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## OSD capabilities overview

Know what's ahead with Thermo Fisher Scientific  
Oral Solid Dose (OSD) solutions

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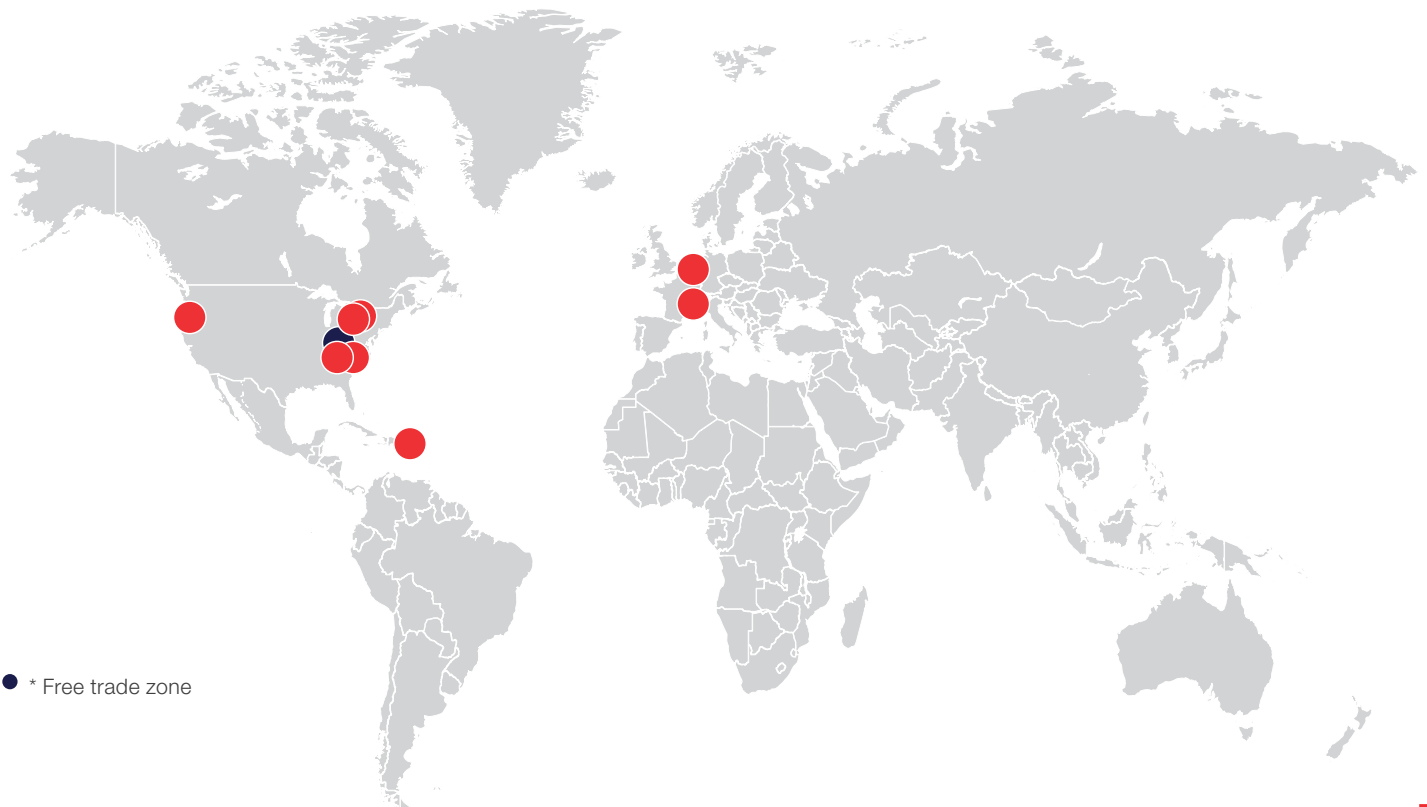
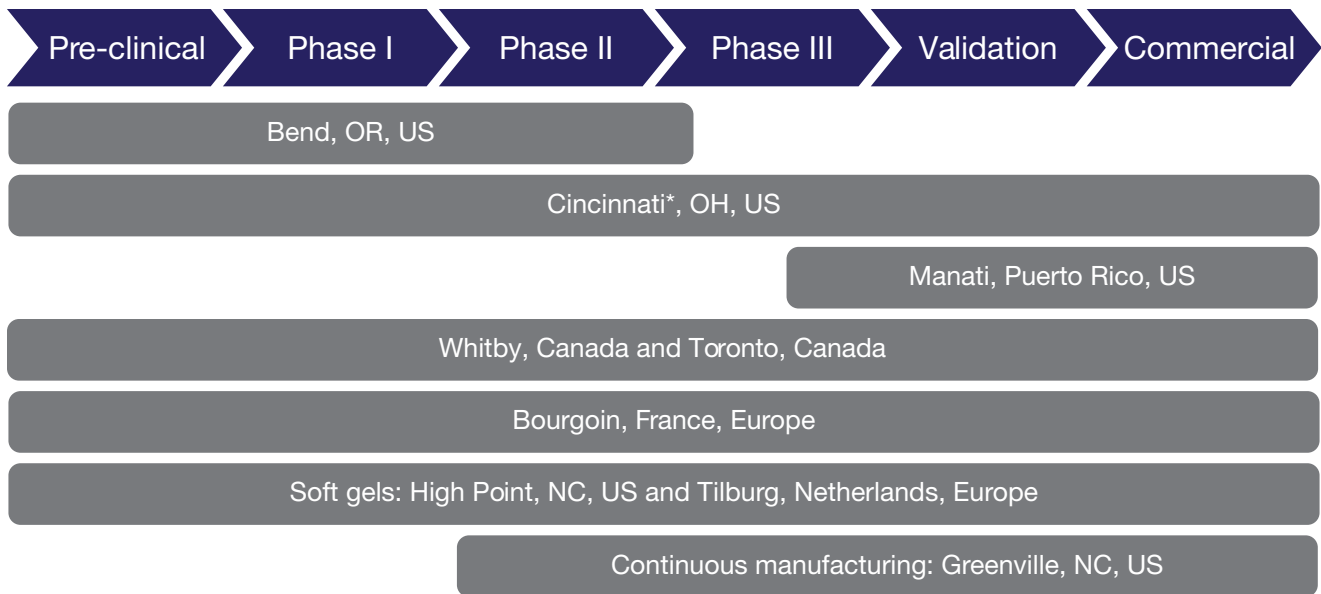
# Making your OSD right the first time

## Comprehensive global capabilities and resources for OSD development and manufacturing

### Global network of OSD development and manufacturing

Thermo Fisher Scientific comprehensive oral solid dose (OSD) services include phase appropriate formulation development, process optimization, and scale up to commercial manufacturing.

Our team of skilled scientists and engineers work closely with clients to develop tailored OSD formulations and optimized manufacturing processes, resulting in cost-effective and high-quality products delivered orally.



● \* Free trade zone

# OSD site specializations

## 9 locations across 2 continents

### Oral solid dose

#### Bend, Oregon, US

Clinical manufacturing

- High potency Cat 3 10 – 1  $\mu\text{g}/\text{m}^3$
- Small-scale formulation and process development
- Digital modeling
- Small-scale formulation and process development
- Gerteis roller compaction
- STYL'One compaction simulation
- Spray drying
- Hot melt extrusion
- Micronization
- Milling and blending
- Tablets and capsules
- Coating
- Packaging and labeling

#### Cincinnati, Ohio, US

Clinical and commercial manufacturing

- Free trade zone designation
- Cat 2 complex formulations
- High potency Cat 3 10 – 1  $\mu\text{g}/\text{m}^3$  controlled substances
- Humidity control
- Solvent handling (granulation and coating)
- Wet granulation, fluid bed drying, and Gerteis roller compaction
- Automated tablet and capsule inspection
- STYL'One compaction simulation
- Hot melt extrusion and spheronization
- OROS (membrane coating and laser drilling)
- Mini tabs and stickpack
- Liquid filled hard capsules
- Serialized bottle packaging
- Tablets, capsules, multiparticulates
- Non-sterile oral liquids
- Conventional extrusion

#### Toronto, Ontario, Canada

Clinical and commercial manufacturing

- High potency Cat 3 10 – 1  $\mu\text{g}/\text{m}^3$  and 10  $\mu\text{g}/\text{m}^3$  – 10  $\text{ng}/\text{m}^3$  tablets and capsules
- High potency Cat 3 10 – 1  $\mu\text{g}/\text{m}^3$  and 10  $\mu\text{g}/\text{m}^3$  – 10  $\text{ng}/\text{m}^3$  wet granulation, fluid bed drying, and Gerteis roller compaction
- Tablets, capsules, bi-layer tablets
- Coating
- Capsules
- Controlled substances
- Segregated hormone manufacturing and packaging
- Automated tablet and capsule inspection
- Serialized bottle and blister packaging
- Powder in bottle
- Laser printing

#### Bourgoin, France, Europe

Clinical and commercial manufacturing

- Low potency tablets
- High potency Cat 3 10 – 1  $\mu\text{g}/\text{m}^3$  and 10  $\mu\text{g}/\text{m}^3$  – 1  $\text{ng}/\text{m}^3$  wet granulation, fluid bed drying, and Gerteis roller compaction
- Bi-layer tableting
- Coating
- Capsules and tablets
- Serialized packaging (blisters and bottles)
- SYTL'One compaction simulation (high potency)
- Controlled substances
- Sachets
- Powder in bottle
- Non-sterile oral liquids

#### Whitby, Ontario, Canada

Clinical and commercial manufacturing

- Low potency tablets and powders
- Bi- and tri-layer tablets
- Bottle and blister packaging
- Humidity control
- High speed sachet
- Wet / dry granulation (Gerteis)
- Coating
- Capsules
- Non-sterile oral liquids
- Controlled substances
- Serialized packaging for all formats

#### Manati, Puerto Rico, US

Commercial manufacturing

- Medium to large scale commercial manufacturing (low potency)
- Free trade zone designation
- Controlled substances (DEA schedule 2 to 5)
- Wet granulation, including solvent
- High shear mixing spherical beads
- Tablets within a tablet
- Capsules
- Powders in bottle
- Coating (aqueous and solvent)
- Tablet printing
- Serialized bottle packaging

### Soft gels

#### High Point, North Carolina, US

Tilburg, Netherlands, Europe

Clinical and commercial manufacturing

- Free trade zone designation
- Soflet® gelatin enrobed tablet
- Highly potent compounds
- Versatrol® controlled release technology
- Sofgels®
- Entericare® delayed release technology
- Chewels®
- Twist-offs
- Soft lozenges
- In-line and off-line printing
- Hormones
- Controlled substances

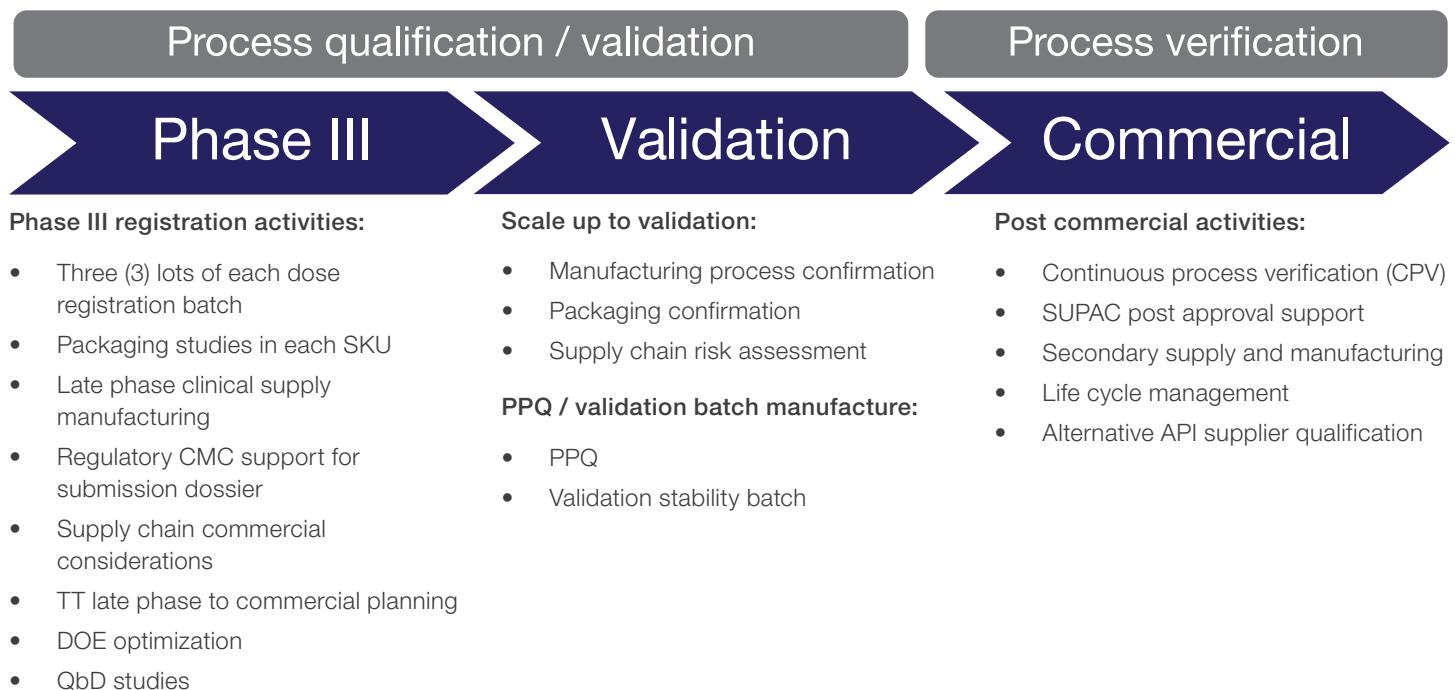
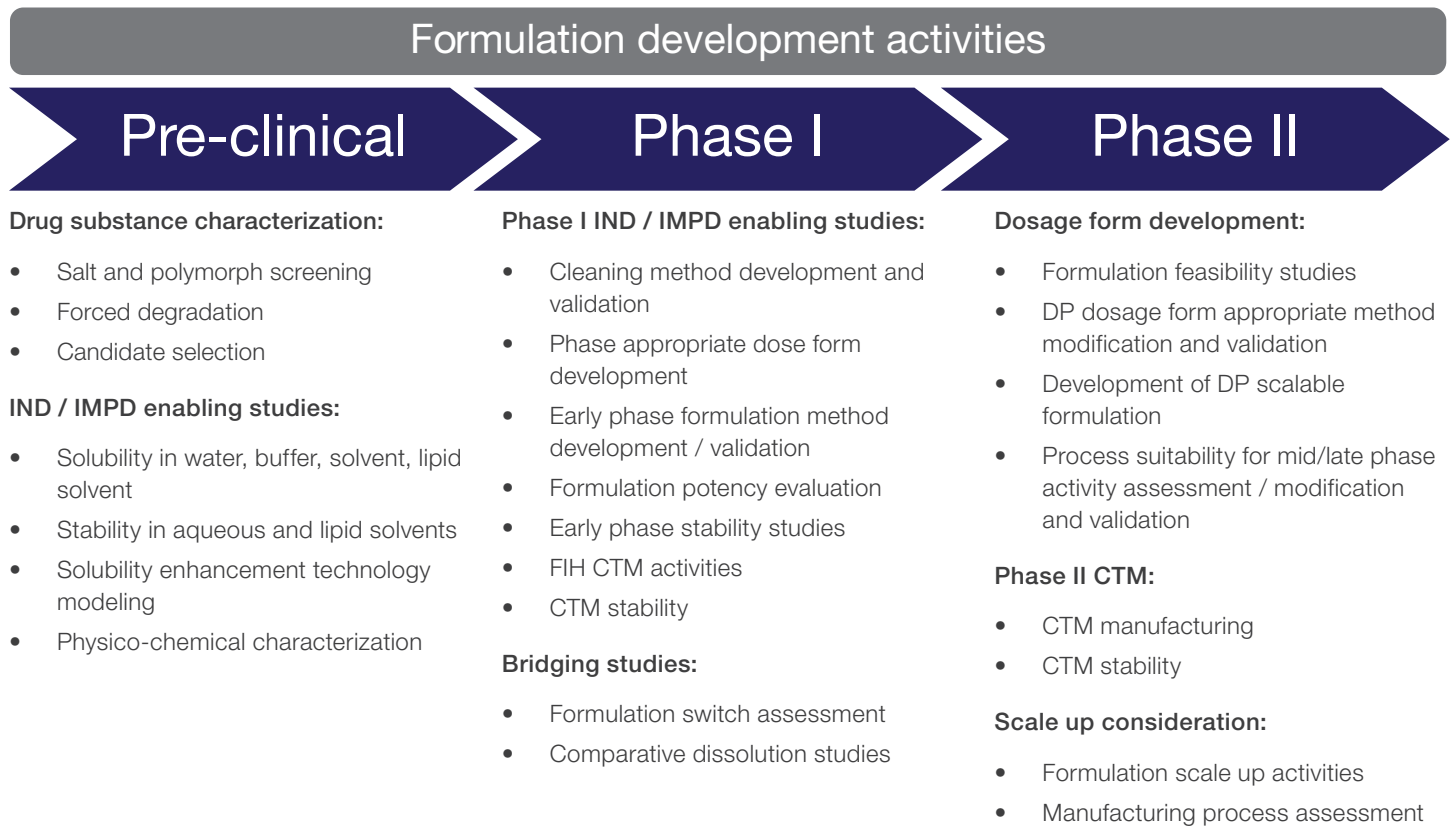
### OSD continuous manufacturing

#### Greenville, North Carolina, US

- Continuous tablet and capsule manufacturing
- Roller compaction (Gerteis)
- Low potency and high potency Cat 3 10 – 1  $\mu\text{g}/\text{m}^3$
- Direct blend and compression
- Controlled substances
- Tablets
- Capsules

# Manufacturing and development services

Phase appropriate activities and support from pre-clinical development to commercial manufacturing



 [Learn more](#)

# Manufacturing capabilities

## A broad range of manufacturing capabilities to meet your molecule's unique needs

### Manufacturing solutions from simple to complex forms

From simple to complex, access to a wide range of conventional and specialized dosage form manufacturing solutions can create an integrated drug formulation program that is customized to

your molecule's unique properties. We will work with you to ensure that speed and efficiency are built in to accelerate your molecule's journey to first-in-human (FIH) studies.

### Manufacturing capabilities

#### Compound types

- Low to highly potent (up to Cat 3 10 µg/m<sup>3</sup> – 10 ng/m<sup>3</sup>)
- Cytostatics
- Hormones
- Controlled / scheduled substances
- Sensitizers and other potent compounds

#### Dosage forms

- Tablets
- Capsules
- Granules / powders in bottles, capsules, stickpacks, sachets
- Softgels / liquid filled hard shells
- Non-sterile oral liquids (solutions and suspensions)
- Non-sterile liquid nasal sprays

#### Formulations

- Immediate release
- Enteric release
- Zero-order release
- Enteric + controlled release
- Colonic release
- Combinations of the above release profiles
- Pediatric dosage forms
- Fix-dose combinations

#### Batch sizes

- 0.5 - 2 kg
- 2 - 10 kg
- 10 - 100 kg
- 100 - 2,000 kg+

#### Processes

- Direct blending
- Dry granulation (roller compaction)
- High shear wet granulation
- Fluid bed granulation
- Film polymer coating
- Other

\* All manufacturing batches include analytical services including method development / validation, testing and release, stability services, and QP release.

#### Continuous manufacturing

- Modular design
- Direct blending
- Dry granulation
- Wet granulation
- Up to high potency Cat 3 10 – 1 µg/m<sup>3</sup>
- Line I (15 kg - 50 kg/hr)

#### Commercial manufacturing analytical solutions

- In-process control production support
- Release testing
- PAR studies
- Stability testing for various ICH climatic zones
- NDA / ANDA dossier support

# Integrated, value add services

## End-to-end support ensures you have the resources and expertise needed for success

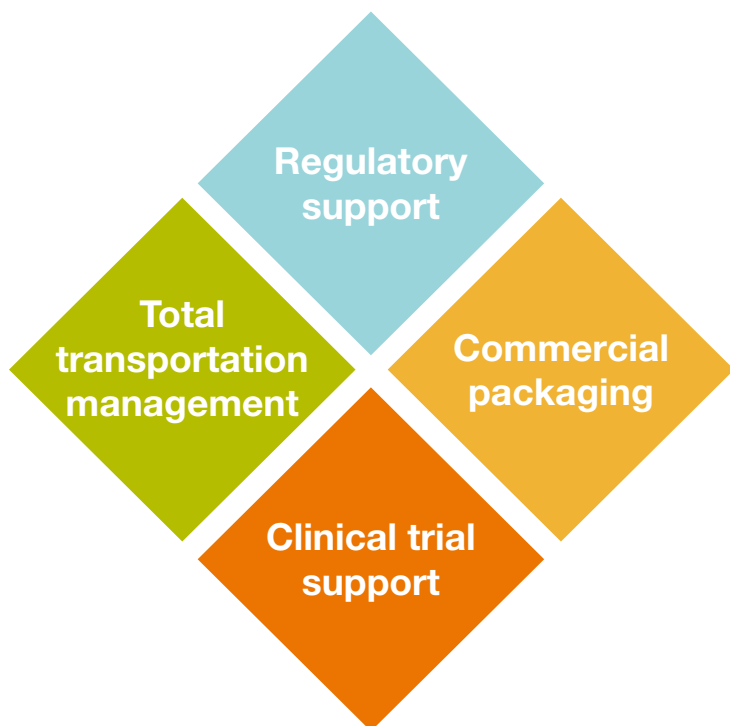
### Simplicity, speed, and scalability

Fully integrated, value add services across the clinical development and manufacturing spectrum ensure you have access to resources and expertise needed for success. For OSD development and manufacturing, integrated regulatory support, commercial packaging, clinical trial support, and total transportation management save time and mitigate risk.

Streamlined project governance, paperwork, and integrated timelines across service offerings ensure **simplicity** is built into the development process.

Improved information access across development and manufacturing services enable **speed** to meet aggressive timelines and proactively mitigate risk.

Global networks with regional expertise ensure **scalability** as the program progresses, leveraging the full suite of services from early development through commercialization.



**Regulatory support** - Regulatory support and consulting for major jurisdictions during dossier review, pre-submission, filing, review, and pre-licensure meetings and inspections

**Commercial packaging** - Reliable service levels and a focus on quality for both small and large volume commercial packaging

**Clinical trial support** - Integrated clinical trial services including packaging, labeling, supply chain optimization, distribution and logistics, and ancillary management

**Total transportation management** - Optimized transport routes and data-driven transportation mode selection provide better resource utilization and reduce risk

# Know what's ahead with OSD solutions

Flexible OSD solutions backed by a global network of expertise to address your small and large molecule's unique needs

## Drug development services

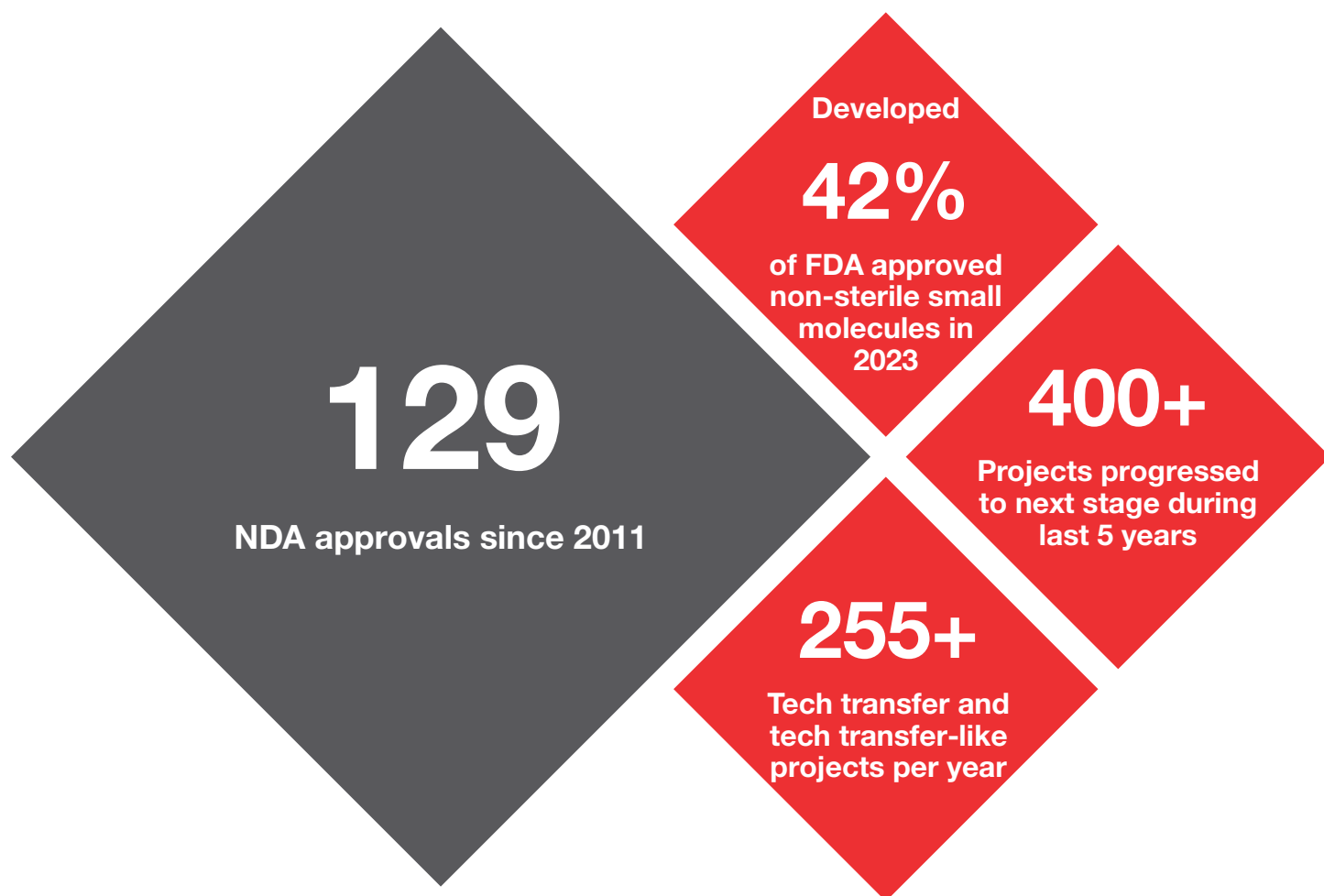
Streamline development with unmatched reliability and tailored expertise.

## Manufacturing services

A high-tech approach to project visibility to ensure quality and reliability.

## The power of one global network

Global network of experts available for your OSD needs during the entire lifecycle



 [Contact us](#) to learn more

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