Oral solids made with intelligent collaboration

Pfizer CentreOne

Listening. Solving. Guiding.

Welcome to Pfizer CentreOne. We're a global CDMO embedded within Pfizer. We excel in the manufacture of oral solid dosage forms.

Working together with our customers, we combine our technical and commercial knowledge with open dialogue to solve challenges.

Intelligent collaboration with Pfizer CentreOne.

For more than 40 years, we've been guiding complex compounds securely and efficiently from development through commercial manufacture.

Backed by Pfizer resources, we have the experience, flexibility and scale to deliver technical expertise, global regulatory support and long-term supply.

More collaboration, better solutions.

Flexible oral solid dose manufacturing.

Pfizer CentreOne has integrated cGMP pilot facilities dedicated to process optimization, clinical drug manufacturing, and scale-up technology transfers.

We offer commercial manufacturing for global / large-volume solid forms production.

We're known for our:

- Specialized solid dose technologies
- Full range of OEB 1-5
- State-of-the-art facility design with segregated areas for multi-product and high containment manufacturing

Our oral solids network includes sites in:

- Germany (Freiburg)
- Ireland (Newbridge)
- Italy (Ascoli)
- Japan (Nagoya)

We offer comprehensive regulatory submission support that has established approvals around the globe, including FDA (United States), EMA (European Union), ANVISA (Brazil) and PMDA (Japan).

You want to get to market as quickly as possible. Let's collaborate and we'll help you navigate the technical and regulatory hurdles of your oral solids project.

Clinical Phases

- Development & manufacturing
- Technical transfer
- Formulation optimization
- Scale-up/validation

Submission

- CMC preparation
- Final package
- Pre-approval inspection

Launch

- Drug to market
- Production efficiency studies

Lifecycle management

- Cold-chain management
- Supply/distribution
- Drug delivery expansion

Capabilities at a glance:

Compound classifications

- Highly active compounds
- Immunosuppressants
- Sensitizers
- Hormones
- Controlled drugs
- Cytostatics/Cytotoxics

Manufacturing capabilities

- Dry granulation
- Roller compaction
- Wet granulation
- Fluid bed granulation
- High shear granulation
- Wet & dry milling
- Extrusion/Spheronization
- Hot melt extrusion
- Compression
- Encapsulation
- Film coating
- Sugar coating
- Active coating
- Solvent coating
- Fluid bed coating
- Branding/Printing
- Automated inspection
- Serialization

Delivery technologies

Capsules

- Immediate-release
- Modified-release
- Powder-filled
- Pellet-filled

Pellets

- Immediate-release
- Modified-release
- Enteric-coated

Tablets

- Immediate-release
- Modified-release
- Fast-dissolve
- Bi-layer
- Active-coated
- Sugar-coated
- Dual-active overcoat
- Laser tablet drilling

Packaging

- Packaging Centers of Excellence for bottle and blister
- Automated lines
- High-volume and flexible-run packaging
- OEB 1-5 (OEL 10,000-0.01 µg/m3)
- Cold-forming and thermoforming capability
- Containment control (i.e. packaging of hormone products)
- Packaging on demand
- Humidity control
- Serialization

Gateway drug product packaging for Japanese market:

- In country Packaging Center of Excellence for Japan inspection/packaging
- State-of-the-art inspection technologies
- On-site PMDA regulatory experts

Regulatory overview cGMP inspections

Major market approvals in over 150 markets served:

AIFA, ANMAT, ANVISA, EMA, FDA, HPRA, IMB, INVIMA, Korean FDA, NMPA, PMDA, Russia MOH, Supervisory Agency Germany, TFDA, Turkey BOH