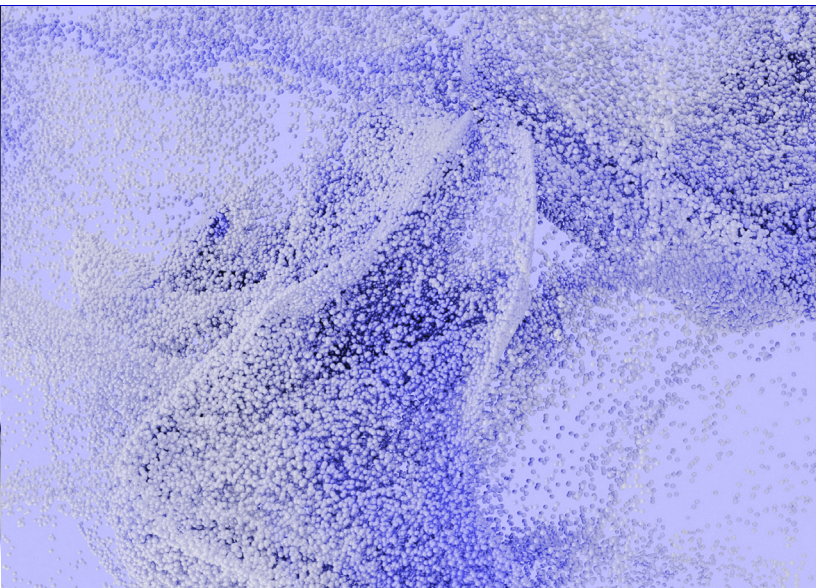


# Making the complex. Simple.



# Ready to meet your complex OSD needs, seamlessly and simply.

## Simplify your OSD's manufacturing with a leading CMO, powered by Pfizer.

### Your complex OSD challenges, expertly handled

Making the complex simple to help meet your OSD needs is our specialty. Leveraging the global Pfizer network of scientific experts, you benefit from our decades of experience in successfully delivering high-quality OSD products – including highly potent, cytotoxic, controlled and immunosuppressant drugs. Paired with specialized technologies like laser drilling, multi layer coating and oral disintegrating tablets in state-of-the-art facilities where we provide you with the infrastructure necessary to help support your most complex OSD needs.

### Unwavering reliability. Uncompromising quality.

To streamline your OSD's production, we provide services designed to help foster reliability, with a right first time approach. A robust technology transfer process ensures a fast start, while our process analytical technology helps increase efficiency and reduce cost – helping your product accelerate to the patients waiting. This methodology has led to a strong track record of success delivering on-time, in-full (OTIF) over 90% of the time, with no issues on audit.

**With a wide range of OSD platform manufacturing and packaging formats, our services are designed to help provide the optimum balance between product customization and effective and reliable supply.**

### Simplicity in scale and scope

From late stage clinical to commercial we have the processes in place to meet your needs even as they evolve. Irrespective of platform or packaging demands and with focus on efficient use of your API. To ensure we understand your evolving priorities, we're committed to transparent communication by leveraging protocols for data-sharing in real time to keep you up to date and solidify trust as we help you build your lasting legacy.

#### We're known for our:

- Ability to support a range of volume requirements
- Specialized capabilities to support complex oral solids
- OEB 1-5 facilities around the world
- State-of-the-art facility design with segregated area for multi-product and high-containment manufacturing
- Experts in a wide range of packaging platforms and formats
- Supply chain reliability

#### Our oral solids network includes sites in:

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



#### Late stage clinical phase

- Manufacturing
- Technical transfer
- Formulation
- 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

Regulatory experience for more than 150 countries, supporting you around the globe



## Capabilities at a glance:

### Compound classifications

- Highly active compounds
- Immunosuppressants
- Sensitizers
- Hormones
- Controlled drugs
- Cytostatics/cytotoxics
- Multi-product
- Steroid & non-steroid anti-inflammatories

### Manufacturing capabilities

- Dry granulation
- Wet granulation
- Fluid bed granulation
- High shear granulation
- Roller compaction
- Wet & dry milling
- Extrusion/spheronization
- Compression
- Encapsulation
- Film coating
- Sugar coating
- Active coating
- Solvent coating
- Fluid bed coating
- Branding/printing
- Automated inspection
- Serialization

### Delivery technologies

#### Capsules

- Immediate- & modified-release
- Powder & pellet-filled
- Orally-disintegrating

#### Pellets

- Immediate- & modified-release
- Enteric-coated

#### Tablets

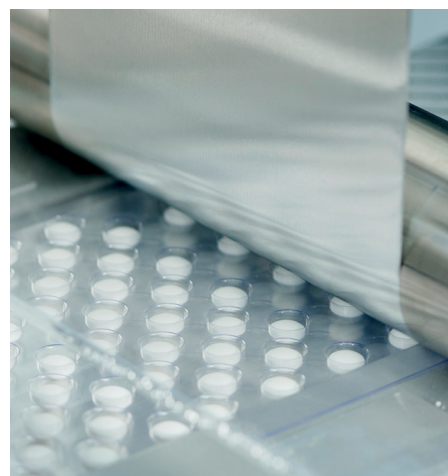
- Immediate- & modified-release (prolonged, delayed and multiphasic)
- Fast-dissolve
- Bi-layer
- Active-coated
- Sugar-coated
- Dual-active
- Overcoated
- Laser drilled
- Mini
- Enteric-coated
- Sublingual instant release

### Packaging

- Packaging Centers of Excellence for bottle and blister
- Automated lines
- High-volume & flexible-run packaging
- OEB 1-5 (OEL 10,000-0.01 µg/m<sup>3</sup>)
- Cold-forming & thermoforming capability
- Containment control (i.e. packaging of hormone products)
- Packaging on demand
- Humidity control
- Serialization
- Primary & secondary packaging

### Regulatory overview cGMP inspections

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



**From pellets, tablets and capsules to innovative release profiles, we have the global expertise to help meet your needs across a wide range of platforms and technologies.**

## Ready to build your OSD legacy?

With a strong track record of delivering on-time, in-full, [click here](#) to learn how we can streamline your OSD manufacturing.



**Regulatory experience for more than 150 countries, supporting you around the globe**

Leveraging Pfizer global expertise and in-depth understanding of the complexity involved in OSD manufacturing, we aim to streamline your manufacturing journey – because time is life.



**Rossella Bruni**

Site lead  
Ascoli, Italy



**Ard Lura**

Process manager in PPD  
Freiburg, Germany



**Lillian Glennon**

Operations director, Pfizer

## Get in touch with our **OSD** experts

Click here to learn more on how we can expertly handle your complex OSD challenges and help you build a lasting legacy.

[pfizercentreone.com/oral-solid-dose](https://www.pfizercentreone.com/oral-solid-dose)



[www.pfizercentreone.com](https://www.pfizercentreone.com)

**A CMO for therapies that define legacies**

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