ThermoFisher SCIENTIFIC

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Vision

API capabilities overview

We were involved in manufacturing 14% of all small molecules approved by the FDA in 2024

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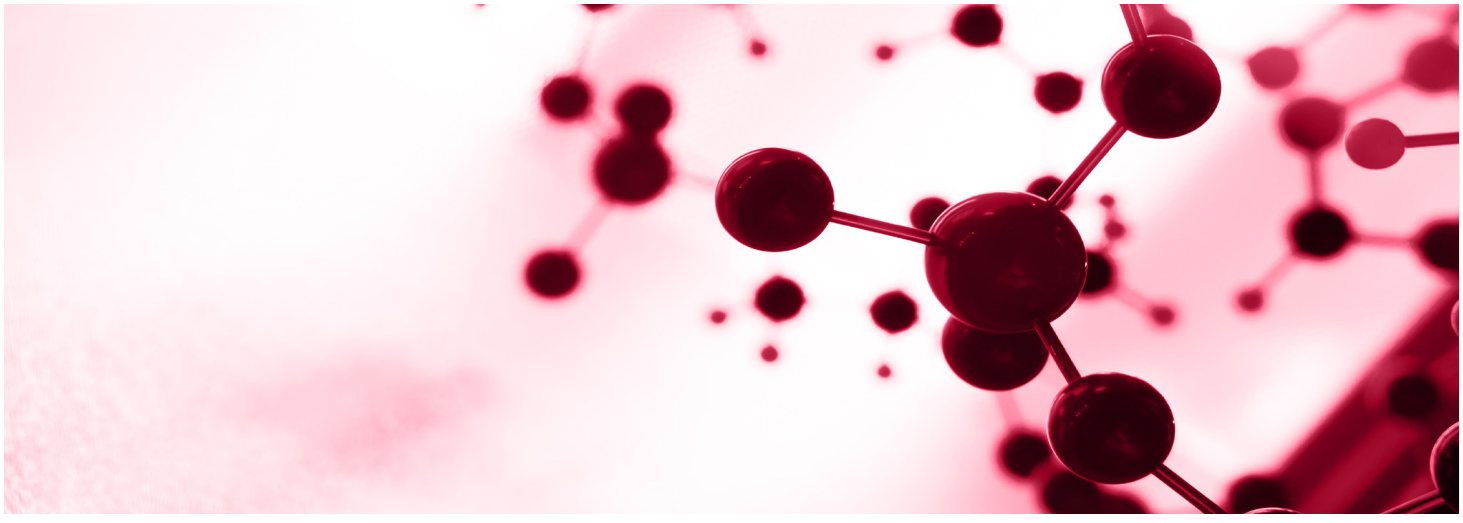


Making your API right the first time

Development and manufacturing services to scale your API from grams to tons

Realize your small molecule's full potential

Don't choose between depth of expertise and breadth of experience. Thermo Fisher Scientific's breadth and depth aligned with your vision minimizes risk and provides holistic product lifecycle management. Flexible API development and manufacturing solutions backed by a global network of industry experts can address your small molecule API's unique needs.

Take advantage of the expertise of our world-class chemists and global network of development and manufacturing facilities. We offer a broad range of chemistries and our ability to integrate drug substance and drug product development with clinical services gives you the ability to scale your project under one roof.

Preclinical

- Route scouting
- Solid state/physical characterization
- Polymorph and salt screening
- Process development
- Complex API development
- Streamlined manufacturing of ADME/TOX batches

Clinical

- Phase appropriate analytical development
- Tox batch manufacturing through clinical Phase III
- Regulatory support through clinical development
- IND/NDA filing strategy support
- Scale up process development and cost optimization

Commercial

- API large scale manufacturing
- Complex API manufacturing
- **Global commercial manufacturing**
- Security of supply
- API sourcing
- **Supply chain management**
- Registration and validation support
- REACH support and registration

Direct access to chemistry expertise				Speed, efficiency, and flexibility
0.1–1 kg	Phase I 5–20 kg	Phase II 20–50 kg	Phase III 50–500 kg	> 5,000 kg
Process development	Process scale-up and optimization			Commercial production
Analytical development and validation				Process validation
Project management and regulatory support				

50 years of API development and manufacturing

5 locations across 2 continents

Development (preclinical to phase I/II)

Florence (West), South Carolina, US

- Process / analytical development for preclinical and clinical supply
- Off-site dedicated β-lactam plant
- Gram to several hundred kg production scale
- OEL: 1–10 µg/m^3

Regensburg, Germany

- Rapid scale-up of intermediates and APIs for Phase I/II clinical trials under cGMP/ISO guidelines
- Dedicated route selection/redesign to costs team
- Gram to 500 kg production scale
- OEL: 1–10 µg/m^3

Manufacturing (phase II/III to commercial)

Florence (East), South Carolina, US

- Commercial drug substance site offering HPC handling, process development, and scale-up
- Capabilities in solid state chemistry, micronization, and spray drying
- Mid to large volume manufacturing assets
- OEL: 0.1–10 µg/m^3

Cork, Ireland

- Small molecule API process development, scale-up, and commercialization
- Medium to large-scale API production
- Mechanical milling and spray drying development and manufacturing
- OEL: 0.1–1 µg/m^3

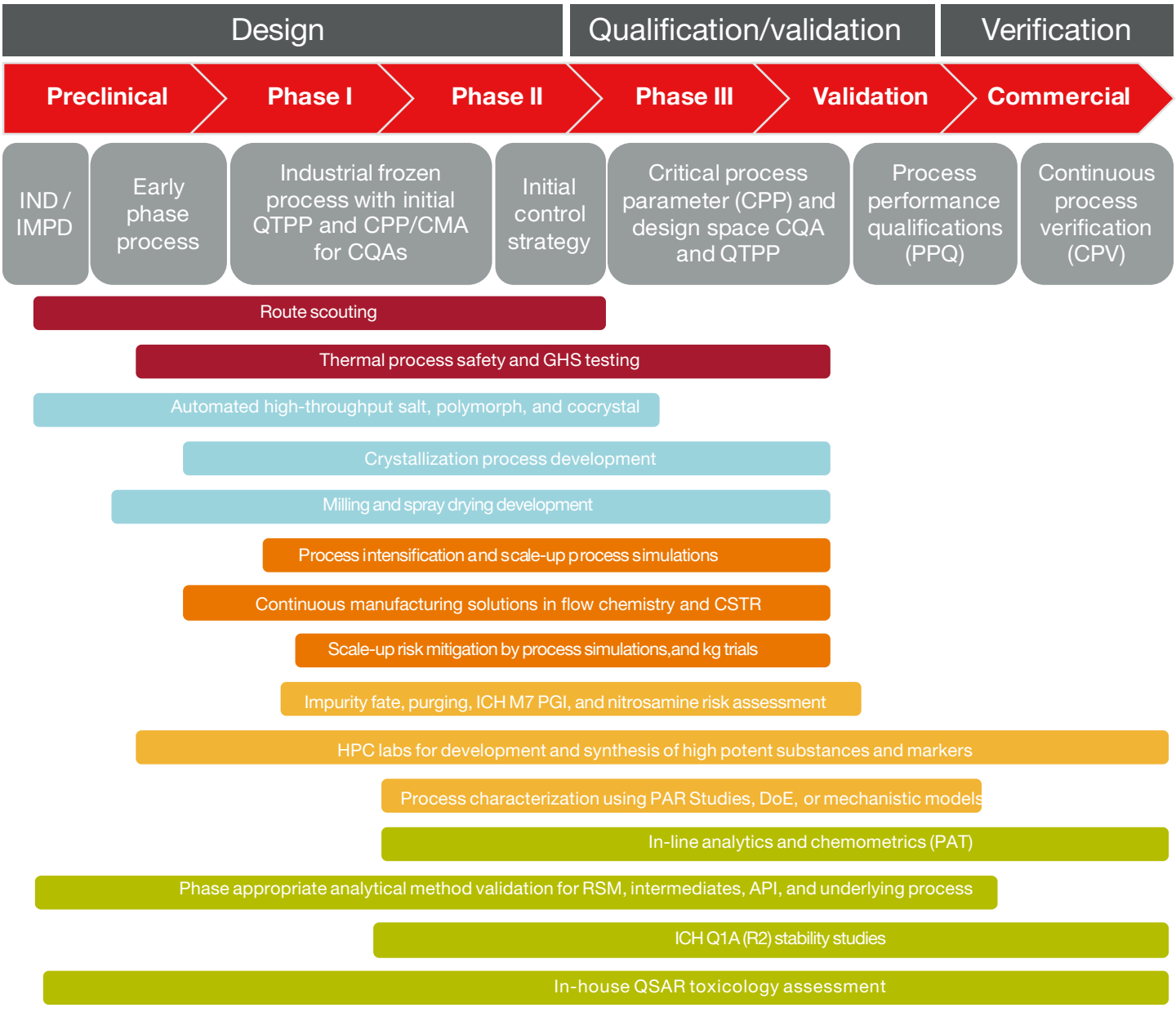
Linz, Austria

- Development, scale-up, and manufacturing of advanced pharmaceutical intermediates and API
- Solid-state R&D center
- Continuous commercial manufacturing
- Safe handling of highly reactive compounds
- OEL: 1–10 µg/m^3

Drug substance development capabilities

Direct access to chemistry expertise

From early process optimization work all the way to commerical-scale development, we provide key services across all phases of development to get your project to market. Work directly with scientists with deep chemistry knowledge and many years of experience in successfully supporting early and later phase clinical development programs. Our experts offer you cutting-edge technology from start to finish in multi-step chemical synthesis and from traditional to complex manufacturing.



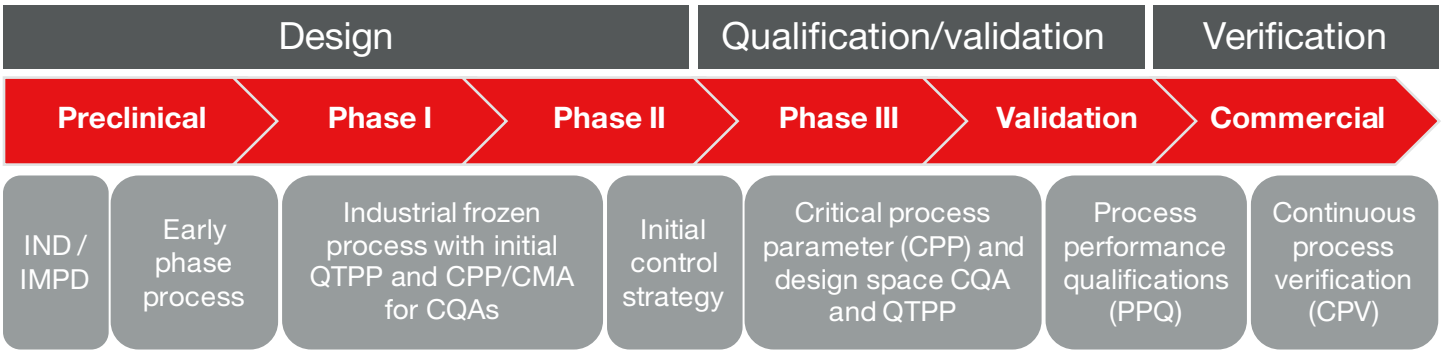
Learn more

Drug substance commercial manufacturing

Speed, efficiency, and flexibility

Thermo Fisher Scientific offers commercial API manufacturing under full cGMP conditions with speed, efficiency, and exceptional quality. We bring flexibility to adapt to changes in your market and will work to optimize your process to increase outputs while reducing timelines and costs.

As your trusted partner, we are committed to delivering the highest possible value while ensuring adherence to the highest level of quality, performance, reliability, regulatory and sustainability standards.



- Sourcing and external manufacturing of qualified (key) raw materials
- REACH registration
- cGMP manufacturing in stirred tank equipment (50L to 16 m^3)
- cGMP continuous manufacturing in CSTR, tube, and microreactors (up to 500 mt/y)
- Jet and mechanical milling for bioavailability enhancement
- Spray drying for bioavailability enhancement
- High potent manufacturing (HPAPI plants)
- Product distillation (fractional distillation, thin film distillation, falling film distillation)
- Large volume solvent recovery
- Continuous extractions
- Model predictive control supported manufacturing
- Process validation (traditional and enhanced approaches)
- Regulatory support

Learn more

Sustainability and clean chemistry

Global responsibility and environmental care

Supporting our net-zero commitment with API manufacturing

Global responsibility and environmental care are a cornerstone of our long-term commitment to continuous improvement. Energy assements have been completed at each facility and over 50 net-zero projects were identified including waste reduction, CO2 emission reduction, energy-saving and renewable technologies, wastewater reduction, responsible sourcing, and design for sustainability programs. In addition, there has also been a site-level decarbonization glidepath initiative commenced at each site to identify the end-of-life condition of all fossil fuel consuming equipment and future electrical capacity needs.

Cork, Ireland awarded best energy achievement in manufacturing and best energy management team

In September 2023, the Cork, Ireland site was awarded Best Energy Achievement in Manufacturing and Best Energy Management Team at the Business Energy Achievement Awards.

Cork's sustainabilty targets include:

- 50% reduction of Scope 1 and 2 emissions by the year 2030
- Net-zero emissions across the entire value chain by 2050

Cork's recent energy-saving initiatives and achievements:

- Thermal system upgrades, waste solvent treatment plant optimization, and HVAC system enhancements
- Powered by 100% renewable electricity in 2022 and operates a 3MW wind turbine that generates approximately 20% of the facilities power needs
- Achieved 44% emissions reduction in the past decade and on-track for a further 42% energy savings by 2025

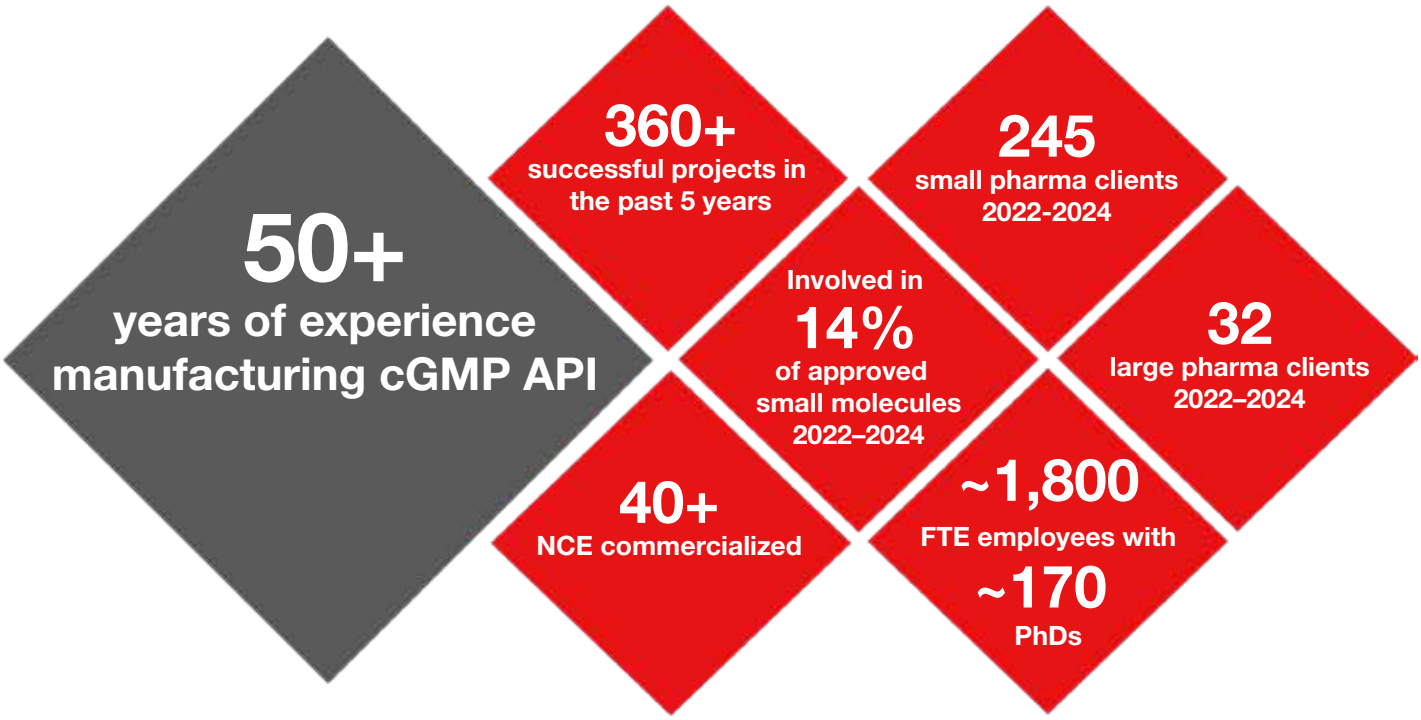
Depth and breadth to take your API from clinic to commercial

Flexible API development and manufacturing solutions backed by a global network of experts

Process and analytical development
Depth and breadth of expertise for complex API development and scale-up

Clinical-commercial manufacturing
Zero-defects mindset delivers successful API manufacturing and support

The power of one global network
Global network of experts available for your API needs during the entire lifecycle



Contact us to learn more

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