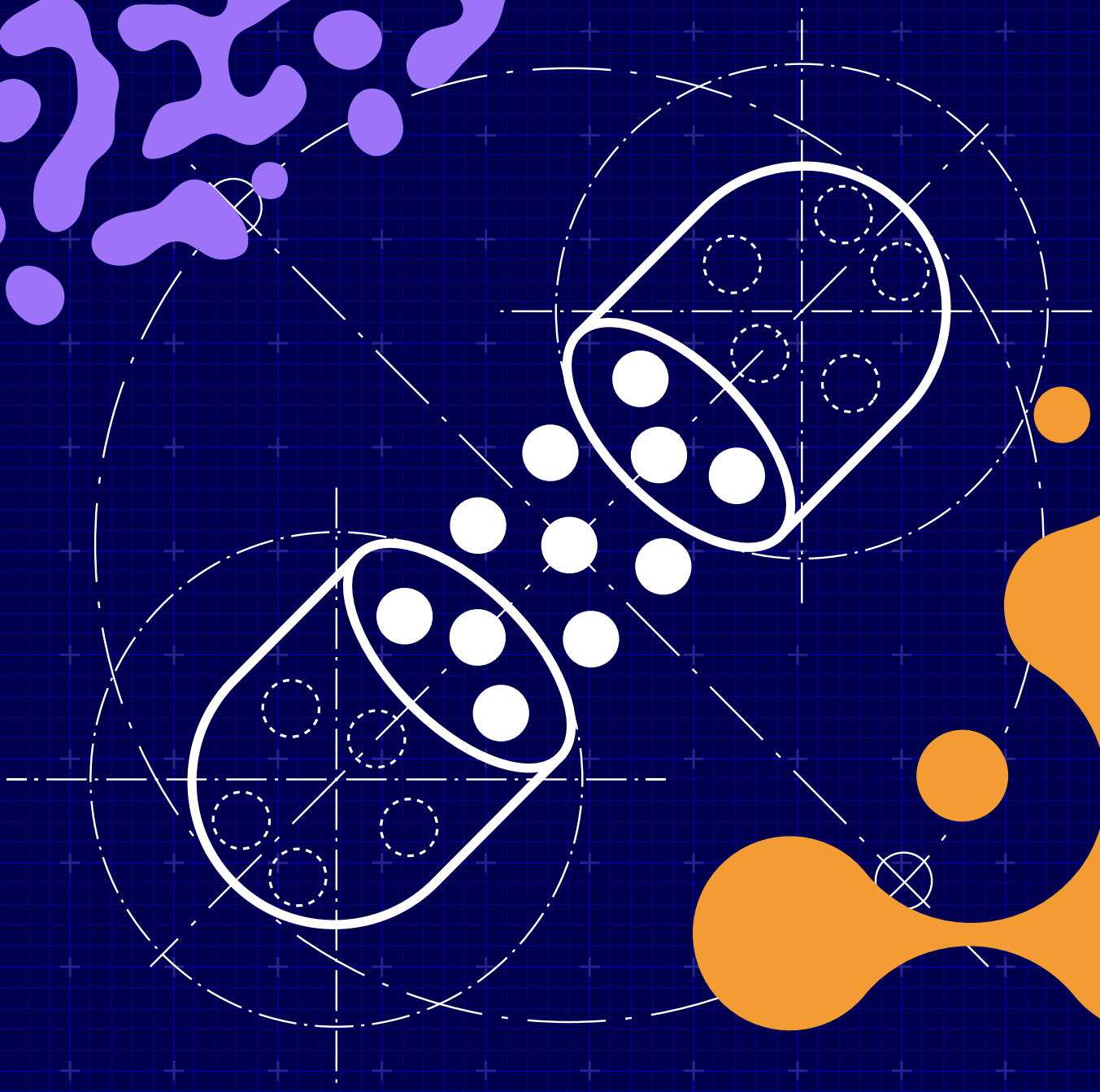
Pfizer CentreOne



Ready to meet your **complex OSD** needs, seamlessly and simply

Making the complex. Simple.

With a leading global CDMO partner, helping simplify your OSD's pathway to commercialization

Expertise to handle the complex

Making the complex simple to help meet your OSD needs is our specialty. By partnering with 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 and state-of-the-art OEB 1-5 facilities we provide you with the infrastructure necessary to help support your most complex OSD needs.

Reliability and quality

To streamline your project's journey to market 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 through key milestones 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

Our processes are further supported by the capability to help meet your changing requirements as the project scales from clinical to commercial levels, no matter your platform or packaging needs. To ensure we understand your priorities at every stage of your project, we're committed to transparent communication by leveraging protocols for data-sharing in real time to keep you up to date and solidify trust in our partnership.

We're known for our:

- Ability to support both high and low 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)
- Japan (Nagoya)

Clinical phases

- Development & 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

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
- 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- & 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/m³)
- Cold-forming & thermoforming capability
- Containment control (i.e. packaging of hormone products)
- Packaging on demand
- Humidity control
- Serialization
- Primary & secondary packaging

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

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 simplify your OSD journey?

With a strong track record of delivering on-time, in-full, click here to learn how we can support your entire path to commercialization.

By leveraging Pfizer's 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

Kentarou Yoshimoto
(吉元 健太郎)
Pfizer CentreOne site lead
Nagoya, Japan

Kieran Coffey
Technical services lead
Newbridge, Ireland

Get in touch with our OSD experts

Click here to learn how we can help meet your needs from clinical development to commercialization.

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