Tjoapack

Solving the PFS quality equation

Why packaging is key to reconciling optimum PFS injectable quality with manufacturing, transport and storage efficiency

Section 01

Introduction

The pre-filled syringe (PFS) market is growing fast. Valued at US $4.5 billion in 2022, the global market is on track to be worth $5.53 billion by 2029, with a compound annual growth rate (CAGR) of 2.9% throughout the forecast period [1].

PFS have vital advantages over the traditional vial and syringe. As the syringe comes already charged with a single dose of the drug product, under- or over-dosing is no longer a risk, making it safer and more convenient for the user. This makes PFS far more suitable than traditional syringes for self-administration by the patient in their own home, freeing them from the inconvenience of travelling to the clinic.

However, adopting PFS presents challenges for drug product sponsors, particularly when it comes to maintaining optimum product quality, all while ensuring production line efficiency, and supply chain efficiency. PFS are inherently more complex than traditional injectable formats, requiring special handling not just during the filling, but the packaging and transit process too to ensure they maintain the sterile integrity of the doses within, enhancing patient safety and minimising product waste.

The right packaging and contract packaging support are key to ensuring a reliable supply of PFS that conforms to the most rigorous quality standards.

This eBook delves into the multifaceted challenges of maintaining the integrity and quality of PFS drug products throughout packaging, transportation and storage processes. In it you will learn:

- The quality risks and vulnerabilities encountered during PFS packaging
- The considerations for safe handling during transport from the packaging facility to the patient
- The value of expert contract packaging support in achieving and maintaining high-quality standards.

Section 02

Defining drug product quality

Drug product quality is paramount, but the word “quality” includes multiple meanings at the same time, for all treatments, not just those in PFS format. These meanings include:

- **Patient safety**

  A high-quality drug product needs to be able to be administered to a patient without compromising the individual’s physical health or wellbeing. This can be by eliminating the risk of microbial or particulate contamination, for example, or by testing to ensure no toxic compounds are present in the formulation or the packaging that could leach into the formulation.

  As PFS deliver medications directly into the patient’s body, bypassing the body’s defence mechanisms in the gastrointestinal and pulmonary tracts, pharmaceutical companies need to ensure optimum sterility of the formulation and needle to safeguard patients. At the same time, companies need to ensure that their primary and secondary packaging are non-toxic and compatible with their drug product to prevent leaching.

- **Achieving the target product profile**

  A high-quality drug product shouldn’t just be safe for patients to use, it must also deliver the required efficacy and therapeutic outcome for patients - ie. achieve its target product profile. It’s not just the formulation that is key here - which must be able to get the active ingredients to the site of action - the packaging - both primary and secondary - must be able to support straightforward administration, and ensure the stability of the formulation throughout its shelf life.

  PFS offers a number of patient convenience benefits, as they are easy for patients to self-administer. A high quality PFS product, however, should also feature secondary packaging that further supports useability of the PFS, through inclusion of extra components, or additions such as sanitary wipes.

- **Regulatory compliance and market access**

  Regulators impose stringent quality standards on all drugs, including those in PFS format, to ensure patient safety and product efficacy. The regulatory landscape for PFS packaging is complex and stringent, reflecting their status as combination products that involve both a drug and a medical device. Key regulations guiding this field include the U.S. Food and Drug Administration’s (FDA) 21 CFR (cGMP for Finished Pharmaceuticals, Biological Products and Medical Devices parts), the European Medicines Agency’s (EMA) EudraLex Volume 4 — Good Manufacturing Practice (GMP), Annex 1 (Manufacturing of Sterile Medicinal Products) and the Medical Devices Regulation (MDR) as well as other regulations specific to their regions. Failure to meet the standards in place in the target market can cause delays in market authorisation, product recalls and reputational damage. In addition, post-commercialisation, drug products must come in secondary packaging that meets the labelling requirements of their target markets, with appropriate user instructions in the local language, as well as labels to support traceability.

If quality is prioritised at every stage of development, production, packaging and distribution, PFS can consistently deliver safe, effective and convenient products to patients.

Section 03

Potential risks to PFS quality

PFS product packaging, transport and storage present several complexities, each with potential risks and vulnerabilities that can compromise the quality of these sensitive drug delivery systems. Factors that impact risk levels include:

- **Compatibility of primary and secondary packaging materials:** Packaging materials must be compatible with the drug formulation, ensuring no leachables or extractables that could compromise drug stability or patient safety. While secondary packaging will not come into direct contact with the formulation, it must be compatible with the materials of the primary container to minimise any risk of degradation or leaching. Additionally, primary and secondary packaging materials must provide adequate protection from light, moisture and oxygen to maximise t he formulation's shelf life.

- **Sterility maintenance and protection:** Packaging must maintain the sterility of the PFS throughout its shelf life. Any breach in packaging integrity can introduce contamination, rendering the product unusable. PFS are also susceptible to damage from shock, vibration and temperature fluctuations during handling and transportation. Secondary packaging must provide adequate cushioning and insulation to prevent breakage of the PFS within.

- **Labelling and identification:** Accurate and clear labelling is crucial for proper identification and safe administration. Labelling errors or illegible information can lead to medication errors with serious consequences.

- **Environmental conditions control:** Many drug products require specific temperature, light exposure and humidity ranges during transport and storage to maintain stability. Deviations from these ranges can accelerate degradation, impacting efficacy and safety. Special handling during the packaging stage is vital to ensure PFS products stay within a suitable environment for formulation stability. Secondary packaging should also be suitable for cold-chain transport and storage, staying in good condition to protect the PFS within, as well as ensuring labelling isn't degraded by the low temperatures.

- **Counterfeit prevention:** The global supply chain is vulnerable to counterfeit products. Packaging and tracking systems must be robust enough to deter tampering and ensure product authenticity.

Mitigating these risks requires a comprehensive approach involving careful material selection, robust packaging design, validated transport and storage procedures and stringent quality control. Addressing these complexities can help ensure that PFS products reach patients in optimal condition, preserving their safety and efficacy.

Section 04

The role of secondary packaging in maintaining quality

Secondary packaging plays a multifaceted and vital role when it comes to the quality of PFS, ensuring its safety and efficacy from manufacture to administration. Here are some of the key functions of packaging:

Protection from contamination

Packaging acts as the primary barrier against external contaminants, like microorganisms, dust and moisture, which could compromise PFS sterility and lead to infections and other adverse events. Secondary packaging is also important here, as it can protect the PFS from breakage which can cause contamination. It can also support the sterility of needles prior to use.

Preservation of drug stability

Primary packaging materials with appropriate barrier properties help maintain the drug's chemical stability and prevent degradation, ensuring its potency and efficiency. Secondary packaging can further protect primary containers to exposure to external elements, which could lead to leaching into the formulation.

Supporting the cold chain

Many drugs are sensitive to temperature fluctuations. Exposure to excessive heat or cold can accelerate degradation, impacting potency and potentially generating harmful byproducts. Secondary packaging specially designed for cold storage can support temperature-sensitive drug formulations, allowing the packaged products to be transported and stored in fresh, frozen or even ultra-frozen conditions until they are needed.

Safeguarding physical integrity

PFS are delicate and susceptible to damage from impact, shock or vibration during handling and transport. Packaging provides cushioning and structural support to prevent breakage, leaks or needle dislodgement.

Facilitating identification and traceability

Clear and accurate labelling on the packaging enables proper identification of the medication, dosage and expiration date, reducing the risk of medication errors. In addition, unique identifiers such as barcodes or RFID tags aid traceability throughout the supply chain.

Tamper evidence

Secondary packaging with tamper-evident features, such as holographic seals, provides visual cues if the product has been compromised, further ensuring its safety and integrity.

Section 05

The role of packaging support from experienced partners

Maintaining the optimum quality of PFS products throughout the secondary packaging process is complex and multifaceted, but expert contract packaging organisation (CPO) partners can provide great support in this endeavour. Their specialised knowledge, technology, regulatory compliance and quality assurance measures ensure that PFS products reach patients in optimal condition, ready for safe and effective administration. By partnering with experienced contract packaging providers, pharmaceutical companies can focus on their core competencies while ensuring the highest quality standards.

Specialised handling and technology

PFS are delicate and require specialised handling to avoid damage to the syringe barrel, plunger or needle, which could compromise sterility or drug delivery. Contract packagers with expertise in PFS packaging have the necessary equipment and trained personnel to ensure safe and efficient handling. Certain products may require specific packaging technologies to maintain drug stability and experienced contract packagers can implement them effectively, safeguarding product quality.

Regulatory compliance and quality assurance

PFS packaging is subject to stringent regulatory requirements to ensure patient safety and product efficacy. Expert contract packagers are well versed in these regulations and have robust quality management systems in place, minimising the risk of non-compliance and product recalls.

Qualified Person (QP) support

Reputable contract packaging partners with in-house QP support can provide critical certification of compliance with GMP and marketing authorisation requirements, ensuring that the product meets all necessary quality and safety standards.

Flexibility and scalability

The demand for PFS can fluctuate depending on market needs and clinical trial outcomes. Contract packagers offer the flexibility to scale packaging operations up or down as needed, ensuring efficient production and timely delivery. Packaging partners can also accommodate specialised requirements, such as kitting or customised labelling, which may be challenging for pharmaceutical companies to handle in-house.

Cost-effectiveness and risk mitigation

Outsourcing PFS packaging to experts can be cost-effective, particularly for smaller companies or those with limited in-house packaging capabilities. Contract packagers can leverage economies of scale and specialised expertise to optimise packaging costs. By entrusting packaging to specialists, pharmaceutical companies can mitigate packaging errors, contamination or non-compliance risks, protecting their reputation, ensuring patient safety and promoting successful treatment outcomes.

How Tjoapack can help

Are you looking for a reliable partner to handle the complex packaging needs of your PFS?

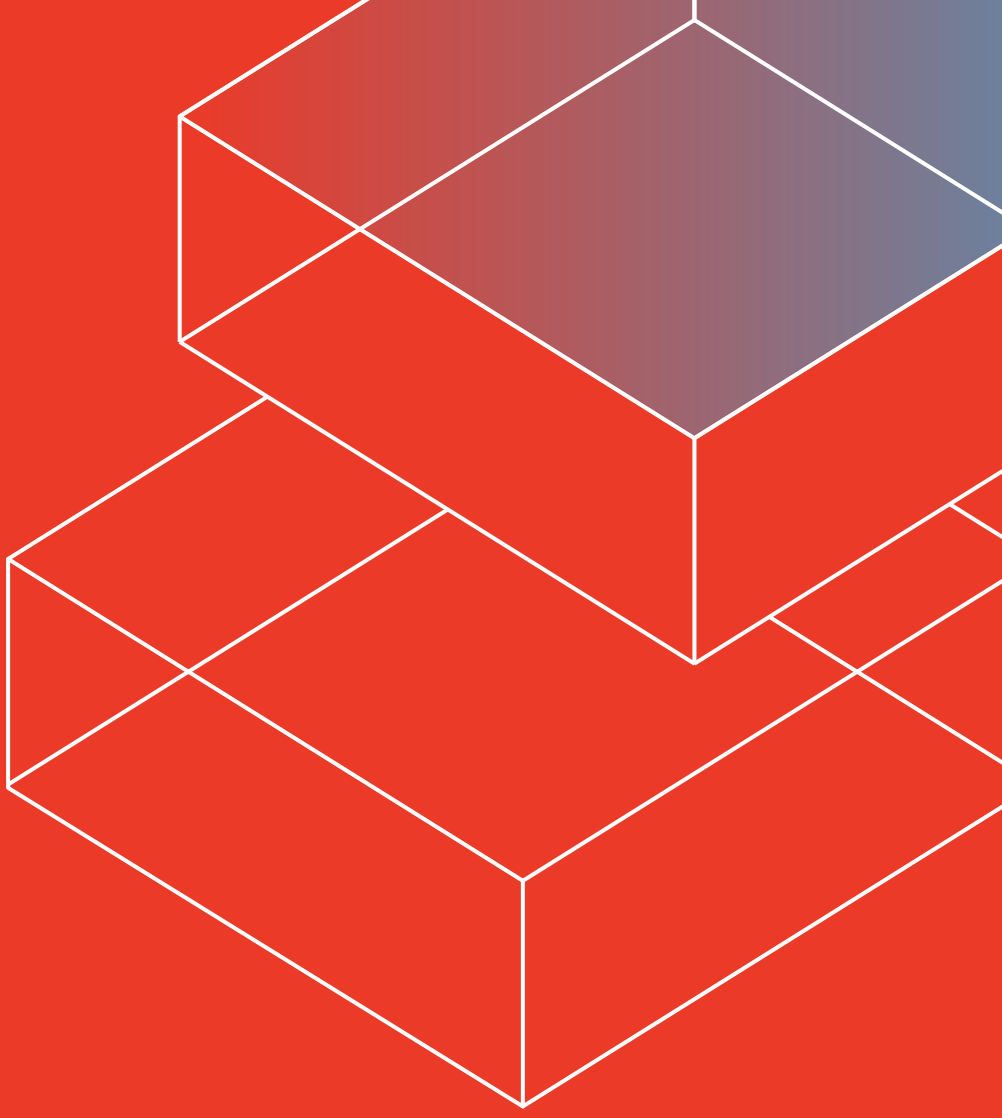
Tjoapack's expertise, advanced technologies and unwavering commitment to quality can help you ensure your products reach patients in optimal condition.

Our team possesses the necessary knowledge and skills to select appropriate packaging materials, design robust packaging configurations and implement validated processes that maintain product integrity and sterility.

Our experts provide specialised solutions for the assembly, labelling, blistering and cartoning of PFS from 1 to 5 ml, with or without a safety device. We can also manually add customer-specific components.

Contact Tjoapack today to discuss your PFS packaging needs and discover how we can help you ensure quality and deliver safe, effective and compliant products to market.

Find out more



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