



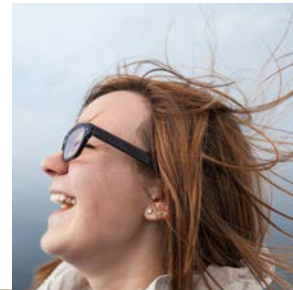
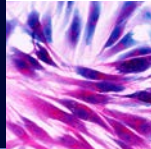
## Contract Manufacturing

Vision. Expertise. Success.

Biologics | Aseptic Fill-Finish | Hot Melt Extrusion (HME)  
Oral Solid Dose | High Potent & Small Molecule APIs | Eyecare  
Antibody Drug Conjugate (ADC) | Prefilled Syringe – Medical Device

AbbVie Contract Manufacturing partners with companies around the globe to develop, scale and manufacture their pharmaceutical products. With decades of experience, we see the complete picture to deliver your vision and real-world results, while improving people's lives.

**Vision.  
Expertise.  
Success.**



## AbbVie Contract Manufacturing

We are the manufacturing division of AbbVie, one of the world's most successful pharmaceutical companies.

As an embedded CMO, we leverage decades of expertise, collaboration and best-in-class facilities to provide you with an integrated, end-to-end solution.

### **Your vision, delivered.**

From development and manufacturing to compliance and commercialization, we can efficiently deliver your vision to market—and into the lives of patients.

**Start the journey, at [abbviecontractmfg.com](http://abbviecontractmfg.com)**



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# Biologics: Development & Drug Substance Manufacturing

When selecting AbbVie, you gain more than a contract manufacturer. We are your pharmaceutical partner, focused on helping mitigate risk and accelerating your drug development time line. Our primary development and manufacturing site in Worcester, MA represents AbbVie's Biologics center of excellence, managing drug complexities from development to commercial launch, and from antibody to ADC with an integrated quality system and top tier pharmaceutical operations team. Our regulatory track record and global biologics network offers a simplified and dependable supply chain, and better project continuity to give you greater confidence in the success of your planned milestones and manufacturing requirements.

**Commercial Success:** 8 programs launched globally

**Scientific Excellence:** Clinical development, managing over 100 molecules

**Biologics Expertise:** mAb, fusion, bi-specific and ADC conjugation expertise

**Partnering Commitment:** Third party manufacturing excellence for over 40 years

## Development Services

- Cell bank generation and qualification (MCB/WCB)
- Upstream and downstream process development
- 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 to 500 L

## Clinical & Commercial Manufacturing

- Over 85,000 L of global capacity across AbbVie's BIO network
- Both single use and fixed stainless-steel equipment options in the US and Europe; 2,000 L to 12,000 L scale range
- Each cell culture suite possesses dedicated DS purification
- Experienced process characterization and validation teams
- Three sites with backup and contingency planning options



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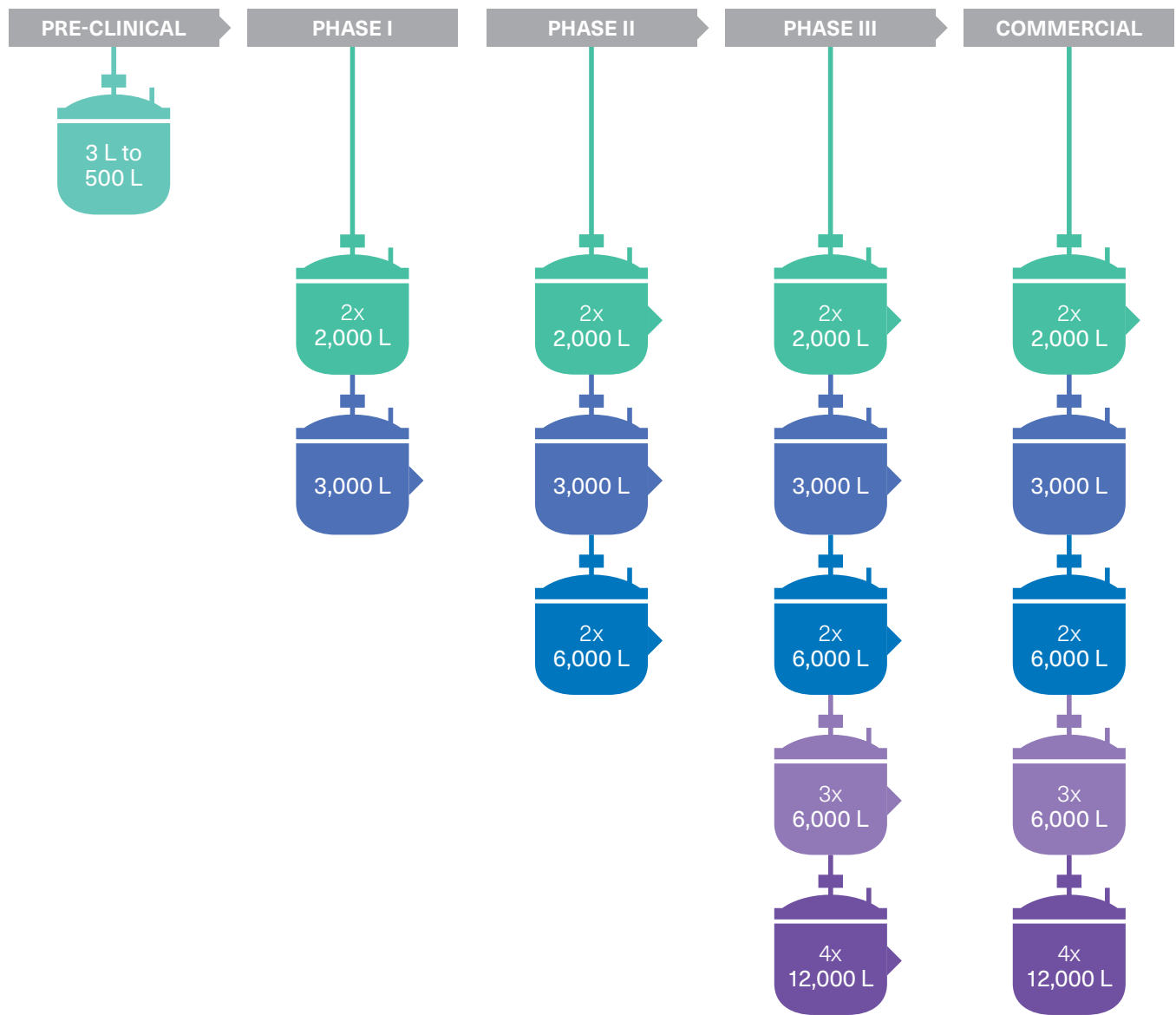
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**Client Services**

- Comprehensive clinical & commercial pharma support
- Global regulatory filing, approval and launch expertise
- Dedicated pharmaceutical planning and project management
- Capacity and scale options to accommodate multiple partner programs and growing demand
- Dedicated capacity options with flexible contracting for strategic partners
- Exceptional track record of scale-up milestone achievement, BLA and ongoing supply
- History of facility expansion for internal and external commercial requirements



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# Plant Capability Matrix

		Europe								USA			Puerto Rico
		Ludwigshafen Germany	Westport Ireland	Sligo Ireland	Cork Ireland	Clonsbaugh Ireland	Campoverde Italy	Martillac France	Pringy France	Chicago Illinois	Worcester Massachusetts	Waco, Texas	Barceloneta
API / Drug Substance	Chemical			●*					●*	●			
	Biologic (Mammalian)							●			●	●	
	ADC Conjugation			●*							●*		
Oral Solid Dosage	Hot Melt Extrusion	●*				●				●*		●*	
	High Shear Granulation	●		●*	●	●	●			●*		●	
	Spray Granulation (Fluid Bed)					●				●		●	
	Roller Compaction			●*			●			●*			
	Particle Coating					●				●		●	
	Tablets	●		●*	●	●	●			●*		●	
	Capsules			●*	●	●				●*		●	
	Bilayer Tablets	●			●	●				●*		●	
	Mini-tablets	●			●	●				●*		●	
	Tablet Coating	●		●*	●	●	●			●		●	
	Liquids						●			●			
	Blisters/Bottles						●			●			
	Sachets/Sticks						●						
	Wallets						●			●			
Aseptic Fill / Finish	Prefilled Syringe	●	●									●	
	Liquid/Lyo Vial	●*	●	●*									
	Syringe Blistering/ Packaging						●			●			
Eye Care	Sterile Eye Ointments										●		
	Multidose (Preserved & Preservative Free)		●								●		
	Unit Dose		●								●		
Medical Device	Prefilled Syringe							●					

\*=High Potent Capable



PLANT CAPABILITIES

● API / Drug Substance | ● Oral Solid Dosage | ● Aseptic Fill / Finish | ● Eye Care | ● Medical Device

EUROPE

**1 Ludwigshafen, Germany**

- Hot Melt Extrusion
- High Shear Granulation
- Tablets
- Bilayer Tablets
- Mini-tablets
- Tablet Coating
- Prefilled Syringe
- Liquid/Lyo Vial

**2 Westport, Ireland**

- Multidose (Preserved & Preservative Free)
- Unit Dose
- Prefilled Syringe
- Liquid/Lyo Vial

**3 Sligo, Ireland**

- Chemical
- ADC Conjugation
- High Shear Granulation
- Roller Compaction
- Tablets
- Capsules
- Tablet Coating
- Liquid/Lyo Vial

**4 Cork, Ireland**

- High Shear Granulation
- Tablets
- Capsules
- Bilayer Tablets
- Mini-tablets
- Tablet Coating

**5 Clonshaugh, Ireland**

- High Shear Granulation
- Spray Granulation (Fluid Bed)
- Particle Coating
- Tablets
- Capsules
- Bilayer Tablets
- Mini-tablets
- Tablet Coating
- Hot Melt Extrusion

**6 Campoverde, Italy**

- Chemical
- High Shear Granulation
- Roller Compaction
- Tablets
- Liquids
- Tablet Coating
- Blisters/Bottles
- Sachets/Sticks
- Wallets
- Syringe Blistering/Packaging

**7 Martillac, France**

- Biologic (Mammalian)

**8 Pringy, France**

- Prefilled Syringe

USA

**9 Chicago, Illinois**

- Chemical
- Hot Melt Extrusion
- High Shear Granulation
- Spray Granulation (Fluid Bed)
- Roller Compaction
- Tablets
- Capsules
- Bilayer Tablets
- Mini-tablets
- Tablet Coating
- Liquids
- Blisters/Bottles
- Wallets
- Syringe Blistering/Packaging

**10 Worcester, Massachusetts**

- Biologic (Mammalian)
- ADC Conjugation

**11 Waco, Texas**

- Sterile Eye Ointments
- Multidose (Preserved & Preservative Free)
- Unit Dose

PUERTO RICO

**12 Barceloneta**

- Biologic (Mammalian)
- Hot Melt Extrusion
- High Shear Granulation
- Spray Granulation (Fluid Bed)
- Tablets
- Bilayer Tablets
- Capsules
- Prefilled Syringe

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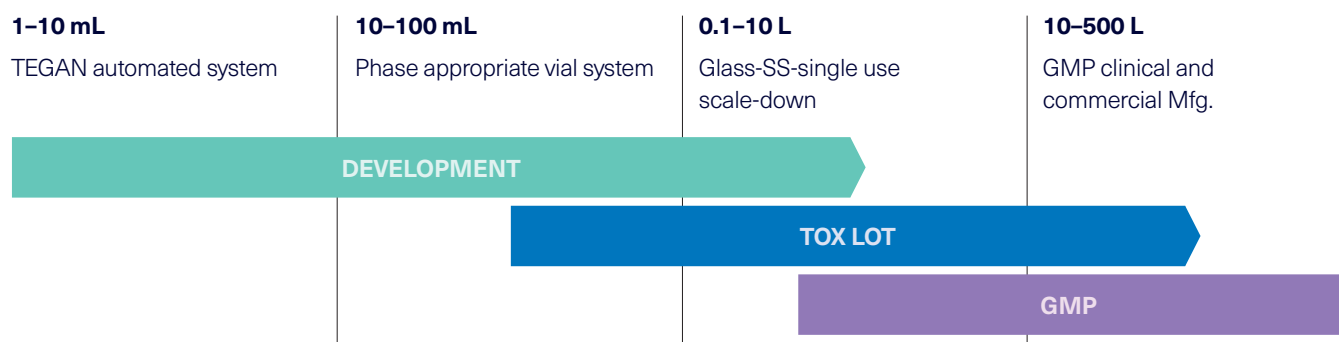
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# Antibody Drug Conjugates (ADC)

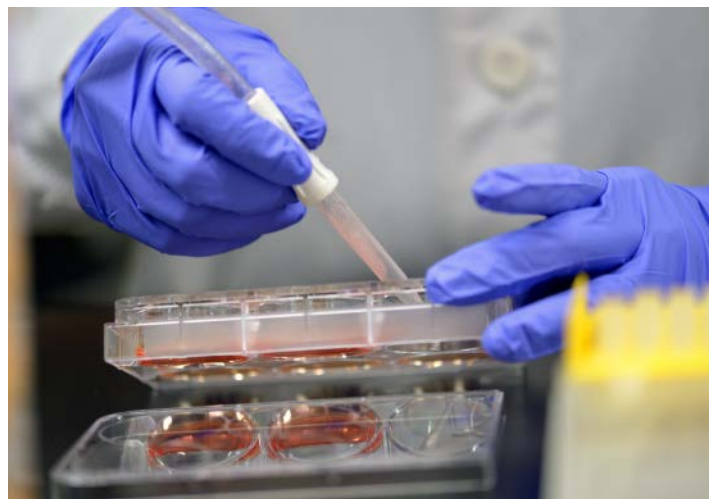
When selecting AbbVie for your ADC, you gain an industry leading biopharmaceutical development partner. AbbVie's experienced scientific team and state-of-the-art facilities are unrivaled in biopharma and antibody drug conjugation. In addition to extensive ADC clinical experience, AbbVie can leverage its regulatory and commercial track record to deliver improved confidence leading to successful milestone achievement.

## Your Conjugation Provider from Clinical to 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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ABBVIE ADC MANUFACTURING NETWORK

**EUROPE**

**1** Sligo, Ireland ●

**USA**

**2** Chicago, Illinois ● ●

**3** Worcester, Massachusetts ● ●

**PUERTO RICO**

**4** Barceloneta ●

● **Antibody Intermediate**

- Dedicated mammalian technologies
- Full pharma 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 — Payload**

- Segregated pilot facility capable of managing containment to <math><1\text{ ng/m}^3</math>
- 20+ years of high-containment GMP manufacturing
- Batches from 1–500g 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 <math><10\text{ ng/m}^3</math>
- Scale options up to 500 L
- Single use and fixed stainless steel options
- Inline antibody remodeling and engineering options



**One proven pharma partner, end-to-end solutions**

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# Aseptic Fill-Finish: Vial

AbbVie offers two convenient Aseptic Fill and Finish options for parenteral drug products: Vials & Prefilled Syringes. As a leading pharmaceutical partner, we can provide all necessary elements of delivering high quality parenteral products for both clinical and commercial requirements. AbbVie will leverage its know-how and proven quality, regulatory, and operational expertise to ensure you achieve your critical milestones as planned. Consistent and reliable pharmaceutical quality in every batch.

## Vial Fill-Finish Drug Product

### Specialized formulation & development support North Chicago, Illinois and Ludwigshafen, Germany

- Extensive formulation and scale-up experience at all phases of development
- Lyophilization process optimization and scale-up transfer
- Method development and phase appropriate qualification

### Clinical & Commercial GMP Manufacturing Sligo, Ireland

- Cutting-edge automated vial fill line with 6-head Bosch peristaltic technology
- Lyo and liquid fill options with 23 m<sup>2</sup> auto-load lyophilizer
- Validated for 6R, 10R & 20R vials with capability to expand from 2R to 50R
- Fully automated isolator line with potent containment handling to <10ng/m<sup>3</sup> OEL
- Single-use fluid path technology designed to minimize loss of drug substance
- 100% headspace analysis, manual and semi-automated visual inspection options
- Comprehensive pharmaceutical support including QC/QA and regulatory



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# Aseptic Fill-Finish: PreFilled Syringe

AbbVie produces tens of millions of pre-filled syringes each year. Our extensive pharmaceutical network offers various manufacturing options for your biopharmaceutical, including aseptic pre-filled syringe manufacturing in North America. AbbVie is a leading commercialization partner with extensive scientific know-how to assist in drug delivery options and commercial readiness.

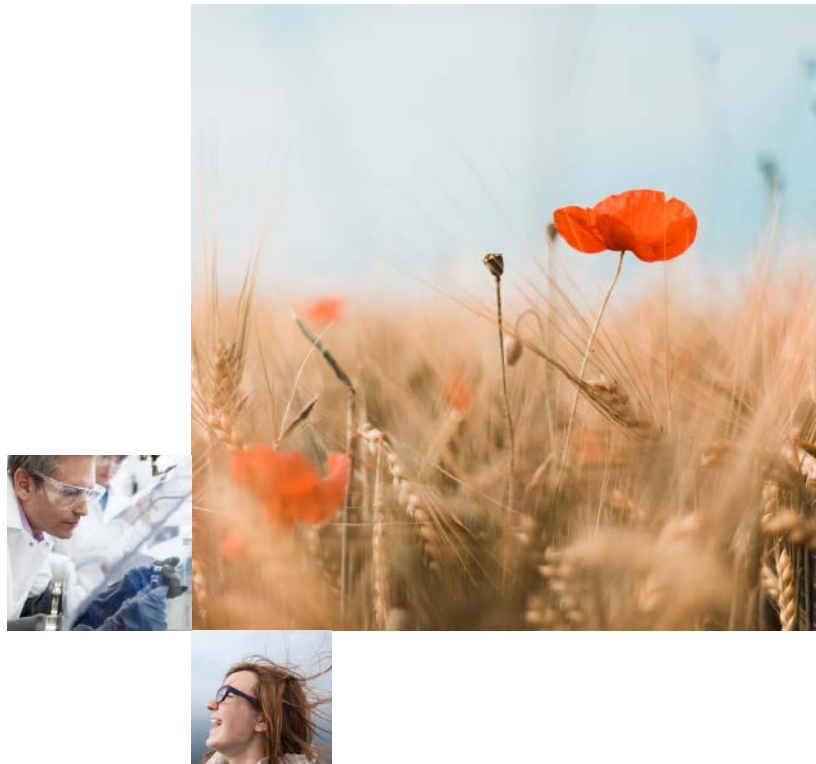
## Prefilled Syringe Drug Product

### 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 with peristaltic technology
- 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



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# 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 manufacturing 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 from 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 µg/m<sup>3</sup>) 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 (see Hot melt extrusion cutsheet for more details)

Pharma partner offering  
technical expertise  
to successfully  
commercialize your  
product



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## Oral Solid Dose Manufacturing

### Blending

- V-blenders (2 ft<sup>3</sup>–150 ft<sup>3</sup> scale)
- Bin blenders

### Granulation & Drying Capabilities

- Roller Compaction
- High Shear 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

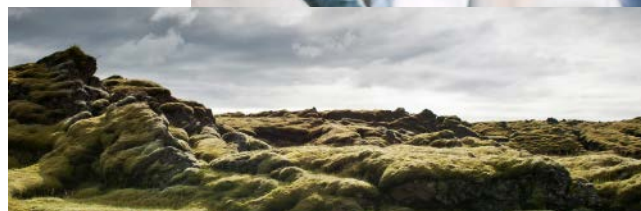
- Single layer
- Multi-layer
- Mini tab

### 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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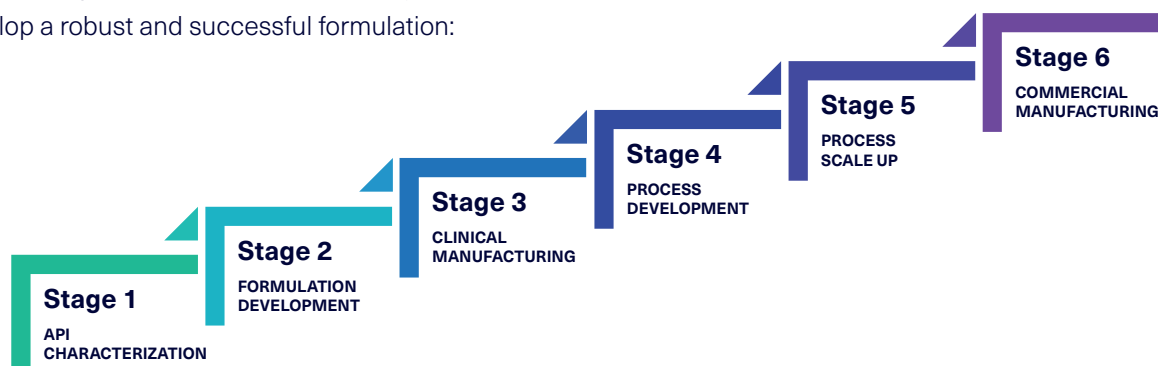
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# Hot Melt Extrusion

HME is a highly effective technology to transform poorly soluble APIs into amorphous solid dispersions, enhancing bioavailability. AbbVie Contract Manufacturing offers hot melt extrusion (HME) development and manufacturing in both the US and Europe. With over thirty-five years of experience, AbbVie is a pioneer having commercialized 10+ products utilizing HME. Upstream API and downstream drug product manufacturing and packaging services are also available, ensuring a complete end-to-end solution.

## AbbVie Formulation Development Process

AbbVie employs a stage-based process with clearly defined success criteria to develop a robust and successful formulation:



	DEVELOPMENT	COMMERCIALIZATION
<b>Locations</b>	Germany and United States	Germany, Puerto Rico, Ireland
<b>Extruder Scale</b>	18 mm – 40 mm	27 mm – 70 mm
<b>Potency</b>	$\geq 1 \mu\text{g}/\text{m}^3$	$\geq 1 \mu\text{g}/\text{m}^3$
<b>Experience</b>	100+ products developed	10+ commercial launches
<b>Capabilities</b>	<ul style="list-style-type: none"> <li>• API characterization</li> <li>• Extrudate and OSD formulation dev</li> <li>• Scale-up modeling</li> <li>• Clinical supply</li> </ul>	<ul style="list-style-type: none"> <li>• Process Scale-Up</li> <li>• Process Characterization</li> <li>• Process Validation</li> <li>• Business Continuity</li> </ul>

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### Analytical Services:

- HPLC (reverse phase, normal phase, ion exchange, gradient, isocratic methods, pulsed amperemeter 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

### Downstream Manufacturing Options:

(see Oral Solid Dose cutsheet for more details)

- Milling
- Tableting (including bilayer & minitab)
- Encapsulation

### Packaging Options

- Blisters
- Bottles
- Sachets/Sticks
- Wallets

One proven pharma partner offering unique solutions to enhance bioavailability



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# Ophthalmics

AbbVie Contract Manufacturing provides aseptic filling for ophthalmic drug product in Waco, Texas. As a trusted global pharmaceutical partner, we deliver high quality solutions for your late-stage clinical and commercial manufacturing needs. With 20+ years of manufacturing expertise for the most common ophthalmic drug products, the Waco facility is equipped to meet your needs. We are committed to help you achieve your milestones through end to end comprehensive manufacturing support.

## Turnkey Solution Includes:

Tech Transfer

Aseptic Filling

Packaging

Analytical Testing

### Sterile Eye Ointment



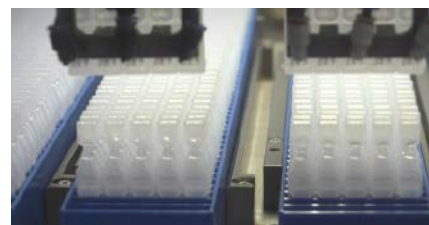
- Fully automated aseptic semi solid filling line
- ~3.5 gram fill weight
- Laminate tubes
- Scale Up and tech transfer services
- Batch size 150–200 L

### Multidose Bottles



- Preservative-free multidose bottle filling
- Preserved multidose bottle filling
- Solutions & emulsions
- Bottle sizes of 5, 10 & 15 mL
- Batch sizes (100–2400 L)

### Unit Dose



- Blowfill seal (BFS) Technology
- Solutions & emulsions
- Fill volume 0.25–0.60 mL
- Batch sizes (600–2400 L)
- Foil wrap and tub packaging options

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## Small Molecule and High Potent API

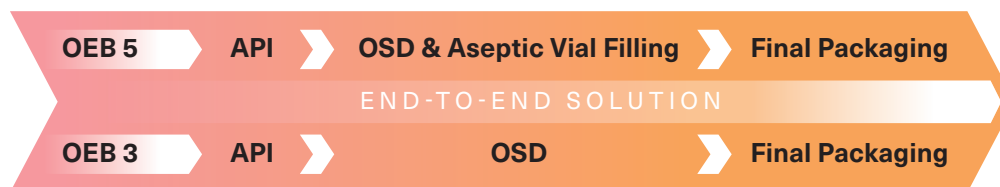
AbbVie Contract Manufacturing offers world-class custom active pharmaceutical ingredient (API) services based on more than 50 years of manufacturing excellence with facilities located in the United States and Europe. AbbVie's API sites have a wide range of scales and potencies supporting late phase clinical and commercial products. AbbVie has on-site QC laboratories as well as extensive CMC, QA and regulatory experience with a proven track record of successful commercialization.

### Wide Range of GMP Manufacturing Capabilities

<b>Batch Size</b>	0.5–5 kg	5–50 kg	50–150 kg	100–400+ kg
<b>Reactor Size</b>	100–1,000 L	1,000–3,000 L	4,000–6,000 L	4,000 – 12,000 L
<b>Potency</b>	OEB 5		OEB 4	OEB 3
<b>Locations</b>	Ireland		Italy	Italy & United States
<b>Capabilities</b>	<ul style="list-style-type: none"> <li>• Ballroom suite for flexibility</li> <li>• Dedicated glass equipment</li> <li>• Chromatography</li> </ul>	<ul style="list-style-type: none"> <li>• Three separate suites</li> <li>• Reactor, filter dryer &amp; mill</li> <li>• Hydrogenation</li> </ul>	<ul style="list-style-type: none"> <li>• Two separate suites</li> <li>• 6 reactors – GL &amp; HA</li> <li>• Filter drying – HA</li> </ul>	<ul style="list-style-type: none"> <li>• Modular design for flexibility</li> <li>• 25+ reactors – SS and GL</li> <li>• HP &amp; LP hydrogenation</li> </ul>

### End-to-End Solutions for Small Molecules

In addition to API, AbbVie offers drug product manufacturing services. This creates a very convenient end-to-end solution with all of the services located at one location; Italy up to OEB 3 and Ireland up to OEB 5. See the Oral Solid Dose, Hot Melt Extrusion, and Aseptic Fill-Finish cut sheets for more details.



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## Manufacturing Capabilities

AbbVie's API manufacturing sites are designed with high flexibility to arrange production trains that fit each process. Unit operations include:

- Hastelloy, glass lined and stainless steel reactors ranging from 50 L–12,000 L
- Low and high pressure hydrogenation
- Carbonylation up to 6 bar
- Crystallization
- Inverting bag centrifuges
- Peeler centrifuges
- Filter, agitated, tumble and fluid bed drying
- COMIL and Pin milling
- Chromatography

## Process Evaluation and Optimization Capabilities

Dedicated technical operations teams and lab scale process equipment supports development work including:

- Transfer of new process
- Process familiarization and optimization
- Troubleshooting/investigations
- Waste stream characterization
- Process validation
- Raw material supplier evaluation

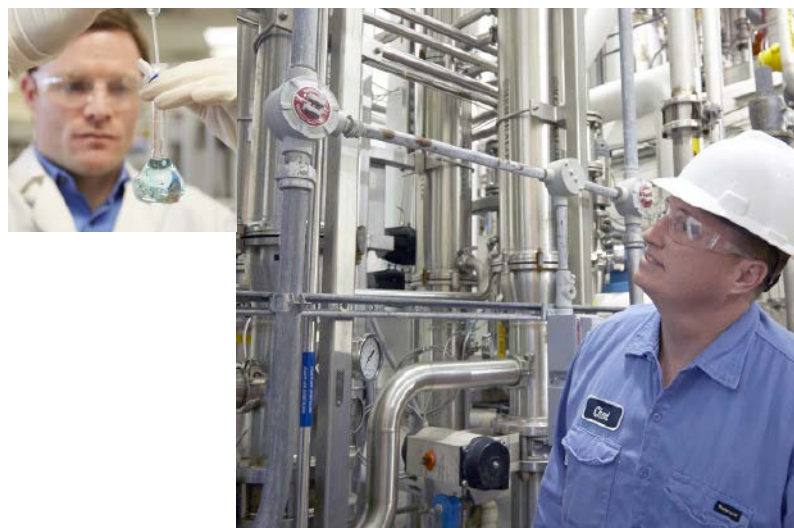
## Analytical Testing

AbbVie offers a full suite of analytical services including:

- Method development, transfer and validation
- Raw material testing
- Final release testing
- ICH stability storage and testing

Analytical techniques include:

- HPLC, UPLC, GC, GC-MS, LC-MS, ICP-OES, ICP-MS
- Spectroscopy (FT-IR, UV/Vis and AA)
- Powder X-Ray Diffraction, DSC and Particle Size Analysis
- Moisture Analysis (KF and water activity)
- Microbiology Testing



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