STERIS

WHITE PAPER

STERIS Purefit™ Sterilization Wrapping: Ensuring Compliance with EU GMP Annex 1

In collaboration with

DUPONT

One Year Since Annex 1 – Are You Compliant?

Contamination Risks in Sterile Drug Production

Pharmaceutical manufacturers producing sterile drug products face significant challenges in preventing contamination. The European Union Good Manufacturing Practice (EU GMP) Annex 1 requires a robust Contamination Control Strategy (CCS) to minimize these risks. Aseptic processes are necessary when terminal sterilization is not feasible; therefore, it is especially important to minimize contamination from materials entering the cleanroom area.

The EU GMP Annex 1 Section 8.48 states the following:

- Where materials, equipment, components and ancillary items are sterilized in sealed packaging or containers, **the packaging should be qualified for minimizing the risk of particulate, microbial, endotoxin/pyrogen or chemical contamination,** and for compatibility with the selected sterilization method.
- The packaging sealing process should be validated. The validation should consider the integrity of the sterile protective barrier system, the maximum hold time before sterilization and the maximum shelf life assigned to the sterilized items.
- The integrity of the sterile protective barrier system for each of the sterilized items should be checked prior to use.

Other Wrapping Methods Fall Short

Many traditional wrapping materials and methods, such as using cellulose blue wrap, have proven inadequate in addressing contamination risks. These methods can create significant issues for your facility.

- **Increased Risk of Contamination:** Cellulose wrapping can release particles and microorganisms, compromising sterility.
- **Time-Consuming Processes:** Traditional methods are labor-intensive and require operator training.
- **Lack of Reproducibility:** Inconsistent wrapping techniques between operators, or even with one operator from one product to another, can lead to variable outcomes.
- **Inability to Confirm Product Dryness:** Visual inspection of product dryness after sterilization is often not possible with traditional wraps.

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Consequences of Ineffective Sterilization Wrapping

Failing to adequately control contamination from improper sterilization wrapping materials and methods has severe consequences for pharmaceutical manufacturers.

- **Product Recalls:** Contaminated products lead to costly recalls and damage to brand reputation.
- **Regulatory Non-Compliance:** Non-compliance with EU GMP Annex 1 results in regulatory actions and fines.
- **Patient Safety Risks:** Contaminated products pose serious health risks to patients, potentially leading to adverse events or fatalities.
- **Operational Inefficiencies:** Ineffective sterilization processes disrupt production schedules and increase operational costs.

Material Qualifications	· Fibre and particle shedding · Microbial barrier properties · Mechanical properties · Seam or weld strength and resistance · Sterilization compatibility · Chemical resistance as applicable
Stability Testing	Product stability after sterilization and over time
Usability Evaluation	· Easy opening of sterile packaging · Aseptic presentation of cover · Cover unfolding · Application of cover in different work scenarios · Removal of cover

STERIS Purefit Sterilization Wrapping

STERIS Purefit sterilization wrapping offers a reliable and compliant answer to these challenges. Designed to meet the stringent requirements of EU GMP Annex 1, Purefit products ensure contamination control and product sterility.

Key Features and Benefits:

- **Qualified Materials:** Purefit products are constructed of Tyvek® 1421B material, known for its low particle generation and effective microbial barrier.
- **Design Excellence:** Purefit sterilization bags and covers are engineered for easy handling, storage, and transport, ensuring sterility throughout the process.
- **ISO 13408-1 Compliance:** Purefit products support aseptic processing with qualified materials and validated sealing processes.
- **Sterilization Compatibility:** Purefit products are designed for use with various sterilization/ decontamination methods, including steam and vaporized hydrogen peroxide.

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Minimize Risk:

- **Low Particulate Generation:** Laboratory testing demonstrates that using Purefit wrapping generates fewer particles than cellulose-based wrapping.
- **Excellent Microbial Barrier:** Tyvek® 1421B material resists penetration of microorganisms, providing an effective microbial barrier.
- **Cleanest Material Available:** Purefit wrapping, have been tested to show undetectable levels of endotoxins/pyrogens, and are manufactured in certified cleanrooms following Good Manufacturing Practices.

STERIS Purefit sterilization wrapping provides a reliable, compliant offering for pharmaceutical manufacturers, ensuring product sterility and regulatory adherence. By addressing the shortcomings of traditional methods and mitigating the risks of contamination, Purefit products elevate your sterilization standards and safeguards patient safety.

To learn more about STERIS's offerings, please contact your local STERIS account representative or visit our website.

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Key Takeaways

1 Compliant:

Meet Annex 1 regulations by using Purefit sterilization wrapping, constructed from a new grade of Tyvek® 1421B that mitigates the risk of residue from the wrapping materials being deposited on critical equipment surfaces during autoclave steam sterilization.

2 Clean:

Purefit sterilization wrapping is the cleanest product on the market. Other materials, such as cellulose wrapping, can release particles, endotoxin/pyrogens and microorganisms, compromising sterility.

3 Effective:

Purefit sterilization wrapping systems have attributes (microbial barrier, steam penetration, and low particulate) that are ideal for use in pharma manufacturing environments.

4 Customizable:

Purefit sterilization bags and covers are available in almost any shape and/or size to meet the specific needs and ensure proper fit during your process.

5 Reproducible:

Purefit sterilization bags and elasticized covers are simple to put on and take off, making them ideally suited for very large, small, or irregularly shaped items for a consistent wrapping experience without the need to blue wrap.

6 Efficient:

Purefit custom sterilization solutions save time. Their custom designed sizes and features make them easy to put on and take off, shaving significant time off of the jobs of wrapping and unwrapping, while lowering your risk from extended handling during these processes.