

abbvie

CONTRACT MANUFACTURING

Biologics | Potent | Drug Product | Fermentation

Experience
Unrivaled

Contract
Manufacturing

When it comes to outsourcing focused on commercial success,
you need a CMO that has been there many times through deep scientific
expertise and world-class manufacturing capabilities.



AbbVie Contract Manufacturing

When you choose AbbVie Contract Manufacturing, you get so much more than a typical CDMO engagement. Through the partnership, you gain integrated access to scientific expertise and processes that have taken many small molecule and biologic medicines through commercialization and on to the forefront of patient care.

Your product is treated with the same commitment as if it were ours at world-class facilities, and you can rest easy being served by our experience of being there before, and one of the industry's most trusted reputations for delivery.

abbviecontractmfg.com

AbbVie is committed exclusively to drug development and the global supply and management of life-changing therapies. We have the expertise to optimize your project, coupled with agility and flexibility that support efficient processes.

Experience Unrivaled

Plant Capability Matrix

		Europe				USA		Puerto Rico
		Ludwigshafen, Germany	Sligo, Ireland	Cork, Ireland	Campoverde, Italy	Chicago, Illinois	Worcester, Massachusetts	Barceloneta
API / Drug Substance	Chemical		●		●	●		
	Biologic						● D,C	●
	Potent		●					
	Fermentation					● D,C	● D,C	
	Conjugation ¹ Linker-Toxin ²		● 2			● 1,D	● 1,C	
Oral Solid Dosage	Tablet Coating	●	●*	●	●	● D,C		●
	Spray Coating (Glatt)			●		● D,C		
	Wet Granulation (High Shear)	●	●*	●	●	● D,C		●
	Wet Granulation (Low Shear)							●
	Wet Granulation (Single Pot)	● D*	●*			● D*,C		
	Spray Granulation (Fluid Bed)			●		● D,C		●
	Dry Granulation	●		●	●	● D,C		●
	Roller Compaction		●*		●	● D*		
	Capsules	●	●*	●		● D*,C		●
	Particle Coating			●		● D,C		●
	Direct Compression (Dry Blend)		●*	●	●	● D*,C		●
	Mini- / Micro-tablets	●		●		● D*,C		
	Bi-Layer	●		●		● D*		●
	Hot Melt Extrusion	● D*,C				● D*		●*
	Liquids	● D,C			●	●		●
	Potent		●*			● D*		
Aseptic Fill / Finish	Prefilled Syringe	● D				● D		●
	Liquid Vial	● D	●			● D		
	Lyophilization Vial	● D	●*			● D		
Packaging	Blisters	●			●	●		
	Blister Foils / Foil				●	●		
	Bottles	●			●	●		
	Sachets / Sticks				●			
	Wallets				●	●		
	Syringe Packaging	●			●	●		

All commercial capabilities unless otherwise denoted as: D=Development Services; C=Commercial; *=Potent Capable

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Plant Capability Matrix



PLANT CAPABILITIES

● API / Drug Substance | ● Oral Solid Dosage | ● Aseptic Fill / Finish | ● Packaging

EUROPE

1 Ludwigshafen, Germany

- Tablet Coating
- Wet Granulation (High Shear)
- Wet Granulation (Single Pot)
- Dry Granulation
- Capsules
- Direct Compression (Dry Blend)
- Mini- / Micro-tablets
- Bi-Layer
- Hot Melt Extrusion
- Liquids
- Prefilled Syringe
- Liquid Vial
- Lyophilization Vial
- Blisters
- Bottles
- Syringe Packaging

2 Sligo, Ireland

- Chemical API
- Potent API
- Conjugation Linker-Toxin
- Tablet Coating
- Wet Granulation (High Shear)
- Wet Granulation (Single Pot)
- Roller Compaction
- Capsules
- Direct Compression (Dry Blend)
- Potent
- Liquid Vial
- Lyophilization Vial

3 Cork, Ireland

- Tablet Coating
- Spray Coating (Glatt)
- Wet Granulation (High Shear)
- Spray Granulation (Fluid Bed)
- Dry Granulation
- Capsules
- Particle Coating
- Direct Compression (Dry Blend)
- Micro-tablets
- Bi-Layer

4 Campoverde, Italy

- Chemical API
- Fermentation API
- Tablet Coating
- Wet Granulation (High Shear)
- Dry Granulation
- Roller Compaction
- Direct Compression (Dry Blend)
- Liquids
- Blisters
- Blister Foils / Foil
- Bottles
- Sachets / Sticks
- Wallets
- Syringe Packaging

USA

5 Chicago, Illinois

- Chemical API
- Fermentation API
- Tablet Coating
- Spray Coating (Glatt)
- Wet Granulation (High Shear)
- Wet Granulation (Single Pot)
- Spray Granulation (Fluid Bed)
- Dry Granulation
- Roller Compaction
- Capsules
- Particle Coating
- Direct Compression (Dry Blend)
- Mini- / Micro-tablets
- Bi-Layer
- Hot Melt Extrusion
- Liquids
- Potent
- Liquid Vial
- Lyophilization Vial
- Blisters
- Blister Foils / Foil
- Bottles
- Wallets
- Syringe Packaging

6 Worcester, Massachusetts

- Biologics API
- Fermentation API
- Conjugation Linker-Toxin API

PUERTO RICO

7 Barceloneta

- Biologic API
- Tablet Coating
- Wet Granulation (High Shear)
- Wet Granulation (Low Shear)
- Spray Granulation (Fluid Bed)
- Dry Granulation
- Capsules
- Particle Coating
- Direct Compression (Dry Blend)
- Bi-Layer
- Hot Melt Extrusion
- Liquids
- Potent
- Prefilled Syringe

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Experience Unrivaled

Biologics Development & Manufacturing

When you select AbbVie Contract Manufacturing for your biologics program, you're partnering with an industry leading biopharmaceutical development partner. Our experienced scientific team and state-of-the-art facilities are unrivaled. We hope to leverage our regulatory and commercial track record to give you greater confidence and improve your success velocity all the way from innovation to commercialization.

Commercial Success: 5 programs commercialized worldwide

Proven Expertise: 30 years and over 70 projects to date

Biologics Leader: Conjugation and biologics liquid filled vial capabilities

Partnering Commitment: Consistent investment in biologics facilities

Development Manufacturing

- Cell line development (MCB/WCB)
- Cell culture process development
- Purification process development
- Media development and optimization
- Analytical method development
- Extended product characterization
- Viral clearance studies

Process scale-up labs feature single-use and stainless technologies, with scales ranging from 3 L–500 L

Commercial Manufacturing

- Single use and fixed suite configurations (1,000 L–12,000 L)
- Cell bank production in a dedicated suite
- Process characterization and validation
- Lifecycle management & scale up planning
- 2 sites for duplicity and backup supply options



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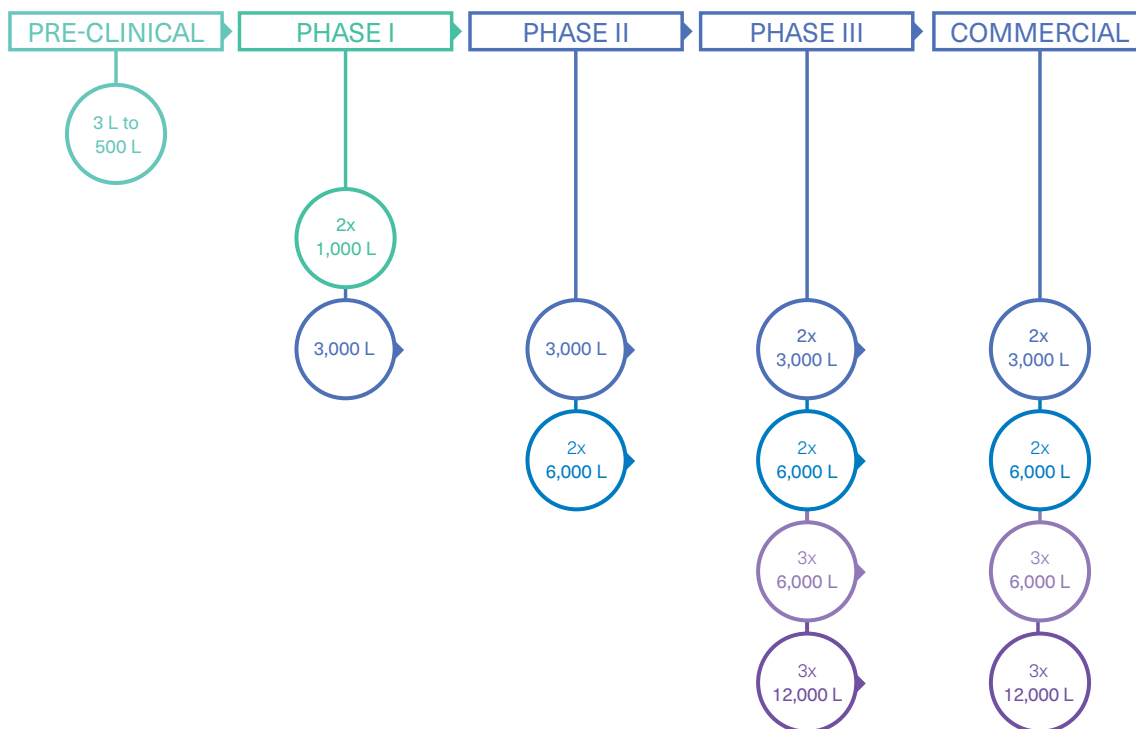
Biologics Development & Manufacturing

Analytical Services

- HPLC (SEC, CEX, HIC, RP)
- Host-cell protein
- Electrophoresis (CE-SDS, mCE, icIEF)
- ELISA
- Peptide structure determination (LC/MS)
- Released glycan analysis
- DNA identification (PCR)
- Spectrophotometry (FT-IR, UV VIS)
- Bioburden / Endotoxin

Client Services

- Stability studies
- Regulatory filing expertise
- Project management and inventory planning
- Scale to accommodate multiple customers simultaneously
- Dedicated time slots for strategic partners
- Exceptional track record of achieving timelines
- History of facility expansion for growing demands



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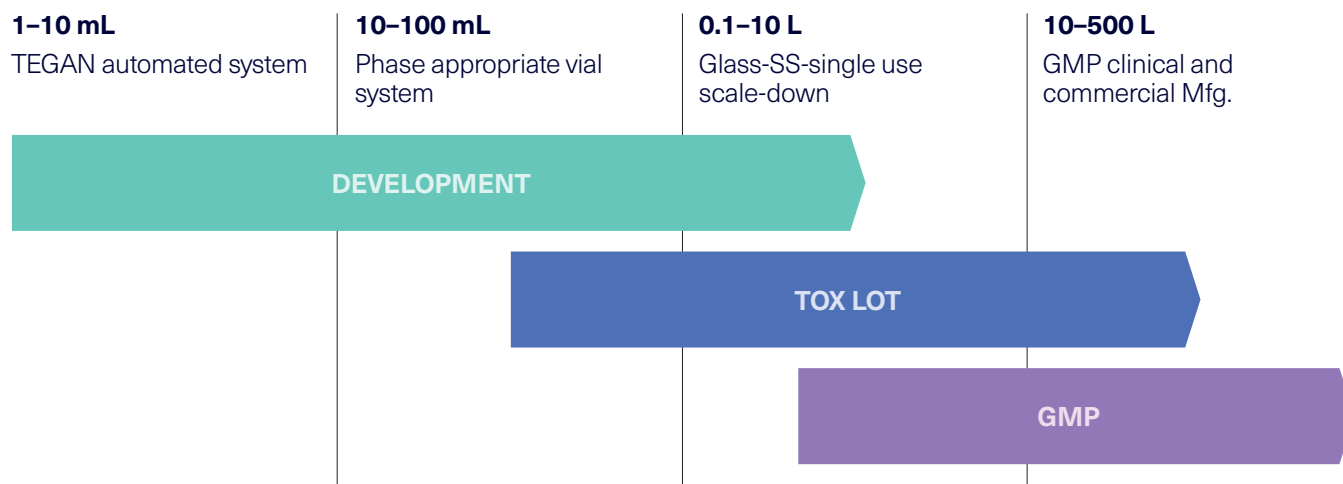
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Experience Unrivaled

Antibody Drug Conjugates (ADC)

When selecting AbbVie, you gain more than a contract manufacturer. We are your pharmaceutical partner, focused on helping mitigate risk and accelerate your drug development timelines. Our site in Worcester, MA represents AbbVie's Biologics/ADC center of excellence, and one of the few sites that successfully manages ADC complexities from antibody to conjugation, with one unified quality system and scientific team. We offer a simplified ADC supply chain and better project continuity to give you a greater confidence in the success of your ADC program.

Your Conjugation Provider from Pre-Clinical through Commercial



Analytical development, release and stability

- Onsite quality and testing (Bio & ADC)
- UV/VIS
- MALS/IR
- CE, icIEF
- CE-SDS (Beckman), mCE-SDS (Perkins Elmer)
- HPLC, UPLC, LC/MS
- LAL, ELISA
- Environmental/bioburden testing
- HIC for DAR



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Experience Unrivaled

Antibody Drug Conjugates (ADC)

Chicago, IL ②

③ Worcester, MA

Sligo ①

④ Barceloneta

ABBVIE ADC MANUFACTURING NETWORK

EUROPE

① Sligo, Ireland ● ●

USA

② Chicago, Illinois ● ●

③ Worcester, Massachusetts ● ●

PUERTO RICO

④ Barceloneta ●

● mAb Production

- Full development and manufacturing support
- Proven leader with two convenient North American sites
- 1,000 L to 12,000 L bioreactors
- Single use and fixed stainless steel options

● Drug-Linker Synthesis and Purification

- Segregated facility within Sligo with exceptional containment down to < 1 ng/m³
- 15+ years of high GMP high containment manufacturing
- Batches from 1 – 500 gram with option to increase capacity
- Scientific excellence to support a range of linker-payload chemistries

● Conjugation

- Primary site in Worcester, MA
- Integrated Biologics-ADC facility
- Highly engineered facility capable of containment < 10 ng/m³
- Scale options up to 500L
- Single use and fixed stainless steel options
- Inline antibody remodeling and engineering options



ONE PROVEN PARTNER, END-TO-END SOLUTION PROVIDER



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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

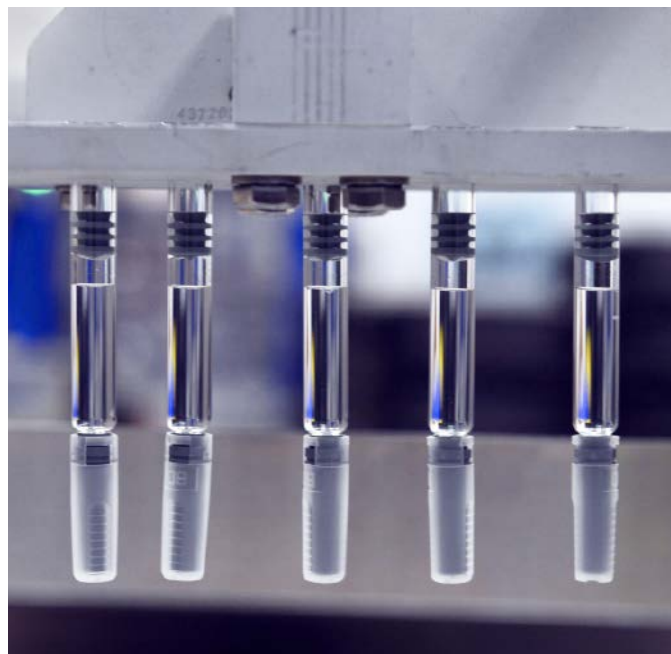
North Chicago, IL & Ludwigshafen, Germany

- 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

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Experience Unrivaled

Aseptic Fill-Finish: Vial

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.

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



DEVELOPMENT



BULK DRUG SUBSTANCE MANUFACTURING



ASEPTIC FILL-FINISH

END-TO-END OPTIONS WITH ABBVIE

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Experience Unrivalled

Oral Solid Dose

AbbVie Contract Manufacturing delivers advantages beyond a typical CMO to the drug product market. As a leading pharmaceutical developer and manufacturer, we have a large and diverse scientific team who bring extensive depth of knowledge and expertise to offer solutions to our clients' most difficult challenges. With manufacturing flexibility across six facilities in the US and Europe, we offer one of the most effective global networks to accommodate oral solid production needs coupled with the most trusted reputation in the industry for quality, reliability and on-time delivery.



AbbVie's Experience

- Flexible scales to for boutique to large scale production network delivers broad flexibility in scale and location
- Solution and consultative partnerships from development through commercial term
- Established wide network of commercial assets to accelerate speed to market

Unique Capabilities

- Potent ($<1\mu\text{g}/\text{m}^3$) manufacturing and storage
- Offer End to End manufacturing from API to bulk oral solid dose to finished Drug Product packaging
- Extensive controlled temperature warehousing capability (2–8 °C API and Drug Product)
- Hot melt extrusion for difficult to formulate compounds/bioavailability enhancement



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Experience Unrivalled

Oral Solid Dose

Oral Solid Dose Manufacturing

Blending

- V-blenders (2 ft³ – 150 ft³ scale)
- Bin blenders

Granulation & Drying Capabilities

- Dry granulation
- Roller Compaction
- High Shear wet granulation (75 L, 300 L and 1,200 L)
- Spray granulation (400 L – 1,100 L)
- Melt granulation (18 MM – 70 MM screw size)
- Fluid Bed Drying
- Tray Drying

Milling capabilities

- Impact milling
- Screen milling
- Separation

Compression Capabilities

- Single layer
- Multi-layer
- Mini tab

Coating Capabilities

- Tablet coating
- Particle coating
- Active coating

Encapsulation Capabilities

- Granule filled
- Liquid filled (hard gelatin)
- Mini tab filled
- Over encapsulation

Packaging Capabilities

- Blisters
- Bottles
- Sachets/Sticks
- Wallets

Oral Liquid Manufacturing & Finishing

- Formulation
- Syrups/Suspensions/Solutions
- Bottle filling (15 ml – 500 ml)

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Experience Unrivalled

Hot Melt Extrusion

AbbVie Contract Manufacturing offers proprietary hot melt extrusion (HME) technology in both the US and Europe. AbbVie is the global leader with more than thirty years of HME extrusion development experience and the most commercial products launched utilizing this unique technology. HME is a robust process that effectively addresses the need to enhance bioavailability of a poorly soluble and potent APIs.

ONE PROVEN PHARMA PARTNER OFFERING UNIQUE SOLUTIONS TO ENHANCE BIOAVAILABILITY

AbbVie's Experience

- Unparalleled industry leader with more than 30+ years of formulation and manufacturing know how
- Integrated development and commercial manufacturing
- Most commercial products launched (>7)
- Academic collaborations to drive innovation; highest rate of HME technical publications

Product Enhancements

- Improved bioavailability via formulation expertise.
- Achieve & optimize amorphous solid dispersion (ASD)
- Enhanced solubility: Excellent integration of difficult-to-dissolve APIs
- Technology able to offer taste-masking and abuse deterrence

Process Advantages

- Solvent free and continuous processing
- Wide range of scale to grow with product needs
- End to End manufacturing from extrudate to packaged drug product production



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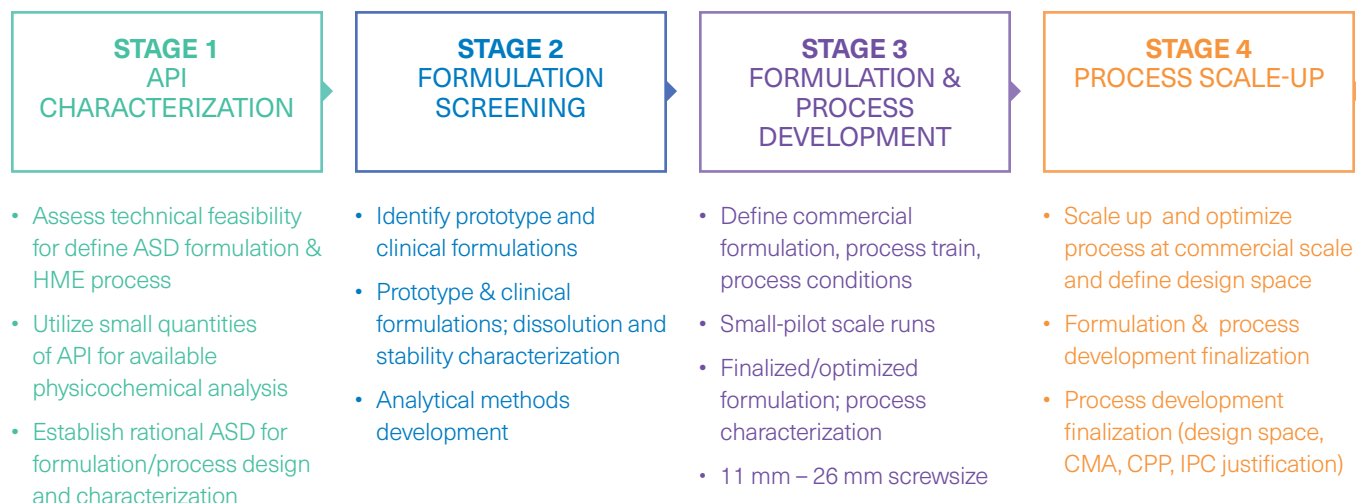
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Experience Unrivalled

Hot Melt Extrusion

AbbVie can take your product from Phase I to commercialization.

Product Development



Commercial Manufacturing

10+ extruders in network

- 18 mm – 70 mm screw size
- Multiple OEMs (Liestritz, Coperion, Bosch)
- Potent capability (<1 µg/m³)
- Extensive experience in various equipment manufacturers, screw size, block and exit die configurations
- Scale-up and technical transfer from site to site
- Melt granulation (continuous)

Manufacturing sites in US and Europe

- Barceloneta, Puerto Rico
- Ludwigshaven, Germany

Downstream Manufacturing Options

- Controlled Release
- Modified Release
- Tablets (including multi-layer)
- Capsules

Packaging Options

- Blisters
- Bottles
- Sachets/Sticks
- Wallets

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Experience Unrivaled

Potent API and Drug Product

AbbVie Contract Manufacturing offers potent capabilities for drug product and APIs covering development phases to commercial production. We are among few companies with potent-capable facilities in North America and Europe, reflecting an advantage of working with a global pharmaceutical developer and manufacturer. Our advantages include the depth of scientific expertise that applies to your project and our exceptional track record for compliance and safety. Our capabilities also encompass the highest Environmental Health and Safety (EHS) industry practices for handling potent compounds.

Overall Capabilities

Potency classification down to $<1\mu\text{g}/\text{m}^3$
Potent active pharmaceutical ingredients (HPAPI)
Dedicated hydrogenation suite (4,000 L)
Process control temperature (-20 °C – 120 °C)

Unique Capabilities

Hot Melt Extrusion
Single pot processing
Split butterfly valve transfers
Identical process train configuration to facilitate scale-up activities

Development Manufacturing (Non-GMP & GMP)

- Blending (3 L – 400 L)
- Dry granulation (Gerteis roller compactor)
- Wet granulation (10 L – 75 L)
- Single Pot Processing (10 L – 75 L)
- Milling
- Compression / encapsulation
- Coating

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Potent API and Drug Product

Commercial Manufacturing

- Independent and configurable glass and stainless steel equipment trains (440 L – 4,500 L)
- Dry granulation (Gerteis roller compactor)
- Wet granulation (120 L – 300 L)
- Single pot processing (100 L – 200 L)
- 3 Class 10,000 suites with Hastelloy and 316 stainless steel filter dryers (5 kg – 150 kg)
- Purified water system
- Small kilo scale reactors (including high pressure reactors)
- In-bin International Bulk Container (IBC) blending capabilities (50 L – 420 L)
 - IBC to IBC transfer and milling stations
- Clean-in-place (CIP) systems
- Containment suites
 - Encapsulation
 - Tableting suite with in-process automatic weight check and in-line metal detection
 - Tablet coating suite with adjustable tablet pan size

Analytical Services

- HPLC (reverse phase, normal phase, ion exchange, gradient and isocratic methods, pulsed amperometric detection, UV visible, diode array, and MS detection)
- LC / MS & GC / MS
- GC (FID and TCD detection, capillary and glass columns, headspace and residual solvents analysis)
- Spectrophotometry (FT- IR, UV visible)
- Atomic absorption, ICP and X- ray
- Optical and electron microscopy
- Surface area and particle size distribution
- Total organic carbon testing
- Microbiology lab for product testing and facility environmental testing
- Stability testing



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Microbial Fermentation Services

AbbVie Contract Manufacturing offers world-class fermentation capabilities based on more than 60 years' leadership in fermentation. Your project will benefit from AbbVie's scientific expertise as a leading development and manufacturer of fermentation processes at our 180-acre facility in Chicago, Illinois. We bring the same degree of expertise and passion to your project as we do with our own, supporting you from cell bank development through to large-scale manufacturing.

Types of Products

- Small molecule API's to be administered orally or as an injectable
- Large molecule API's to be administered orally
- Bulk food ingredients
- Agrochemical active ingredients
- Semi-synthetic products

Types of Organisms

- GMO & non-GMO manufactured under GLSP (good large scale practice)
- Experience with:
 - Actinomycetes
 - *E. coli*
 - Fungi
 - *Bacillus*
 - Yeast

Development Manufacturing (Non-GMP)

- Strain improvement via classical and recombinant methods
- Preparation of R&D, master and working cell banks
- Inoculum process development
- Fermentation and downstream process development and characterization including:
 - 55-500 L fermenters in pilot plant
 - Track key parameters including pH, DO, temperature, agitation and off-gas
 - Recovery operations that are representative of commercial scale
- Method development and transfer for analytical, microbial and cleaning methods

Clinical and Commercial Manufacturing

- Over 3000 m³ fermentation capacity
- Fermenter working volumes from 10,000 L – 100,000 L
- Batch and continuous sterilization of media
- Dedicated facility for cell bank preparation and storage with redundant equipment and controls
- Broad range of downstream capabilities including:

- Microfiltration	- Chromatography
- Centrifugation	- Crystallization
- Liquid / Liquid extraction	- Fluid bed drying
- Ultrafiltration	- Filter drying
- Evaporation	
- Packaging liquids into presterilized totes or tanker trucks and dried solids into drums

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Microbial Fermentation Services

Analytical Services

- High Performance Liquid Chromatography (HPLC) – reverse phase, normal phase, etc.
- ICP-OES and ICP-MS
- Gas Chromatography (GC) analysis
- GC-MS and LC-MS
- Reference standard & purity characterization
- Spectrophotometry (FT-IR, UV-Vis, GC Mass Spec)
- Wet chemistry (titrations, LOD, pH, heavy metals, etc.)
- Biopotency
- Turn-key stability testing service
- Cleaning method development via LC and TOC
- X-ray diffraction, TGA and DSC
- Optical and electron microscopy
- Surface area and particle size analysis on site
- Specific organism detection
- Microbial identification and limits testing
- Bioburden (AMC / Endotoxin – LAL)
- Environmental testing

Manufacturing Excellence

- Class-A certified operation, focused on efficient processing
- Key Performance Index (KPI) monitoring
- Environmental Health and Safety (EH&S) programs to ensure pollution prevention and resource conservation
- Process Analytical Technology (PAT) and process control systems
- Distributed Control Systems (DCS)
- Continuous improvement

Client Commitment

- Reliable supply through established supply and operations planning (S&OP) processes
- Dedicated project management
- New product introduction business process
- Global Chemical Manufacturing Control (CMC) filing support
- Information confidentiality and security via cyber and physical controls



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Active Pharmaceutical Ingredient Product List

AbbVie manufactures a wide range of compendia-grade active pharmaceutical ingredients (APIs). We have one of the most trusted reputations in the industry for timely delivery of high quality product. State-of-the-art facilities worldwide and a highly experienced scientific team offer further assurances that you will experience worry-free, reliable service.

Antibiotics

International Nonproprietary Names

Erythromycin Base

Compendia: USP, EP

Therapeutic Category: Macrolid antibiotic

CAS Number: 114-07-8

Erythromycin Ethylsuccinate

Compendia: USP, EP

Therapeutic Category: Macrolid antibiotic

CAS Number: 41342-53-4 / 1264-62-6

Erythromycin Stearate

Compendia: USP, BP

Therapeutic Category: Macrolid antibiotic

CAS Number: 643-22-1

Erythromycin Thiocyanate

Therapeutic Category: Macrolid antibiotic

CAS Number: 7704-67-8

Finished dosage forms may be available on specific request for selected products.

Fine Pharmaceuticals

International Nonproprietary Names

Biperiden Base

Compendia: N / A

Therapeutic Category: Anti-Parkinson's disease

CAS Number: 514-65-8

Biperiden Hydrochloride

Compendia: EP

Therapeutic Category: Anti-Parkinson's disease

CAS Number: 1235-82-1

Cyclosporine

Compendia: USP, EP

Therapeutic Category: Immunosuppressant

CAS Number: 59865-13-3

Divalproex Sodium

Compendia: USP

Therapeutic Category: Bipolar Disorder

CAS Number: 99-66-1

Enflurane

Compendia: USP

Therapeutic Category: Local anesthetic

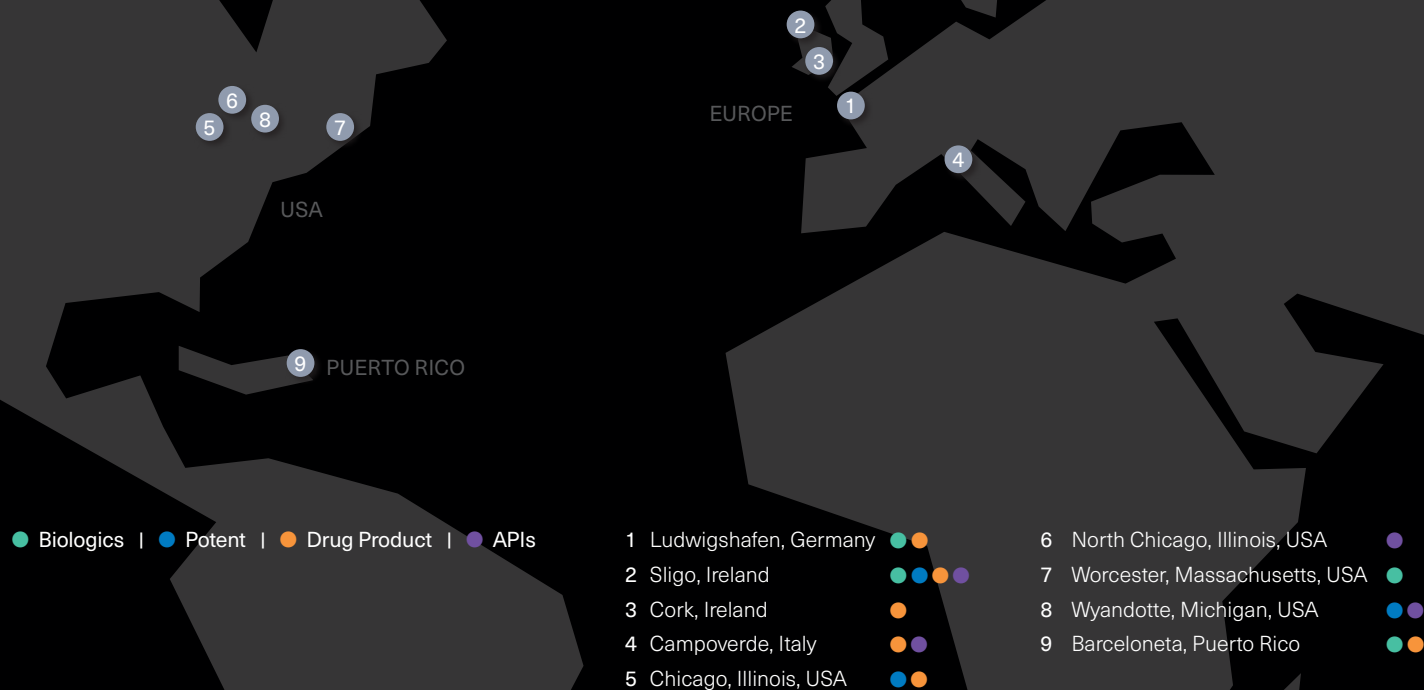
CAS Number: 13838-16-9

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Locations & Capabilities

Contract Manufacturing



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