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“Plug and Play” Precision Dispensing:

Making Safe, Productive, Efficient Bioprocessing Technology a Reality

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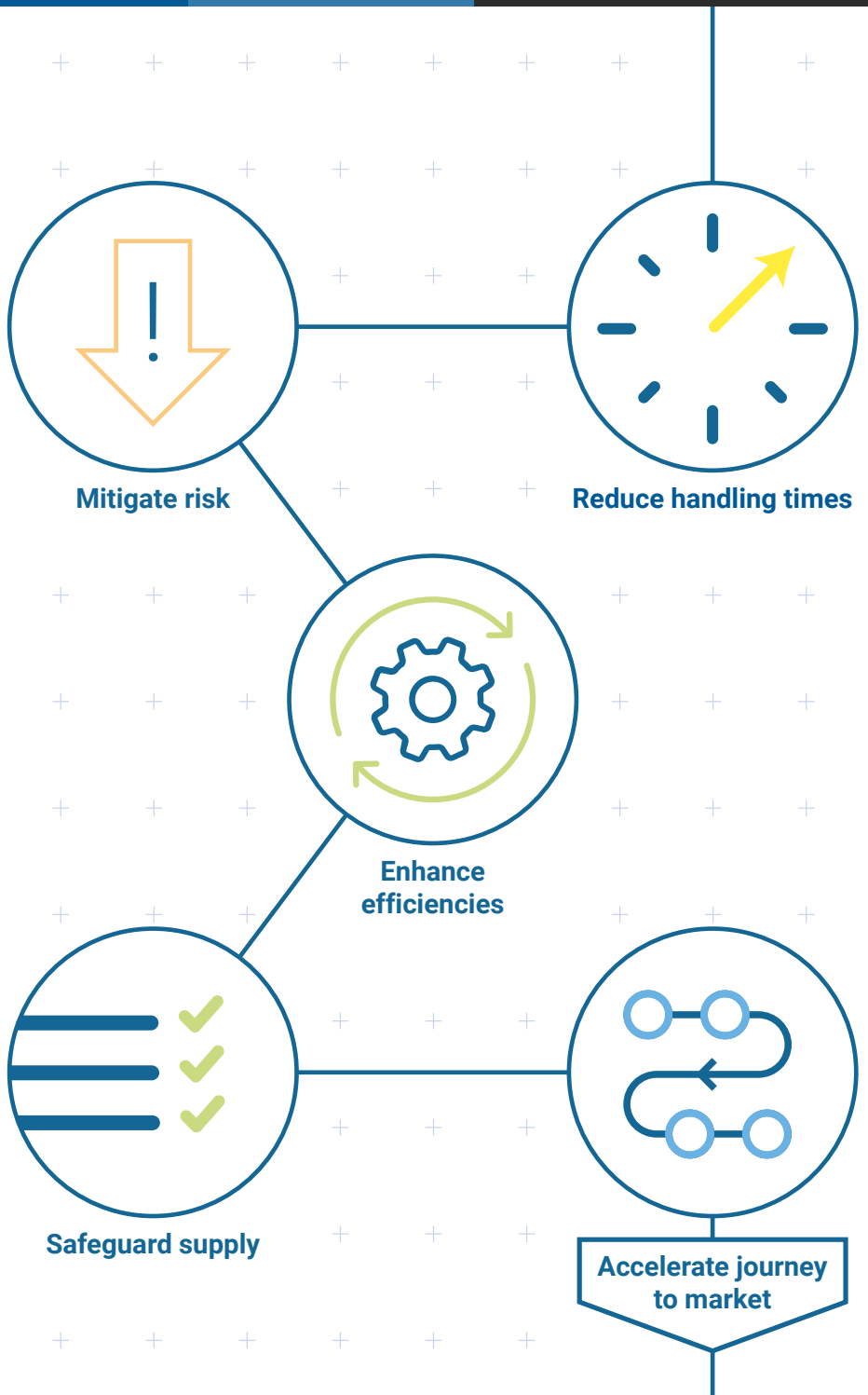


Rethinking pharmaceutical workflows can reduce handling times, mitigate risk, enhance efficiencies, safeguard supply—and accelerate a valuable drug product's journey to market.

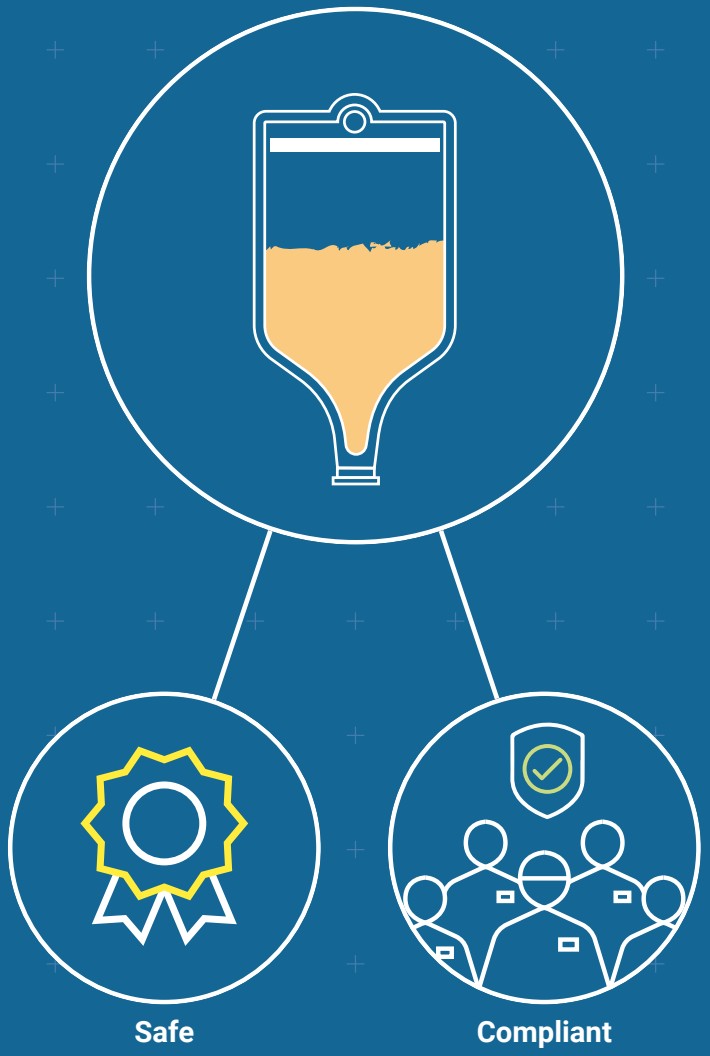
Bringing a valuable drug product quickly and safely to market is a complex and challenging endeavor. The pharmaceutical industry is under increasing pressure to speed up production and lower costs—without compromising on quality. As a result, facilities continually seek to increase capacity, reduce turnaround times, and minimize risk throughout the production pipeline. All processes must be robust enough to assure ready compliance with relevant regulation, while remaining flexible enough to adapt to stochastic events such as the COVID-19 pandemic.

To meet these and other challenges, bioprocessing facilities use manufacturing workflows based on stainless steel and single-use technologies. While the industry is trending towards single-use, which involves technologies that are only used once before being discarded, existing stainless setups remain important in pharmaceutical manufacturing. Configurations that are used multiple times for different product batches, however, bring a higher risk of contamination. To minimize such risk, stainless steel equipment undergoes extensive cleaning and sterilization between production runs—something that requires significant system downtime and can introduce delays and bottlenecks to the manufacturing process.

Precision dispense technology offers a way to overcome such delays and hurdles, enabling both single- and multi-use setups to streamline operations and maximize safety and efficiency.

Precision dispense technology is, as the name suggests, highly precise; its single-use nature removes the need for complex handling and manipulation of raw materials, and reduces the risk and timelines associated with material handling to optimize turnaround and productivity. It is available in a range of customizable, scalable, adaptable, easy-to-integrate containment options which are suitable for use across a diverse range of workflows. These bring the flexibility needed to keep pace with the ever-changing pharmaceutical landscape while remaining fully cGMP compliant.

Chapter 1:
Putting Safety First



Whether reliant upon single-use or stainless steel workflows, a key aim for pharmaceutical facilities of all scales and scopes is to manufacture safe, compliant products. Drug products must be handled, stored and manufactured using validated processes and equipment in order to protect the integrity of the final product, and assure the health and satisfaction of the end consumer.

Contaminants can be introduced at all steps of the manufacturing chain, from the earliest stages at which ingredients are weighed and measured to their storage and transfer between different parts of a facility.

To avoid contaminating extremely valuable batches of product, pharmaceutical organizations must implement extensive cleaning- and sterilization-in-place (CIP, SIP) workflows to ensure the sterility of their multi-use equipment. This can, however, be challenging; CIP and SIP workflows require time, cost, energy and space, and force manufacturing downtime. Equipment must be completely shut down while it is cleaned, sterilized and validated. For large operations, CIP and SIP apparatus is cumbersome and sizeable and, therefore, needs a lot of space to operate, making such workflows even more challenging for smaller manufacturers. Together, all of these aspects can result in up to two weeks of downtime between batches, creating a significant bottleneck in pharmaceutical production.

While system downtime is costly, sterilization procedures are necessary to protect product integrity. In order to further reduce contamination risk and meet quality assurance and control guidelines, the pharmaceutical industry uses closed systems as best practice for material handling and containment, and is required to implement aseptic controls and techniques (including the use of personal protective equipment, surface disinfectants and cleanrooms). Closed systems allow materials to enter or leave a given container via predetermined routes and mechanisms with greater amounts of control, and without exposure to the surrounding environment.

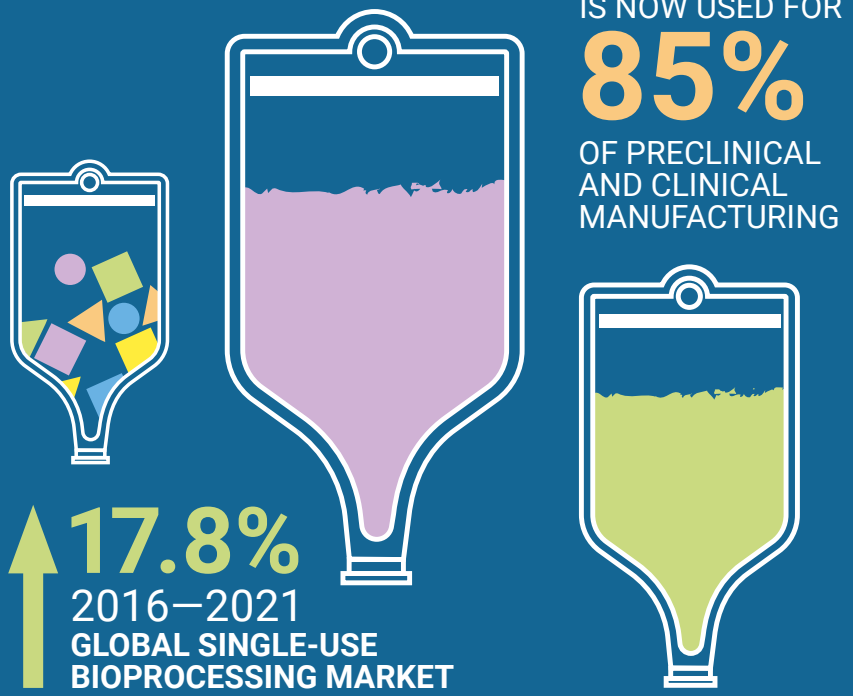
As well as safeguarding consumer health, protecting a product, process and facility from contamination is hugely important for an organization's profitability. A final drug product is incredibly valuable—some biologic medicines can be worth hundreds of millions of euros per kilogram. If contamination is not prevented, entire batches can fail, critically damaging a company's reputation and negatively impacting its profitability.

In short, the less a product must be handled and manipulated within a workflow, the better.

Chapter 2:
Stainless Steel and Single-Use

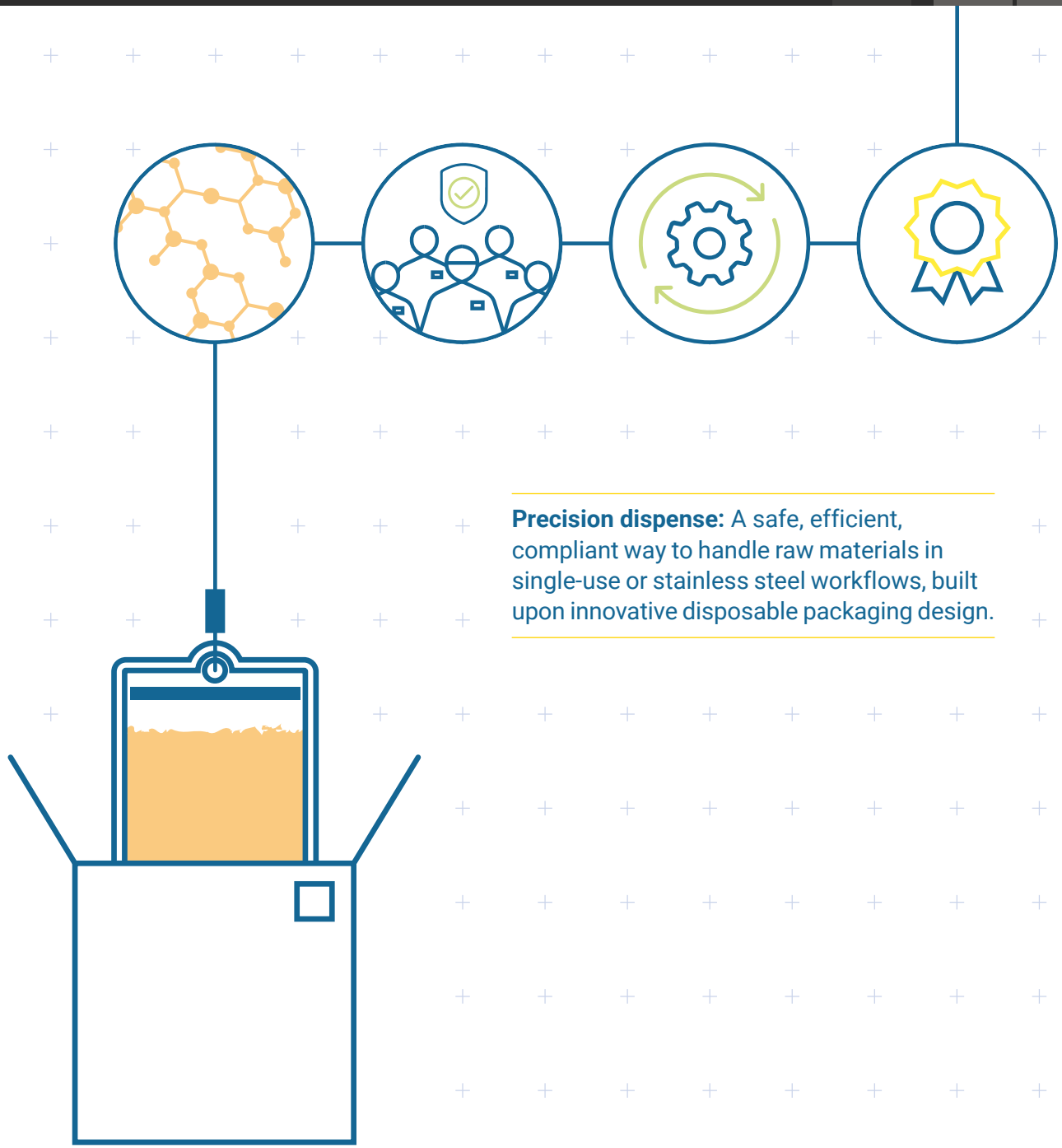
Single-use technology is dominating pre-commercial bioprocessing activity.

It is now used for over 85% of preclinical and clinical manufacturing[1], and the global single-use bioprocessing market is predicted to grow by 17.8% between 2016 and 2021[2]. Single-use, or disposable, technologies for bioprocessing offer a number of options for material containment and transfer, and are appropriate for numerous applications throughout the production process. They enable robust laboratory scale-up that is cGMP compliant, require far lower investment in facility infrastructure, and eliminate the need for sterilization-related system downtime.



Despite this shift, multi-use facilities remain important in bioprocessing, and are often more economically feasible than single-use technologies at large scales and high volumes. Despite the success of single-use technologies, stainless steel workflows are unlikely to disappear, and so manufacturers must seek innovative ways to bring versatility and efficiency to their existing setups.

Here, precision dispense technologies hold promise. These precise, flexible, disposable solutions do not require a complete overhaul of a facility to bring optimization; they can achieve a wide range of efficiencies as part of both single- and multi-use setups. Precision dispense containment and transfer solutions are especially well-suited to applications like raw material handling, in which they can minimize the amount that a product must be manipulated within a workflow to safeguard its sterility and integrity.



Precision dispense: A safe, efficient, compliant way to handle raw materials in single-use or stainless steel workflows, built upon innovative disposable packaging design.

A versatile solution for any pharmaceutical manufacturing workflow

Single-use precision dispense technologies, such as Roquette's Precision Dispense service, can be applied across all bioprocessing setups: single-use, stainless steel, or hybrid. This technology is highly flexible, adaptable and scalable, allowing pharmaceutical manufacturers to increase efficiency and take full advantage of cutting-edge innovation in biologic production techniques.

Precision dispense technology offers numerous benefits to pharmaceutical manufacturers of all kinds through its closed architecture and customizability. Containers are available for various and custom product weights, for example, so larger product amounts need not be split and weighed before processing. This helps to protect valuable product batches to ensure bioprocessing success.

Chapter 3:
Six Benefits of Precision Dispense Technology

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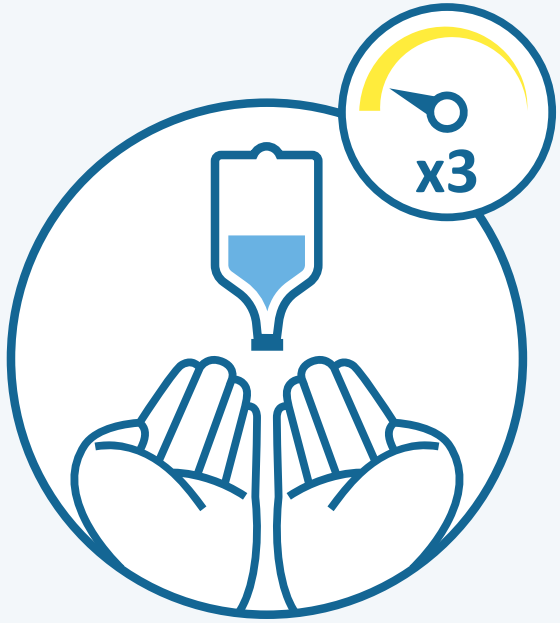
Precision dispense solutions offer many benefits over traditional pharmaceutical packaging options. The technologies are available in a range of formats and sizes for all types of formulation, and offer purpose-built, bespoke containment for efficient, precise, low-risk material handling.

Precision dispense packaging can be created to suit specific fill weights and quantities, removing the need for larger containers to be opened for product weighing and transfer. In this way, precision dispense solutions eliminate raw material manipulation and quality validation steps from production workflows.

Materials can be directly dispensed, in precise and predetermined quantities, into a process from the initial container. This saves time and money—and speeds up manufacturing pipelines for potentially life-saving drug products.



1. Reduced handling times

As closed, single-use systems, precision dispense workflows require no cleaning and no time spent opening large product drums to weigh out different quantities of product. In fact, across the stages of receipt, sample warehousing, dispensing and hydration, user interviews have shown precision dispense processes to be up to three times faster than standard packaging workflows.

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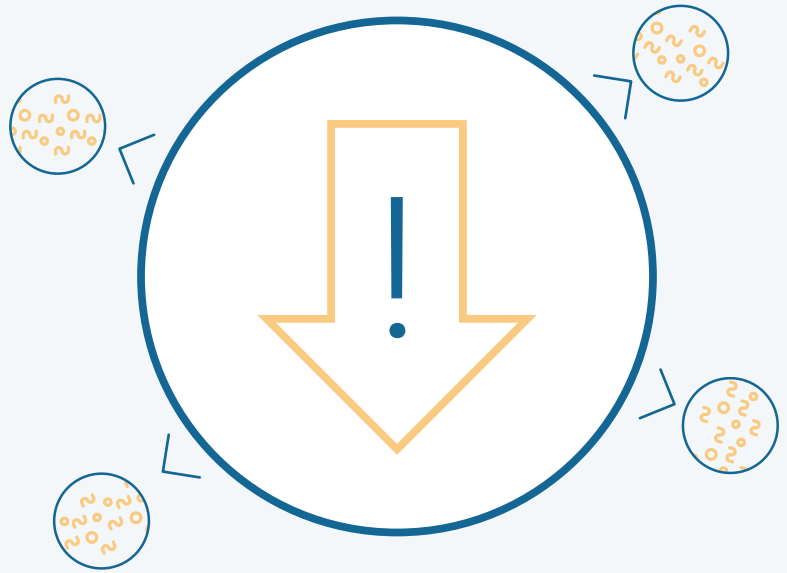
2. Lower risk of contamination or error

By reducing the need to handle or manipulate raw materials in pharmaceutical workflows, precision dispense technology minimizes the risk of external product contamination from handlers, equipment, and the surrounding environment. Such technologies also streamline and eliminate entire steps of the production process, increasing efficiency while also removing many manual processes that can introduce inadvertent error (for example, weighing product incorrectly).



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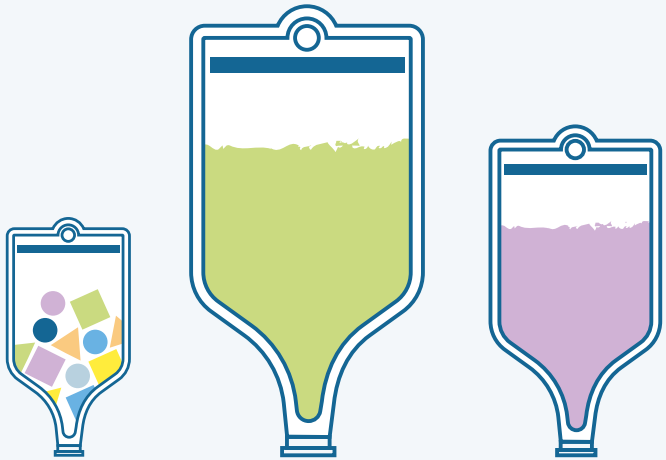

3. Greater customizability

Precision dispense packaging is designed with the end user in mind, and is purpose-built to meet customer needs. There is no longer a need to break open larger containers of product to create aliquots, again reducing the risk of contamination and streamlining raw material handling workflows.

As suppliers offer precision dispense packaging at a wide range of weights and custom fills, product features can be matched to the desired chemistries and operational architectures. Packaging and outlet port size can be changed to suit the application, with suppliers allowing for customer input and customization.

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4. Increased productivity

By reducing the amount of time needed for product receipt, sampling, dispensing and processing, precision dispense technology optimizes turnaround time and accelerates the journey to market for novel drug products. Crucially, such technologies reduce the significant system downtime that accompanies the need to clean, sterilize and validate product containers and transfer assemblies, greatly reducing changeover times between processes and batches. This enables facilities to process more batches per year, resulting in increased productivity, capacity and profitability.

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VERSATILITY
SCALABILITY
ADAPTABILITY

5. Ease of integration

By introducing versatility, scalability and adaptability to pharmaceutical production processes, precision dispense solutions bring new opportunities for manufacturers reliant upon either stainless steel or single-use equipment. While precision dispense is itself a form of single-use packaging, it can be integrated quickly and easily into any manufacturing process, with the same benefits realized regardless of setup specifics.

Precision dispense offers a "plug and play" solution that also reduces the amount of training required after implementation. In turn, this reduced need for training lowers the number of work hours a facility must invest in material handling workflows, streamlining workflows and further enhancing process efficiencies.

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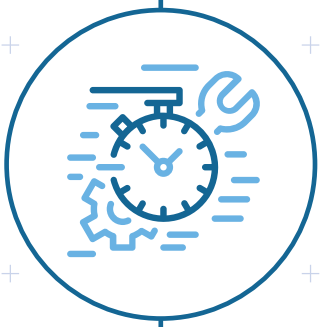
6. Greater compliance and control

Precision dispense packaging can be procured from a vertically integrated organization with a single point of audit, enabling high levels of transparency, easy compliance, and extensive in-house knowledge about packaging production and material provenance. Additionally, available packaging is not proprietary; constituent materials are sourced from a widely used industry supplier, and packaging is produced in-line with the highest standards of production (ICH Q7 GMP). Importantly, precision dispense packaging complies with extractables and leachables regulation for single-use technologies, guaranteeing minimal risk of contamination from the packaging itself.

Speed up productivity



Assure profitability

Moving away from the "blockbuster" mindset

The pharmaceutical industry is experiencing a shift from "blockbuster dependence," in which manufacturers target large, generalized patient populations with "blockbuster" drug products to assure predictable profit, towards smaller patient populations and personalized medicines. As a result, the personalized medicine market is seeing significant growth, and is expected to reach a value of US$3.18 trillion by 2025[3].

Manufacturing personalized medicines for more targeted patient populations requires the ability to produce smaller amounts of more specialized product, rather than large quantities of homogenous product.

The growing focus on personalized medicines and smaller populations increases the complexity of pharmaceutical manufacturing, and requires the swift repurposing of existing assets—making it critical to optimize efficiency wherever possible.

While mass production of blockbuster products may require a few colossal batch runs per year, manufacturing smaller amounts of more specialized product instead requires a rethink of existing processes: batches must be produced more often, raw material weights and properties will vary more considerably, and multi-use apparatus will require more frequent cleaning. To keep pace with these developments while assuring profitability and productivity, manufacturers require innovative technology. Precision dispense technology enables greater flexibility across single-use and stainless steel architectures, facilitating the safe, efficient production of smaller quantities of more specialized product.

The keys to a successful partnership: From procurement to process development

Pharmaceutical manufacturers work with an array of partners and suppliers—and it is important to ensure that these collaborators can optimize processes across the production pipeline.

Procurement managers must source appropriate suppliers and partners that satisfy the diverse needs of many stakeholders and decision-makers, while adhering to various financial, regulatory and chain-of-command constraints.

Opting for a vertically integrated partner—in which a partnering organization owns the entirety of its supply chain, or controls multiple stages of production in-house—can bring cost and efficiency benefits, as turnaround times are reduced across the manufacturing life cycle.

As vertically integrated organizations hold a complete understanding of their processes and supply chains, they can also offer the right technical knowledge and timely end-to-end product life cycle and regulatory support—in addition to assessing new markets and securing novel opportunities for profitability and competitiveness.

Additionally, developing and implementing new pharmaceutical processes and best practices that are simultaneously innovative and cGMP compliant can be highly challenging. Bioprocessing often experiences a culture of risk aversion, as manufacturers must stay abreast of an ever-changing regulatory landscape and ensure that any innovative activity—for example, making alterations to an existing supply chain—is sustainable and robust. In such an environment, process development scientists must source innovative apparatus, such as precision dispense technologies, from a partner that is flexible, offers customizable options, has a well-controlled and transparent supply chain, and possesses expertise and experience of appropriate regulatory and cGMP requirements.

A "Plug and Play" Solution for Pharmaceutical Manufacturers

Precision dispensing is hugely valuable in bioprocessing. Such technologies minimize and move away from the contamination risks of multi-use systems, and are helping to streamline ever-more complex workflows.

Overall, precision dispense technology enables pharmaceutical manufacturers to optimize efficiencies across a wide range of processes throughout the production pipeline. It reduces handling times and eliminates sterilization-related bottlenecks, bringing significant time and cost savings. It is versatile and flexible, with a range of customizable "plug and play" options available to suit numerous applications. Importantly, it allows facilities to maximize productivity—while remaining easily compliant and avoiding costly batch failure.

Seeking safe, efficient, compliant solutions that are tailor-made for your bioprocessing needs?

Contact us now to discuss how precision dispense technology—from an experienced and vertically integrated supplier—can optimize your pharmaceutical workflows.

Get in touch

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Why Roquette?

Roquette is a key player in the pharmaceutical industry, with a long track record and presence in global markets. Roquette's Precision Dispense service uses materials that are industry-approved and produced in a vertically integrated process, offering a single point of audit and providing clarity over the provenance of different ingredients and technologies. As a vertically integrated supplier, Roquette controls and owns its entire supply chain. This assures lower risk and complexity, tighter control, reduced logistical costs, and security and stability of supply.

Roquette offers end-to-end product lifecycle support—including regulatory support where needed, to ensure that compliance is easy and hassle-free—and actively fosters an environment of collaborative innovation. In fact, Roquette's portfolio began with customizable, customer-led solutions. Roquette has a proud history of innovating with customers to meet their diverse and changing needs—and, as the only vertically integrated supplier for single-use technology for excipients and raw materials, the company is ideally placed for such innovation and collaboration.

About the Expert Authors

Mr. Peter Ferguson

Peter Ferguson is the global market manager for biopharma at Roquette and is based in the United Kingdom. In his role, Peter is leading the development of a technology-driven portfolio of products and services, designed to support the biopharmaceutical industry's development of the next wave of life-saving medicines. Peter earned an undergraduate degree in Chemistry and a Master's degree in advanced therapeutic medicinal products (ATMPs), both from University College London (UCL).

Udo Losehand, PhD

Udo Losehand is the Head of Roquette's Global Technical Developer team, where he leads a global team of technical developers helping customers solve challenges and save time in their formulation development, wherever in the world they are located. Prior to Roquette, Udo spent ten years in a variety of business development roles at Avantor Performance Materials, Inc., and several years with Procter & Gamble Pharmaceuticals, where he held various positions of increasing responsibility in the company's sales division.

Udo holds a Ph.D. in chemistry from the Technical University of Munich, Germany, and completed a postdoctorate research fellowship, awarded by the German Research Foundation (Deutsche Forschungsgemeinschaft), at the University of British Columbia in Vancouver, BC, Canada. He is based in Graz, Austria.

About Roquette

Roquette is a global leader in plant-based ingredients and a pioneer of new plant proteins. In collaboration with its customers and partners, the group addresses current and future societal challenges by unlocking the potential of nature to offer the best ingredients for food, nutrition and health markets. Each of these ingredients responds to unique and essential needs, and they enable healthier lifestyles. Thanks to a constant drive for innovation and a long-term vision, the group is committed to improving the well-being of millions of people all over the world while taking care of resources and territories.

Roquette currently operates in over 100 countries, has a turnover of around €3.7 billion and employs 8,670 people worldwide.

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or visit
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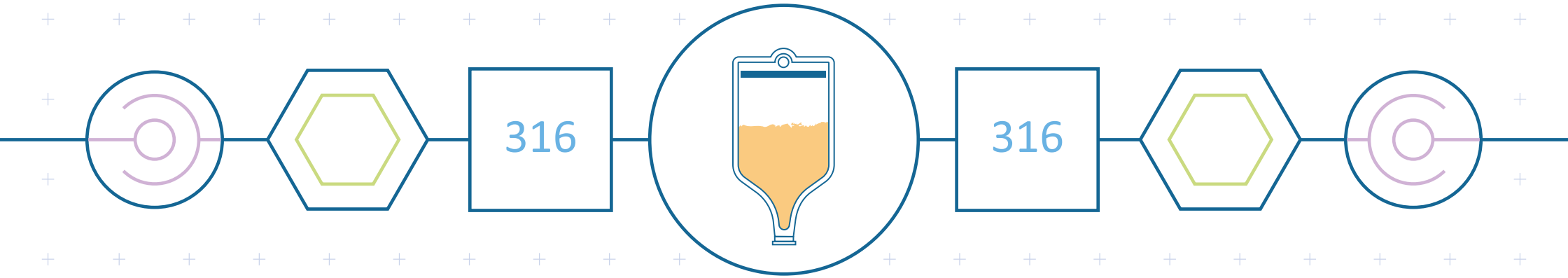

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