote consulting support for up to five days to support your or regulator queries and responses during the inspection. • Remote integration support for demo batches that will have regulator review. • Review of materials that are prepared in response to regulator queries.	✗	✓
Early-stage support	• Support for early interactions with regulatory agencies (e.g., FDA Type-C meeting or EMA ITF meeting).	✗	✓
Post-inspection support	• Our SMEs provide consulting support for response preparation if findings are deemed critical or prevent manufacture of your drug product.	✓	✓
	• We support you to develop a corrective and preventive action (CAPA) plan (where necessary and related to our aseptic filling equipment).	✗	✓

Why collaborate with Cytiva?

Our inspection support services will guide you in achieving GMP readiness with our gloveless, robotic aseptic filling technologies. Designed to streamline your path to compliance, this offering delivers informed regulatory guidance, robust documentation support, and personalized coaching to help you confidently navigate inspections and meet evolving global standards. Whether you're preparing for your first audit, scaling up for commercialization, or entering a new market, your Cytiva team is here to help you succeed.

Ready to start?

Connect with your Cytiva account manager to explore how the Cytiva aseptic filling inspection support service can accelerate your journey and minimize regulatory risk or to discuss personalized options that fit your specific needs. We will help you navigate compliance with certainty.

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