Dual Chamber Syringe Filling Inside an Aseptic Isolator

Powder Handling Excellence

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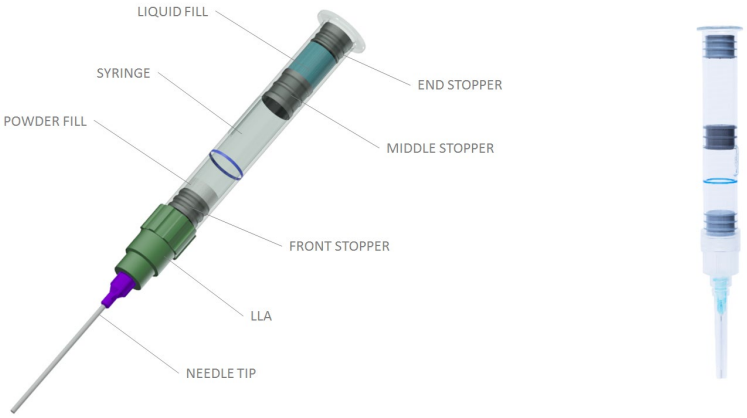
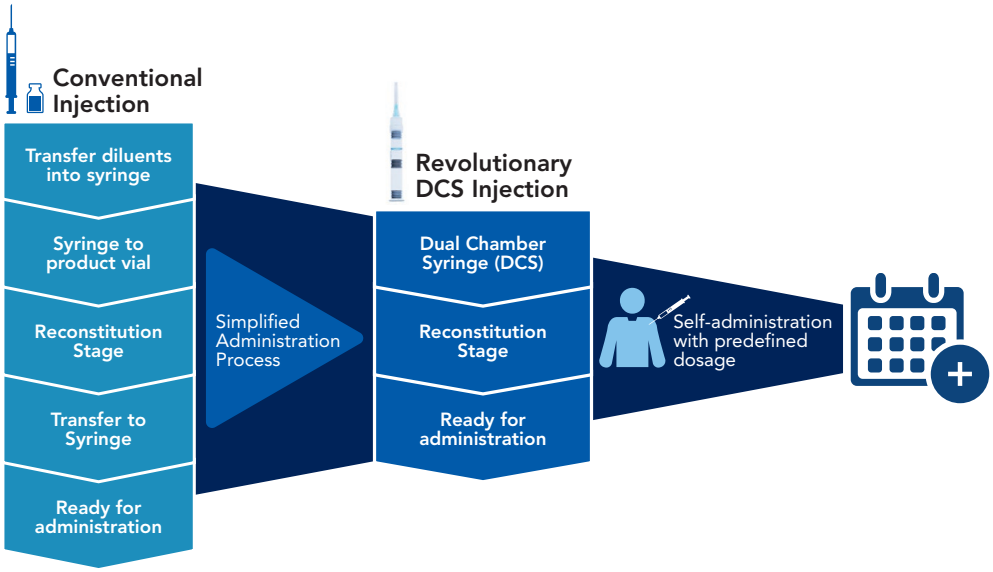
Introduction

In the medical and healthcare industry, there is an increasing demand for prefilled syringes as a drug delivery format. It offers various advantages such as ease of drug handling, high dosing accuracy and maintaining drug stability. This form of drug delivery system minimizes potential contamination from bacteria which further ensures patient safety.



Dual chamber syringes combine the storage of a powdered and a diluent into one primary packaging. By simply exerting pressure on the plunger, the liquid of the lower chamber is forced into the chamber that houses the drug substance, allowing the content of both chambers to be mixed and easily administered. This simplifies the administration process and ensures a longer shelf life of the drug substance, which provides great advantages compared with conventional vial drug delivery systems.



Main Drives for the Growth of the DCS Filling Market

1) Development of advanced technologies

Technological advancements of isolators and restricted-access barrier systems (RABS) allow for greater control of the manufacturing environment thus allowing greater adaptation towards DCS technology.

2) Increasing demand for lyophilized drug product

The increasing number of lyophilized drugs to stabilize formulations is the key factor in the growing demand for the dual chamber prefilled syringe, as drug stability and shelf life is greatly increased with these manufacturing methods.

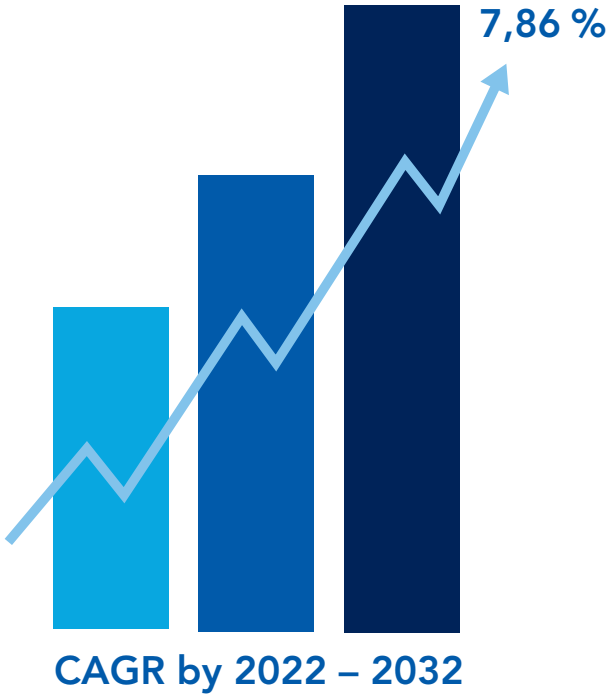
3) Increased investment into biopharmaceutical R&D

There has been significant investment into biopharmaceutical R&D leading to the rapid growth of the fill finish market. The COVID-19 pandemic and an increasing prevalence of chronic diseases have also driven the demand for further investment in the biologics market.

Global Dual Chamber Prefilled Syringes Market Forecast

The ease of use of dual chamber prefilled syringes is encouraging their popularity among end users, which is increasing demand for them. Furthermore, dual chamber prefilled syringes offer next-generation medication delivery technology and are more patient-centric than earlier systems.

Global Dual Chamber Prefilled Syringes Market



Source: Visiongain Reports Ltd [I]

The prefilled syringes' design allows pharmaceutical companies to increase their lyophilized and biological medication capabilities. Dual chamber prefilled syringes are developing as one of the promising drug delivery mechanisms, thanks to their great efficiency and precision in administering lyophilized and liquid formulations. Liquid/lyophilisation-based dual chamber prefilled syringes are projected to have a higher clinical demand than conventional ones due to their diverse applications.

Dual Chamber Syringe (DCS) Filling Challenges

Maintaining sterility during the filling operations

Patient safety is an utmost important factor for pharmaceutical companies; therefore, ensuring sterility is critical as any failure can lead to life-threatening effects on patients as well as huge financial and reputation impacts. Sterilization with pressurized steam, irradiation, or hydrogen peroxide must be performed in a manner that does not affect the stability of the drug product. This indicates the need for carefully designed cleanroom facilities to ensure process sterility.

Impact of the Annex 1 – Significant Changes in Contamination Control Strategy (CCS)

Precautions to minimize any cross contamination should be taken during the preparation of sterile product aseptic filling. It is highly recommended to use equipment such as RABS, isolators or other high containment systems as well as robotic and automation processes in order to minimize or eliminate any critical interventions into the Grade A zone. The importance of a controlled and compliant system should be constantly reinforced, as it is critical to monitor any potential particle and microbiological contaminations.

Source: Annex 1 „Manufacture of Sterile Medicinal Products"[II]

Growing Demands in Pre-Sterilized Containers to Ensure Sterile Packaging

Pre-filled syringe products offer a distinct advantage when it comes to providing a pre-sterilized unit for easy removal and application. DCS technology fits perfectly into this category of ready-to-fill/ready-to-use (RTF/RTU) products. It is important to find a partner who understands these systems and can assist with enabling your process to meet the growing market demands.

Provided a facility has the right equipment and technology to facilitate the filling and packaging process of pre-filled drug delivery systems, the owner will be delivering market-leading products to the consumer.

How DecFill® can help overcome the challenges to optimize your production efficiency

Capable of Handling Various Containers in One Isolator

DecFill® aseptic filling lines are designed to meet a wide range of applications from laboratory needs to commercial production. The DecFill® range features semi-automated to fully automated filling lines which can both be optimized for different speeds, capacities, and container types such as:

- Vials
- Syringes
- Cartridges (also available for RTU/RTF)
- Dual Chamber Syringes (DCS) with high filling accuracy

	DecFill® – SB (Small Batch)	DecFill® – PS (Production Scale)
Product Loading	Semi- / Automatic	Automatic
Drug Type	Liquid / Powder	Liquid / Powder / Gel
Product Container Dosing Range		
· Vials	2 – 100 ml	2 – 100 ml
· Syringes	0,5 – 20 ml	0,5 – 20 ml
· Dual Chamber Syringes	–	✓
· Cartriges	0,5 – 20 ml	0,5 – 20 ml
· Ready-to-use	✓	✓
· Sachets / Pouches	–	✓
· Special Packaging	✓	✓
Capacity [max pp/m]²	60 ppm	300 ppm
Barrier systems		
· Safety guard	✓	✓
· oRABS	✓	✓
· Isolator	✓	✓

High Containment Systems to Protect Both Products and Operators

DecFill® aseptic filling lines can be easily integrated into high containment solutions designed and engineered by Dec Group according to clients' specific requirements. Dec Group supplies turnkey process-integrated containment technology solutions for both potent and aseptic materials. Our custom-made containment systems meet the growing challenges with complete flexibility whilst complying with all current health, safety and regulatory standards.

	O-RABS	**Aseptic Isolator** (Liquid)	**Aseptic Isolator** (Powder/Liquid)
Purpose	Product protection	Product protection	Operator & Product protection
Airflow	Uni-Directional	Uni-Directional with recirculation through double visors	Uni-Directional with recirculation through terminal exhaust filters
Inlet Filtration	H14 HEPA Filtration	H14 HEPA Filtration	H14 HEPA Filtration
Exhaust Filtration	None	Single H14 HEPA	Double Safe Change H14 HEPA
Entry Method	Mousehole	Fast Gassing Airlock	Fast Gassing Airlock/RTP
Exit Method	Mousehole	Continuous liner/RTP/ Mousehole	Continuous Liner/RTP
Access to inside	Gloves / Opening doors	Gloves	Gloves
Decontamination	Hand sanitization	H_2O_2 gassing	H_2O_2 gassing

DecFIll®-SB (Small Batch) Tray Gassing Chamber – Hydrogen Peroxide (vH_2O_2)

Due to potential product contamination, the manufacture of sterile medicinal products involves high operational risks that may endanger human life. In addition, the potency of the ingredients is constantly increasing, which means additional risks for the operators in the manufacturing process.

The impact of EU GMP Annex 1 „Manufacture of Sterile Medicinal Products" [II] on the importance of isolators and their design has increased as isolators prevent possible particulate or microbiological contamination of the sterile products or, in the case of a multi-product system, avoid cross-contamination. The overall design of the isolators is also important for the subsequent surface decontamination with vaporized hydrogen peroxide (vH_2O_2). The introduction of isolators and restricted access barrier systems (RABS) creates a sterile production environment that can effectively isolate human operators from the filling and finishing process.

Unique Features and Benefits of DecFill®

DecFill® Key Features and Benefits

- Ergonomic and easy-to-operate enclosed filling line concepts
- Flexible use with various speeds & containers – all RTUs/RTFs, vials, cartridges, syringes and dual chamber systems
- Multi-container handling in one filling line
- High filling accuracy, no product waste
- Various containment systems (oRABS, isolators & safety guards)
- Seamless integration & state-of-the-art robotics
- cGMP compliant – Annex 1 Manufacture of Sterile Medicinal Products guidelines [II]
- Fully integrated aseptic upstream handling, blending, micronizing and conveying possibilities with Dec's unique PTS Powder Transferring System® and MC DecJet® micronization technologies.

DecFill® Liquids Filling Technology

Technology	BoMa	Peristaltic Pump	Rotary Piston Pump	Net weight
Principle	Volumetric displacement	Positive displacement	Positive displacement	Pressure/Gravity displacement
Accuracy	± 0.5 %	± 1 %	± 0.5 %	0.5 – 1 %

Dec's patented BoMa™ technology is designed to provide a gravimetric dosing pump without scale. It transports liquids via the pressure difference of gas in the head space. For defining a dose volume, the gas pressure in the confined dosing chamber is measured before and during filling of the liquid product. The dosing process is stopped at a certain gas pressure difference, which corresponds to the dose volume defined by the Boyle-Mariotte's law.

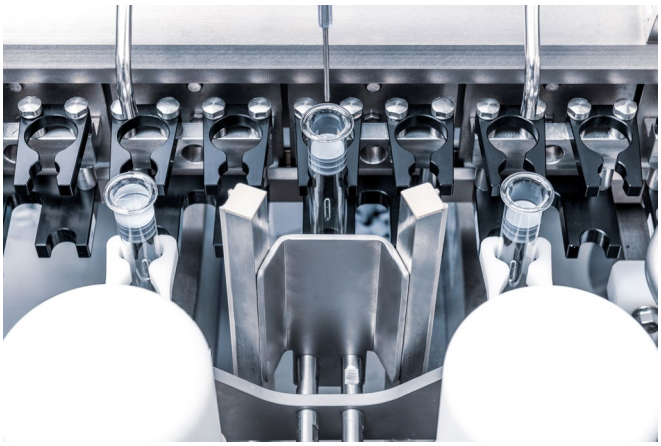
BoMa™ is differentiating itself with the ability to transfer simple and complex liquids but also with its installation versatility so that the freedom of design is almost unlimited even for large quantities of primary products.

DecFill® Powder Microdosing Technology

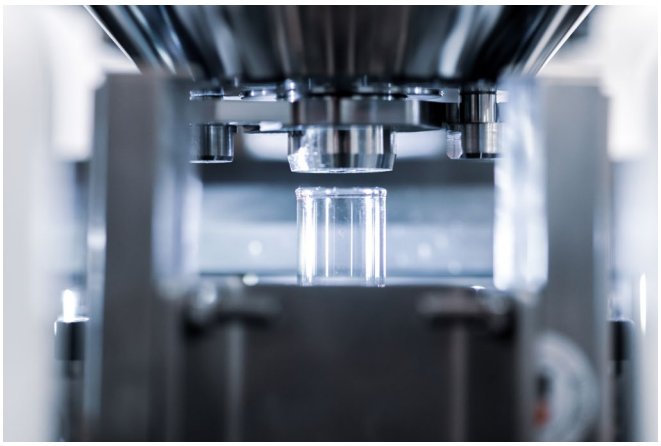
Technology	µPTS	flexPTS	Auger system
Principle	Volumetric by pre-defined chamber		Volumetric by Auger rotation & accurate level control
Dosing Range	1 – 500 mg	200 mg – 10 g	20 mg – 5 g
Accuracy	1-2 % RSD		1-2 % RSD

DecFill® microdosing devices are based on Dec's PTS Powder Transfer System technology® and allow precise and rapid dosing of very small quantities (< 1 mg) of powder in less than a second.

High accuracy, up to 2 % RSD, is achieved even with variations in bulk density, as the powder in the chamber is be pre-compacted by the vacuum effect.



Syringe filling with liquids



Syringe filling with powder

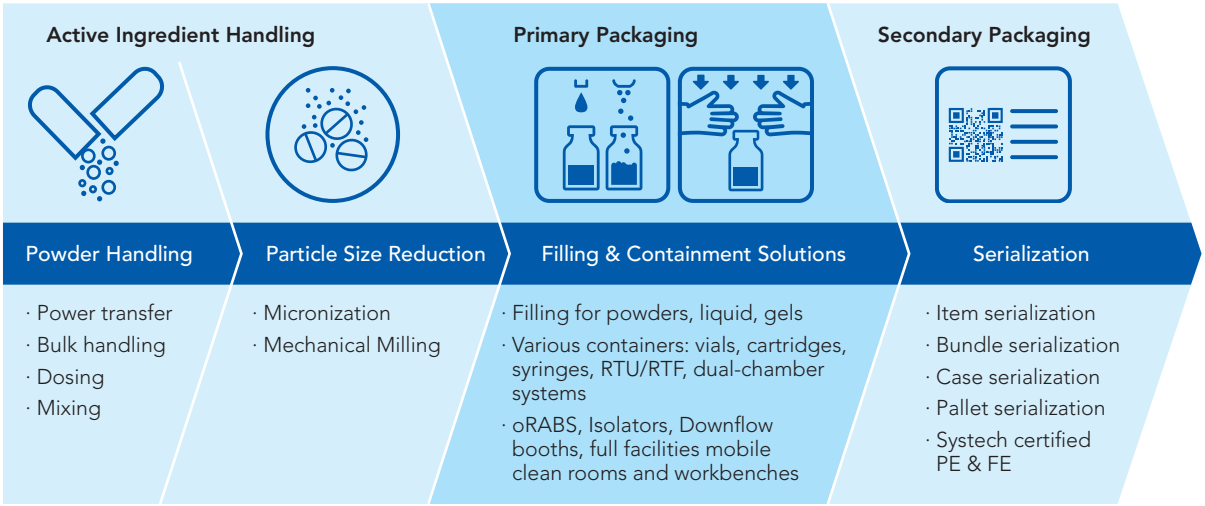
Why Choose Dec Group as a Trusted Supplier for the Dual Chamber Syringe (DCS) Filling Machine?

End-to-End Solution Provider

For the DCS sterile filling process, Dec Group is a one-stop point for end-to-end solutions – from raw material handling to the final product packaging process, including Dec designed and built isolators for high containment. Offering upstream process solutions is the group's unique strength – from active pharmaceutical ingredient (API) handling, powder transfer and bulk handling to dosing, mixing and particle size reduction to fill-finish operations housed in easily integrated solutions of high containment isolators and systems designed and developed by Dec.

High Accuracy in Powder Dosing & Liquid Filling

With Dec´s unique micro-dosing technology based on the PTS Powder Transfer System®, DecFill® can handle powders of various properties and dose with high accuracy and flexible speeds. Filling levels must match the ingredients list and dosing schedules, not only for regulatory compliance, but also for patient safety and comfort. With high dosing accuracy, DecFill® avoids overfilling and can fill the ingredients efficiently into the intended quantity of primary packaging.



Handling Multiple Container Types in One Filling Line

The DecFill® aseptic filling lines are capable of handling and filling various container types in the same filling line in the isolator, i.e. flexible production and integration of highly complex processes. Unique in design, these systems are easy to use, streamline production with minimal changeover times and help to save initial investment costs.

Executive summary

The Dual-Chamber Syringes (DCS) are in high demand across pharmaceutical and hospital industries. Introduction of advanced technologies, increasing demand for lyophilized drugs and high investment for biopharmaceutical clinical research influence the growing demand for DCS drug delivery systems.

Challenges of DCS Filling Manufacturing Market

One of main challenges in dual chamber syringe (DCS) filling process is to maintain sterility during the entire filling process. Sterilization has to be conducted in a compliant way to maintain the stability of the drug that leads directly to the safety of the patients.

Due to the increasing concern over the sterility of the products, there is a growing demand for pre-sterilized products such as Ready-to-Use (RTU) and Ready-to-Fill (RTF). Therefore, DCS filling machines must be modified to meet new technical specifications to handle the new packaging products accordingly.

How DecFill® Overcomes the Challenges

DecFill® aseptic filling line is configured to accommodate various containers such as RTUs/RTFs, vials, cartridges, syringes and dual chamber systems. DecFill® is cGMP compliant and is continuously adapting to up-to-date regulations of Annex 1 Manufacture of Sterile Medicinal Products Guidelines. DecFill® is easily integrated with Dec's high containment systems, oRABS and isolators including fast decontamination compartment (FDC) and safety guards for operators' safety as well as to ensure product stability in a sterile environment. Our aseptic containment solutions are designed and developed to meet the client's requirements.

DecFill® Your Ultimate Aseptic Filling Solution

The unique benefit of the DecFill® aseptic filling line is that it provides an end-to-end solution from raw material handling to the final aseptic packaging processes. The entire DecFill® range is capable of handling multiple containers in one filling line with various speeds. This range comes with Dec's tailor-made high containment solutions to ensure the sterility for the entire filling process as well as managing operator safety. This all-in-one system will not only maximize your production efficiency but also brings great opportunities to save cost, stay competitive in the market, and to work in a limited space of production environment.

Together with Dec's unprecedented PTS powder handling technology and dosing/filling technologies for both powders and liquids, the DecFill® range can perform filling processes with the highest accuracy.

Legal Notice

Acknowledgements

Initiated and released by the Dec Team, this document was developed with support from across the organization and in direct collaboration with:

Giel van Veen
Director Business Development
Dec Netherlands

Sources

I Source: Visiongain Reports Ltd | https://www.globenewswire.com/en/news-release/2022/06/28/2470350/0/en/Global-Dual-Chamber-Prefilled-Syringes-market-is-projected-to-grow-at-a-CAGR-of-7-86-By-2032-Visiongain-Reports-Ltd.html

II https://www.gmp-compliance.org/files/guidemgr/2020_annex1ps_sterile_medicinal_products_en.pdf

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