

EXPERIENCE
UNRIVALED

PREFILLED SYRINGE
MANUFACTURING

AbbVie Contract Manufacturing offers development to commercial manufacturing services for prefilled syringes at our Barceloneta and Lake County facilities. Barceloneta is one of the world's most advanced facilities for biologics syringe filling and Lake County has broad packaging services from blister packs to auto-injectors. This combination ensures you can meet your production objectives and have confidence in reliable delivery. You also have the support of a global leader in this fast-growing choice for dose medication.

STATE-OF-THE-ART ASEPTIC FILLING

- › Aseptic filling suite utilizing Restricted Access Barrier System (RABS) technology
- › Fill volumes from 0.4 – 8 mL in BD Hypak or equivalent type syringe
- › Inova filler utilizing peristaltic pump technology
- › Non destructive weight checks
- › Compatible with plungers packaged in rapid transfer port system
- › Nested syringes in tubs
- › Cold chain warehousing
- › Remote process monitoring
- › Dedicated and/or disposable fluid path
- › 100% manual visual inspection or 100% automatic visual inspection via AVI (Automated Visual Inspection) equipment

BROAD PACKAGING CAPABILITIES

Injector Assembly

- › Packaging engineering experts on-site
- › Fully automated auto injector assembly
- › 100% visual and automated inspection
- › Labeling and cartoning of auto-injectors

Syringe Packaging

- › Fully automatic assembly for plunger and finger grips
- › Labeling of individual syringes
- › Blister packaging and cartoning for individual syringes
- › 100% visual and automated inspection

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ANALYTICAL SERVICES

- › On-site micro laboratory
 - Sterility testing via isolator technology
 - On-site microbial identification via DNA sequencing
 - Visible and non-visible environmental monitoring
- › On-site chemistry
 - Variety of HPLC testing
 - Particulate testing
 - UV-Vis
 - FTIR
 - ATR
 - Incoming raw material testing
- › Device functional testing
 - Container closure integrity
 - Glide force
 - Break loose force
- › Stability services
 - Full range of temperature chambers

DEVELOPMENT SERVICES

- › Laboratory-scale pumping capacity
- › Full-service process validation for large molecule biologics
- › High-speed camera system
- › Capability for filling clinical lots

QUALITY

- › In-coming commodity testing
- › On-line non-destructive check weighing
- › Robust environmental monitoring program, including:
 - 100% manual or automated visual inspection
 - Electronic batch records
 - Automated process tracking and trending
- › On-site Biologics testing
 - SDS PAGE
 - Capillary Electrophoresis
 - ELISA
 - DNA threshold
 - Host cell protein

CLIENT SERVICES

- › Global regulatory support
- › Exceptional project management / responsiveness
- › Dedicated time slots for contract manufacturing
- › Comprehensive regulatory expertise
- › Licenses for global market distribution
- › Excellent reputation for on-time delivery

CONTRACT MANUFACTURING

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