

Experience Unrivaled

Aseptic Fill-Finish: PreFilled Syringe

AbbVie offers two convenient fill-finish options for parenteral drug products: prefilled syringe and vials. As a leading pharmaceutical partner, we can provide all necessary elements of delivering high quality parenteral products for clinical and commercial needs. AbbVie will leverage its know-how and proven quality, regulatory, and operational network to help you achieve your milestones through comprehensive development and manufacturing support for your vial and syringe drug product formulations.

Prefilled Syringe Drug Product

Formulation & Development Services

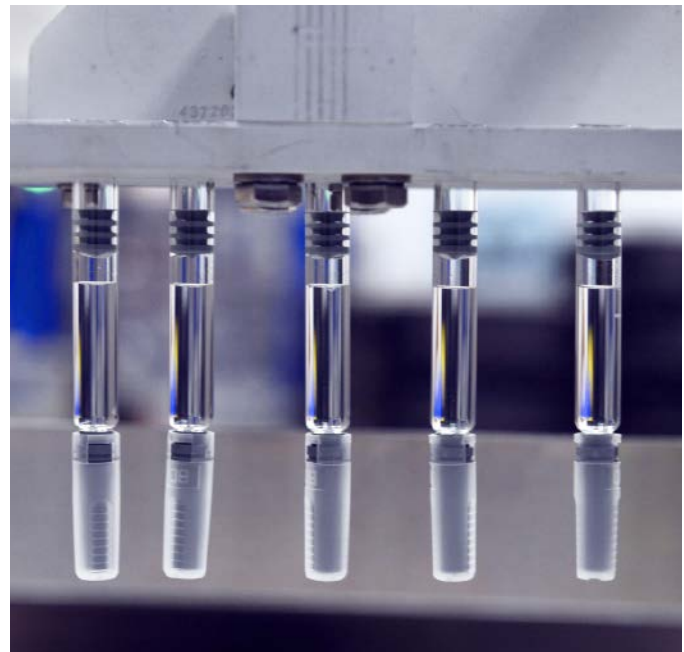
North Chicago, IL & Ludwigshafen, Germany

- Extensive formulation and scale-up experience at all phases of development
- Lab scale fillers for feasibility and development
- Method development and phase appropriate qualification

Clinical & Commercial GMP Manufacturing

Barceloneta, Puerto Rico

- Biologics-focused Inova line peristaltic fill line
- Nested syringes in tubs with validated fill volumes from 0.4 – 2 mL
- Non-destructive weight checks
- Experience with disposable and stainless equipment
- Manual and automated visual inspection
- Syringe blister pack options, with plunger and finger grips
- Full analytical capabilities including biologic, chemical, micro, stability and device functional testing



DEVELOPMENT



BULK DRUG SUBSTANCE MANUFACTURING



ASEPTIC FILL-FINISH

END-TO-END OPTIONS WITH ABBVIE

CONTRACT MANUFACTURING

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Experience Unrivaled

Aseptic Fill-Finish: Vial

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Vial Fill-Finish Drug Product

Formulation & Development Services

North Chicago, IL & Ludwigshafen, Germany

- Extensive formulation and scale-up experience at all phases of development
- Lyophilization process optimization, scale-up and technical transfer
 - Computational Fluid Dynamic modeling
 - Differential Scanning Calorimetry for understanding critical product temperatures
- Lab scale filler and lyo capable of 10–500 vial feasibility batches
- Method development and phase appropriate qualification

Clinical & Commercial GMP Manufacturing

Sligo, Ireland (Online late 2020)

- Bosch aseptic 6 head filling line with peristaltic pump technology
- Liquid fill and lyophilization capabilities with 23m² automated lyophilizer
- Equipped for 6R, 10R & 20R with capability from 2R to 50R
- OEL <10ng/m³ for potent containment requirements
- Single-use fluid path designed for low line loss
- 100% headspace analysis, visual and semi-automated inspection
- Full analytical capabilities including biologic, chemical, micro, stability and container closure testing



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