

INSIGHT

cmo@fresenius-kabi.com

Your Partner for Solutions

Nicholas Baraie
Key-Account Manager
Contract Manufacturing Grand Island



To Our Valued Partners,

Industry trends indicate that the market for pre-filled syringes is continuing to grow. Healthcare staff and patients are turning to them because they are extremely easy to use and provide increased safety. Pre-filled syringes are cost-effective, reduce drug waste, and allow safe administration through patient-friendly use in self-care. With the emergence of new vaccines and biologics, they are a preferred choice by doctors and patients.

Realizing this trend and given the company's commitment to continuously improving patient-centric therapies, Fresenius Kabi has triggered multi-million-dollar investments to extend capacities for the manufacture of pre-filled syringe drug products in both the US and Europe to strengthen its global manufacturing and supply footprint.

These investments added state-of-the-art equipment for the manufacture of 1mL to 50mL pre-filled sterile

syringes and can support products that have high complexity and stringent quality requirements.

Our experienced operational and project management teams support you during the implementation of your drug product, so you can focus on market authorization and commercialization.

This edition of Insight sheds light on Fresenius Kabi's investments in new pre-filled syringe capacities and we are very interested to learn how we can help you manufacture your product.

We look forward to meeting with you to discuss your needs and to develop customized solutions for your products.

With Kind Regards,

Nick

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IN THE SPOTLIGHT: PRE-FILLED SYRINGES

As a safe, effective and convenient way to administer injectable medications, pre-filled syringes (PFS) have become the injection system of choice for a growing number of drugs.

PFS allow healthcare professionals to easily handle syringes, reduce waste and save time by providing a ready-to-use container, while also allowing them to precisely dose and minimize overfill.

PFS are also the system of choice for cost-intensive drugs, as they optimize product yield. Fresenius Kabi Contract Manufacturing offers PFS expertise and service at our manufacturing sites in Graz, Austria and Wilson, USA. These sites have significant experience with PFS and therefore, have the flexibility to accommodate the needs of your product.



Advantages of glass and polymer-based pre-filled syringes:

Pre-Filled Syringes	Polymer	Glass
Absence of heavy metals	✓	
Breakage resistance	✓	
Design space / customizing	✓	
Oxygen protection		✓
Integrated luer-lock/needle	✓	
Long term experience		✓
Multiple sources	✓	✓
Tight tolerances	✓	

From customer need to commercial manufacturing

We accompany our partners from the early stages of development through commercial manufacturing and offer pre-filled syringes from formats of 0.5 mL - 50 mL, can do high volumes, and both low and high complexity products via customized adaptations.

In order to find the right product for our customers, we evaluate drug specific, manufacturing specific, and user specific requirements. The Fresenius Kabi Contract Manufacturing team offers you services and expertise for manufacturing PFS and has the flexibility to accommodate the needs of your product.



Filling process

- Use of sterile primary packaging components
- Nested syringes, ready-to-fill
- Closed RABS
- Stoppering with vacuum or positioning pipe
- Option for aseptic and non-aseptic filling of all formats available
- Use of dedicated equipment if required



Formats

- Glass and plastic PFS
- Depending on materials and size, PFS can be supplied with Luer cone, Luer Lock, or staked needle
- 0.5 mL-50 mL PFS
- Qualified suppliers



Secondary packaging

- Cardboard boxes
- Pouches with/without oxygen protection
- Blisters with/without oxygen absorber
- As bulk product in tubs
- Serialization to be implemented

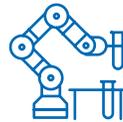


Critical quality attributes of your product

- Oxygen sensitive
- High viscosity
- Light sensitive
- Water-based solutions and water-free products
- Emulsions and suspensions
- Biological products, hormones
- Small molecules
- High-potency compounds

WILSON SITE IN NORTH CAROLINA

High-throughput filling of Pre-filled Syringes and IV-Bags



The Wilson, North Carolina plant is a state-of-the-art, fully-automated manufacturing facility whose expansion has seen \$100 million in investment.

Capabilities include formulation, syringe filling, and packaging of aseptic and terminally sterilized drug products and diluents.



The plant offers large-scale manufacturing and flexibility in the syringe portfolio and sizes. PFS drug products and diluents are produced on fully automated manufacturing, inspection, and packaging lines in a continuous process under controlled conditions.

This facility, half of which is dedicated to pre-filled syringe production, has a unique capability and capacity to launch a wide variety of new and existing commercial PFS drug products, including biologics, highly active compounds, products with maximum OEL of 0.1µg/m³, and products that are sensitive to temperature, light, and/or oxygen. The facility also offers various configurations of syringes, such as Luer lock and staked needle syringes, in volumes of 0.5mL to 3mL. This includes unlabeled bulk nested syringes, cases of labelled and blistered syringes, and syringes that are kitted with additional product. The development of a production for 5mL syringes is currently in progress and further updates are planned in the future.

GRAZ SITE IN AUSTRIA

Fill & Finish services for Pre-Filled Syringes up to 50 mL for Global Supply



Following the company's philosophy of caring for life, Fresenius Kabi is making further investments in its Graz facilities in Austria. The latest investment of more than € 60 million is a clear commitment of the company to the region. The project is scheduled for completion in 2023. Manufacturing and packaging capacities will be expanded at two of its locations in the wider metropolitan area of Graz in Austria.

The Graz site specializes in complex products and processes by providing expertise in aseptic production, a diverse portfolio of high-end products, a wide variety of container options (1 mL - 2.5 L) with flexible production configurations, and a comprehensive service package from first feasibility studies to worldwide approval strategies. Besides filling pre-filled syringes aseptically, the

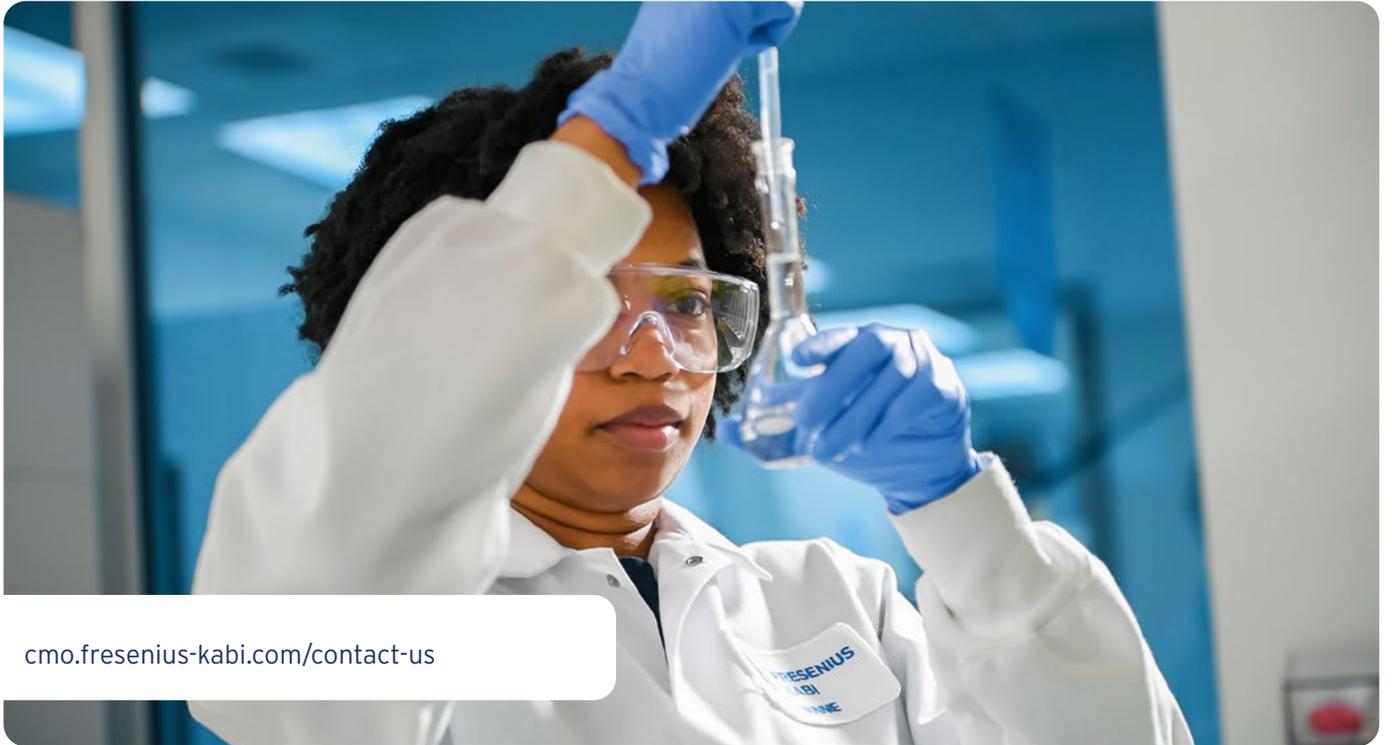
production process also allows to terminally sterilize pre-filled syringes for APIs suitable for heat treatment according to ICH/GMP guidelines.

The plant operates in compliance with national, European, and US FDA GMP regulations, supplying domestic and international markets through affiliate structures.



GET IN TOUCH

with our pre-filled-syringes experts



FIND OUT MORE ABOUT OUR CAPABILITIES



SIMPLIST
pre-filled syringes



Stronger Together
Your Partner for Diluents



Solutions through Connections
Your Partner for Devices



Webinar
MDR conform development of sterile medical devices



Webinar
How to choose the appropriate PFS for your product



Be prepared!
Combination products under MDR (Article 117)



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CONTRACT MANUFACTURING

cmo@fresenius-kabi.com
<https://cmo.fresenius-kabi.com>



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Fresenius Kabi Contract Manufacturing is the contract manufacturing platform of Fresenius Kabi, providing partners easy access to the expertise of more than 20 manufacturing sites worldwide. Capabilities include the fill/finish of sterile pharmaceuticals in a wide variety of containers, as well as sterile devices and APIs. Insight is a publication of Fresenius Kabi Contract Manufacturing. The content of Insight is offered in good faith, believed that it is accurate and correct. Fresenius Kabi Contract Manufacturing expressly disclaims any liability for errors or omissions in such information. Copyright © 2022 Fresenius Kabi AG. All rights reserved.