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.
AbbVie can take your product from Phase I to commercialization.

**Product Development**

**STAGE 1**
**API CHARACTERIZATION**
- Assess technical feasibility for define ASD formulation & HME process
- Utilize small quantities of API for available physicochemical analysis
- Establish rational ASD for formulation/process design and characterization

**STAGE 2**
**FORMULATION SCREENING**
- Identify prototype and clinical formulations
- Prototype & clinical formulations; dissolution and stability characterization
- Analytical methods development

**STAGE 3**
**FORMULATION & PROCESS DEVELOPMENT**
- Define commercial formulation, process train, process conditions
- Small-pilot scale runs
- Finalized/optimized formulation; process characterization
- 11 mm – 26 mm screwsize

**STAGE 4**
**PROCESS SCALE-UP**
- Scale up and optimize process at commercial scale and define design space
- Formulation & process development finalization
- Process development finalization (design space, CMA, CPP, IPC justification)

**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