The Importance of Uniform, High-quality Containers for Effective Drug Manufacturing

To maintain efficiency and profitability in competitive marketplaces, pharmaceutical companies must adjust to ever-increasing complexity, stricter regulations, and growing costs.

Ensuring drug quality is crucial. If a drug's effectiveness is reduced or safety issues arise, it can endanger patient health, erode trust, damage the brand's reputation, and incur significant costs to address contamination problems. For instance, in 2024, there were nine recalls due to contamination issues, highlighting the serious impact foreign particles in a closed container can have on patients (Source: U.S. Food and Drug Administration).

A factor that impacts both the cost and overall quality of finished drug products is their containers, which are crucial for maintaining the sterility, stability, and efficacy of the drugs. However, with increasing cost pressures, some manufacturers might be tempted to choose cheaper alternatives. While these may seem cost-effective in the short term, they can lead to significant long-term issues.

So how can you choose drug containers that maximise product quality while maintaining cost efficiency?

Reducing the Costs of Pharmaceutical Manufacturing

The pharmaceutical sector is extremely competitive, and cost constraints are a continual reality. Global competition, regulatory monitoring, and consolidated buyers all put pressure on the price of generic drugs, which frequently sell for a fraction of their branded equivalents. Similar to this, biologics need significantly greater R&D expenditure, but producers are under continuous pressure from biosimilars to implement cost-cutting measures that preserve compliance and quality requirements.

Key approaches to cost reduction in pharmaceutical manufacturing are similar to those in other industries:

- **Scaling up production** to achieve economies of scale, which lowers unit costs as output rises.
- **Improving operational efficiencies** with the use of cutting-edge equipment or simplifying procedures to cut expenses through waste reduction, increased productivity, and improved quality control.
- **Sourcing Lower-cost Raw Materials and Packaging** to reduce expenses.

Among these strategies, drug packaging materials and containers are frequently proposed as cost-saving initiatives, and procurement departments regularly assess ways to reduce production costs by evaluating these components.

The Hidden Costs of Low-quality Containers

In pharmaceutical manufacturing, it's a frequent but dangerous misconception that reduced initial costs translate into better value. Although using cheaper containers may seem like a sensible method to save money, doing so frequently results in unanticipated expenditures that, over time, can cause disruptions and reduce profitability.

Pharmaceutical manufacturing always prioritises patient safety, so it is imperative that containers preserve the stability and sterility of medical supplies.

To protect patients' health, it's vital to avoid interactions between a drug and its glass container, so the material used for the container is extremely important. SCHOTT FIOLAX®, a Type I Borosilicate Glass, minimises the risk of such interactions, with excellent chemical resistance and optional UV protection. In addition, a controlled conversion process ensures that the interior quality of the pharmaceutical containers remains high.

As well as safety, two other important factors that should not be disregarded are production process efficiency and Total Cost of Ownership (TCO). The use of poor-quality containers can lead to production line interruptions, due to their frequent inability to satisfy the specifications of current fill-and-finish machinery. These inefficiencies have a major influence on operational productivity because they lead to unscheduled downtime, reduced throughput, and increased manpower requirements. Furthermore, greater rejection rates during quality checks result in a loss of time and resources, raising overall costs.

By investing in highly uniform containers that meet precise tolerances, manufacturers can optimise processing efficiency by increasing automation, minimising downtime, and reducing waste – all of which lead to indirect cost savings that far outweigh the initial cost savings from lower-priced goods.

Key Attributes of High Uniformity Drug Product Consumables

Selecting the correct drug container should be viewed as an investment rather than a cost, and the use of high-quality containers has several important advantages that gradually reduce the TCO. Despite the potentially higher initial investment, these containers lower long-term costs and improve operational efficiency.

Production-line problems, such as trembling, sticking, or climbing, which exponentially increase as machine speed rises, can be resolved by high uniformity containers. Quality glass containers reduce the possibility of breakage, which frequently halts production since all impacted areas and equipment must be cleaned to remove shattered glass and product spills.

To illustrate the magnitude of the situation, consider a new fill-and-finish machine that can fill small glass containers (1–3 millilitres) with a generic drug at a rate of approximately 36,000 pieces per hour. If production needs to be stopped for one hour each day, five days a week, this results in 180,000 unfilled containers per week or 8.6 million unfilled containers per year.

Containers that don't satisfy the strict quality standards of the pharmaceutical business are rejected throughout the inspection process, whether that's done manually or with the use of a camera. The risk of drug contamination or cosmetic flaws in the container is reduced by employing superior quality containers, which also prevent unnecessary waste and related expenses.

Using high-quality containers greatly reduces the risk of expensive disruptions, while increasing operational output and product quality. Since fewer finished drug products are thrown away, the increased cost of superior containers is frequently offset, thereby lowering the TCO and increasing profitability.

Selecting the Ideal Containers

Highly uniform drug containment solutions that are tailored to the exacting specifications of contemporary drug manufacture are a priority to pharmaceutical companies. To guarantee smooth integration with automated filling lines, reduce delays, and cut down on waste, pharmaceutical packaging prioritises uniform dimensions and excellent cosmetic quality.

SCHOTT Pharma uses a highly standardised procedure to make its glass containers, which involves inspecting the empty containers both during and after production to ensure consistent internal and external container quality.

Precise measurements are crucial for efficient fill-and-finish processes and patient safety. The most important dimensions are automatically measured by visual inspection equipment, which compares the results to the specification. For instance, height differences in vials may jeopardise container closure integrity (CCI). In addition, vial movement on the filling line is significantly influenced by the heel radius, particularly in cases where surfaces are uneven. For the vial to remain stable, the bottom depth and stamp are essential. Therefore, a vial with imprecise dimensions may cause serious issues during filling or post-fill procedures.

In order to identify and classify a variety of defects such as surface scratches, airlines, and scuffs, as well as critical defects such as cracks, chips in functional areas, glass particles, and inside particulates, the final visual inspection step is cosmetic inspection. These defects can pose a serious risk to the patient by compromising the sterility or functionality of a drug.

Core Portfolio

SCHOTT Pharma's Core portfolio offers a wide range of packaging options that are designed to satisfy the demands of the whole pharmaceutical sector. These vials, ampoules and cartridges are all manufactured with an emphasis on quality and dependability to maintain both product integrity and operational effectiveness.

Our StandardLine quality products ensure dependability and safety in pharmaceutical applications by strictly complying with the latest industry standards. They adhere to the guidelines in PDA Technical Report 43 to support their suitability for pharmaceutical packaging and fulfil the strict Accepted Quality Limits (AQL) listed in the Defect Evaluation List (DEL), offering minimal faults and excellent performance.

TopLine quality products embody SCHOTT Pharma's commitment to redefine industry standards. With improved dimensional accuracy and cosmetic quality, TopLine containers have stricter AQL requirements than DEL. Strict quality controls and adherence to cGMP standards also result in all TopLine products having flaws deemed "critical" removed to ensure uncompromised quality.

The Core portfolio features three types of containers:

Core Vials

Core Vials are a trusted choice for injectable drugs, including generics, chemicals, and traditional vaccines, and feature StandardLine quality with the option of enhanced cosmetic improvements through TopLine quality. The

vials are engineered for ease of filling and administration, and designed to provide safe, long-term storage by using high-quality glass and stoppers, which are the only materials that come into direct contact with the drug products.

Core Ampoules

Core Ampoules are available in StandardLine quality, providing excellent AQL levels and reliable performance for use with anaesthetics, emergency drugs, and a broad range of chemicals. Made exclusively from pharma-grade glass, the container is sealed directly on the filling line. The ampoules eliminate the need for rubber closures and seals, without compromising on product integrity. With pre-defined breakage systems at the constriction, they enable precise and reliable drug administration.

Core Cartridges

Core Cartridges are available in StandardLine and TopLine quality, offering advanced reliability and performance for a variety of drug formulations, including generics, chemicals and emergency drugs, and insulin. Cartridges require a rubber stopper, seal, and plunger to enable easy self-administration through pen injectors or on-body devices, enhancing patient comfort and compliance. Their uniform dimensions and high cosmetic quality enhance fill-and-finish line efficiency, resulting in lower reject rates of finished drug products.

SCHOTT Pharma also provides an expert technical team, which offers personalised and ongoing support along the value chain to optimise processes and address individual challenges. Their global and local infrastructure ensures smooth integration of containment solutions across various manufacturing steps at the pharmaceutical company. Their extensive knowledge and experience also positively impact the production of premium drug containment solutions.

Integrating Sustainability into Drug Manufacturing

SCHOTT Pharma places a high priority on investments in green technologies in order to provide environmentally friendly packaging solutions that meet manufacturers' ESG goals while maintaining environmental responsibility without compromising performance or quality.

The company's worldwide manufacturing network is essential to lowering its operational carbon footprint. With production plants strategically located around the world, transportation-related greenhouse gas emissions can be kept to a minimum.

Another noteworthy development in lowering the overall carbon footprint of pharmaceutical products is the launch of FIOLAX® Pro vials, ampoules, and cartridges. For instance, SCHOTT Pharma's 10 ml vials are manufactured using climate-friendly melting technologies and achieve a 50% reduction in emissions when compared to conventional methods. Higher yields are produced in conjunction with FIOLAX® Pro's improved manufacturing efficiency, which reduces the waste of carbon-intensive raw materials.

The Value of Quality: Enhancing Efficiency and Integrity in Drug Manufacture

In pharmaceuticals and drug manufacturing, the stakes are too high to compromise on quality.

Although cutting costs is crucial in markets with intense competition, short-term cost savings from using cheap containers can result in long-term hazards and inefficiencies that will compromise overall profitability. By lowering rejection rates, cutting waste, protecting medicine integrity, and promoting regulatory compliance, the use of high-quality glass containers is essential to production efficiency.

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