EXPERIENCE UNRIVALED

Potent Drug Product and API

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 pharmaceutical developer and manufacturer. Other 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.

CAPABILITIES

Potency classification down to OEB 5 (OEL <1 µg/m³)

- Potent active pharmaceutical ingredients (HPAPI)
- Potent drug product
- Process development & kilo labs
- Analytical capabilities
- Security infrastructure for controlled drugs

DEVELOPMENT SERVICES

Drug Product Development (Lake County, IL)

- Tablet and capsule production from Phase I–III
- Blending (3 L – 300 L bins)
- Dry granulation (Gerteis roller compactor)
- Wet granulation (10 L – 75 L high shear)
- Drying (single pot processing)
- Milling (Comil)
- Compressing and coating (1 kg – 15 kg)

CONTRACT MANUFACTURING
USA **+1 800 240 1043** | Outside USA **+1 847 938 8524** | **abbviecontractmfg.com**

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COMMERCIAL MANUFACTURING SERVICES

API production (Sligo, Ireland)

- Dedicated hydrogenation suite (4,000 L)
- Independent and configurable glass and stainless steel equipment trains (400 L– 4,500 L)
- Wet mill technology
- Identical process train configuration to facilitate scale-up activities
- Class 10,000 suites with hastelloy and 316 stainless steel filter dryers (3 suites ranging: 5 kg – 250 kg)
- Process control temperature (5°C – 105°C)
- Split butterfly valve transfer technology
- Purified water system
- Small kilo scale reactors (including high pressure reactors)

Drug product manufacturing (Sligo, Ireland)

- Tablet (IMA 300) and capsule (Imtric 150) production (Phase I – Commercialization)
- In-bin International Bulk Container (IBC) blending capabilities (50 L– 420 L)
- Contained IBC to IBC transfer and milling stations (Comil)
- Dry granulation (Gerteis roller compactor)
- Wet granulation (high shear) and drying single-pot processors (120 L– 300 L Collette single pot processing)
- Contained encapsulation suite with 100% weight checking and online metal checking (29 L– 250 L)
- Contained tableting suite (IMA Tablet Press) with in-process automatic weight check and in-line metal detection
- Contained tablet coating suite (Bahle 200) with adjustable tablet pan size – capable of color, enteric and active tablet / core coating
- Clean-in-place (CIP) systems

CLIENT SERVICES

Analytical services

- HPLC (reverse phase, normal phase, ion exchange, gradient and isocratic methods, pulsed amperometic detection, UV visible, diode array, and MS detection)
- LC / 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

Technical capabilities

- Licensed, state-of-the-art, multipurpose facilities in Europe and North America
- High containment capabilities
- Manufacture of potent drug substance and drug product
- FDA / EU approved
- Lean Six Sigma methodologies
- Licensed for investigational medicinal product supply
- Method transfer capability, product testing and GMP compliance
- Chemical, process engineering, pharmaceutical and project managers

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