ThermoFisher SCIENTIFIC

ORAL SOLID DOSE FOR ONCOLOGY

ACCELERATE THE DELIVERY OF YOUR LIFE-SAVING THERAPY

- API
- BIOLOGICS
- VIRAL VECTOR SERVICES
- EARLY & LATE PHASE DEVELOPMENT
- CLINICAL TRIAL SOLUTIONS
- LOGISTICS SERVICES
- COMMERCIAL MANUFACTURING

patheon

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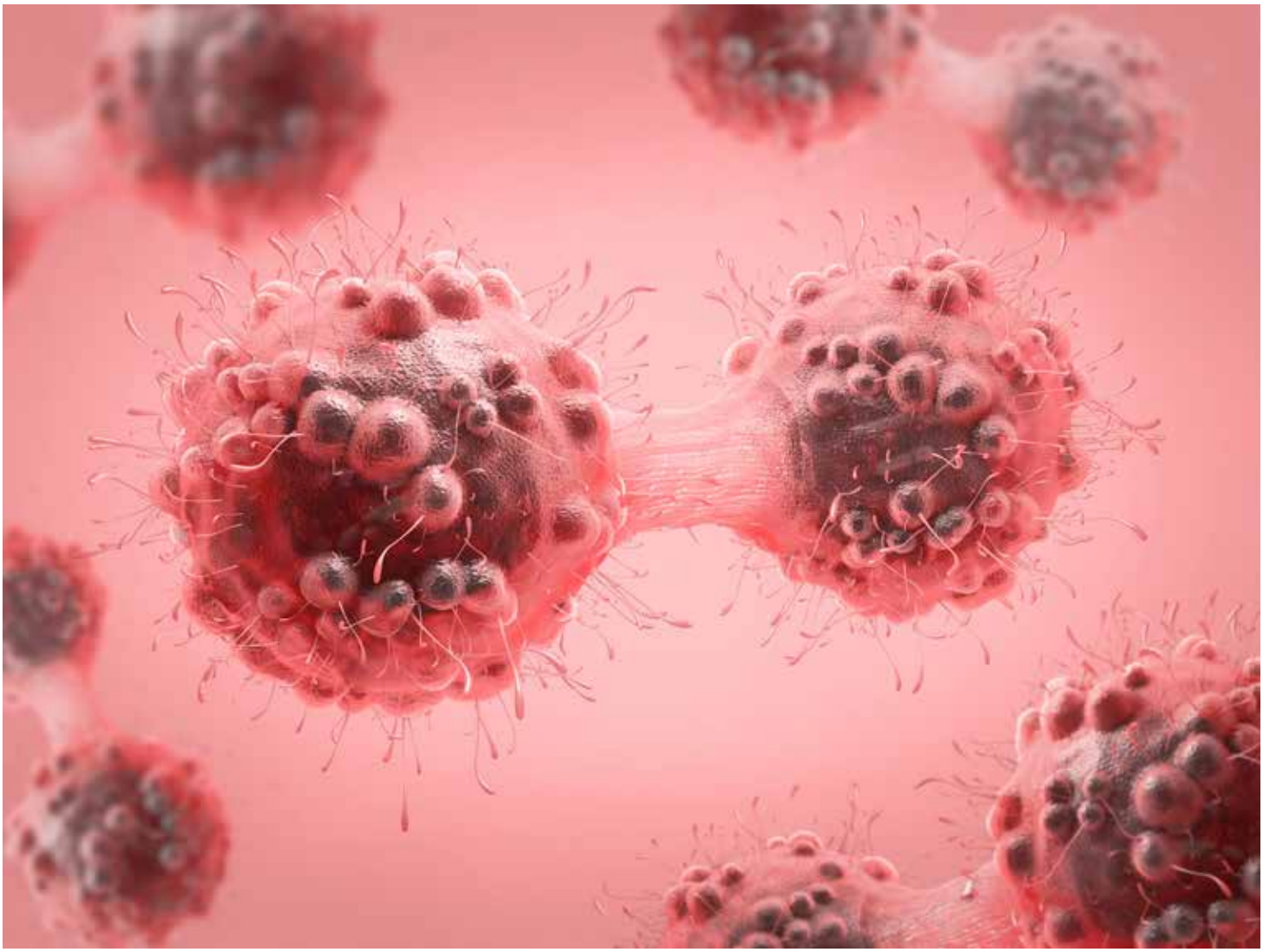


Introduction

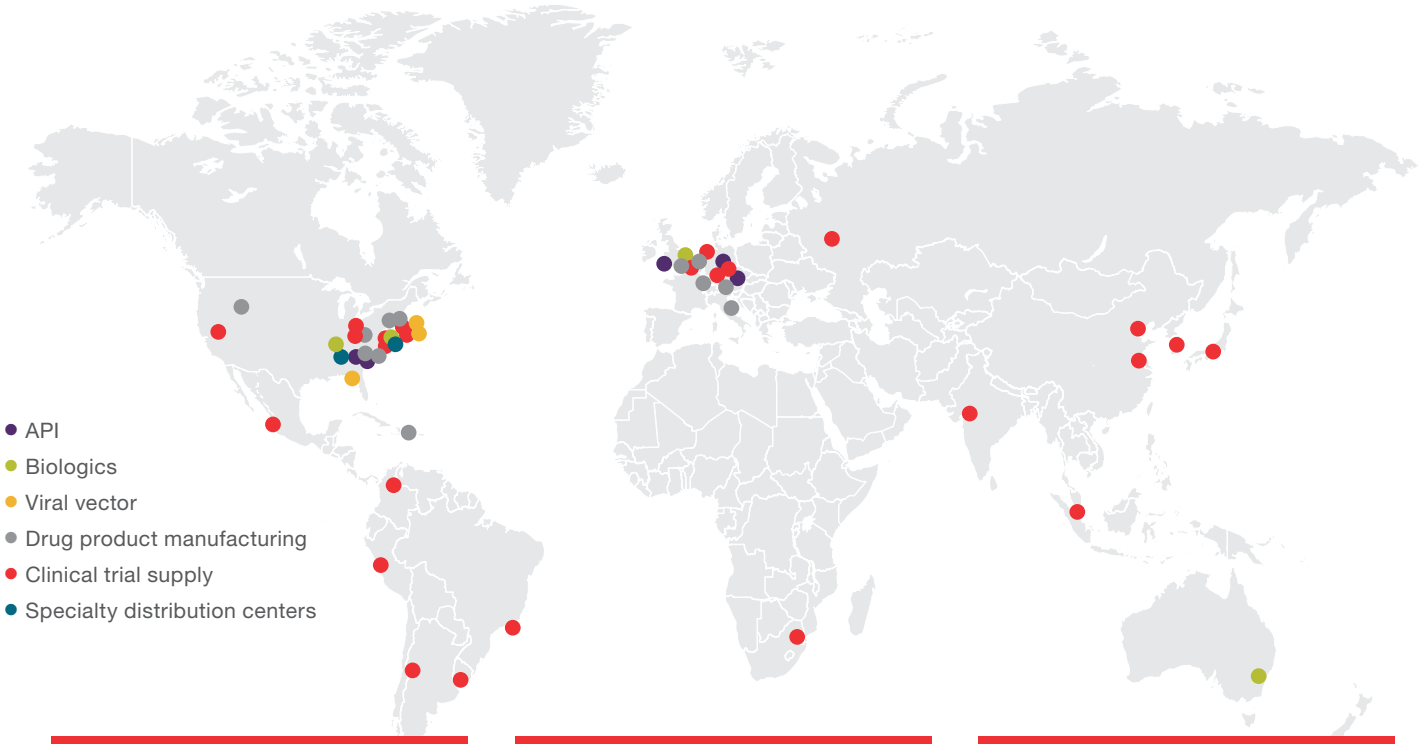
Fifty-eight percent of medications in development today are small molecule drugs, and many of them are earmarked for oncology drug products. Worldwide, the market demand for oncology products is attributed to regional and environmental factors. Your ability to navigate a complex regulatory environment, handle high-potency materials, overcome bioavailability challenges, and optimize the supply chain is vital to the success of your oncology drug product. Thermo Fisher Scientific provides a range of small molecule solutions that you can leverage to address your oncology program's unique needs and challenges, while being backed by a global network of technical, quality, and customer engagement teams and industry experts.

Streamline your supply chain and accelerate development

Thermo Fisher Scientific's small molecule offerings include robust **drug substance**, **drug product**, and **clinical trial supply** solutions that enable you to scale your project with speed and agility under one roof. Our global integrated network of 65+ sites comprises technical, quality, and customer engagement teams with the skills and expertise to help you resolve complex challenges through every phase of your small molecule's lifecycle.

In drug development, working with and coordinating multiple vendors requires additional time, resources, and expertise, and often results in delays in development and miscommunication among vendors. Our **Quick to Care™** single-vendor solution streamlines the supply chain and accelerates the development timeline so that you can bring your new oncology medication to market safely, quickly, and efficiently.

Integrated global network of technical, quality, and customer engagement teams to support the journey of your oncology drug product



~17,000
colleagues at **65+** sites

~3,500
experts with deep knowledge of science, engineering, and technology

~3,000
quality specialists

"Exceptional speed and responsiveness."

—Biotechnology company focused on oncology, USA

Avoid rework and costly delays in early development by getting your formulation right from the start

Speed and quality are essential in the development and manufacture of your cancer-fighting small molecule API. While you must reach several milestones along the way, you do not have to navigate this journey alone—Thermo Fisher offers a full range of services to help you quickly and efficiently bring your oncology project to clinical trial and further accelerate your path to commercialization.

Take advantage of the expertise of our world-class chemists and our state-of-the-art solutions that span all phases of development:

- Route scouting
- Solid-state chemistry and crystallization
- Commercial supply manufacturing
- Micronization
- Physical characterization

Getting your **formulation** correct in the early development stage can help you save time and money as your product advances through each phase and on to commercialization. Our scientists and experts in early development formulation are here to support every phase of your oncology program. Gain access to an integrated drug formulation program for flexible and tailored solutions to:

- Evaluate your formulation options
- Accelerate your project to first-in-human (FIH) studies
- Overcome formulation challenges (e.g., bioavailability, stability, and solubility)
- Gain a clear view of your path through preclinical and clinical studies
- Develop and manufacture fit-for-purpose, early-phase clinical materials
- Design, validate, and implement **analytical and process** methodologies
- Generate the data required for IND filings

Navigate the complexity of handling and containing high-potency compounds

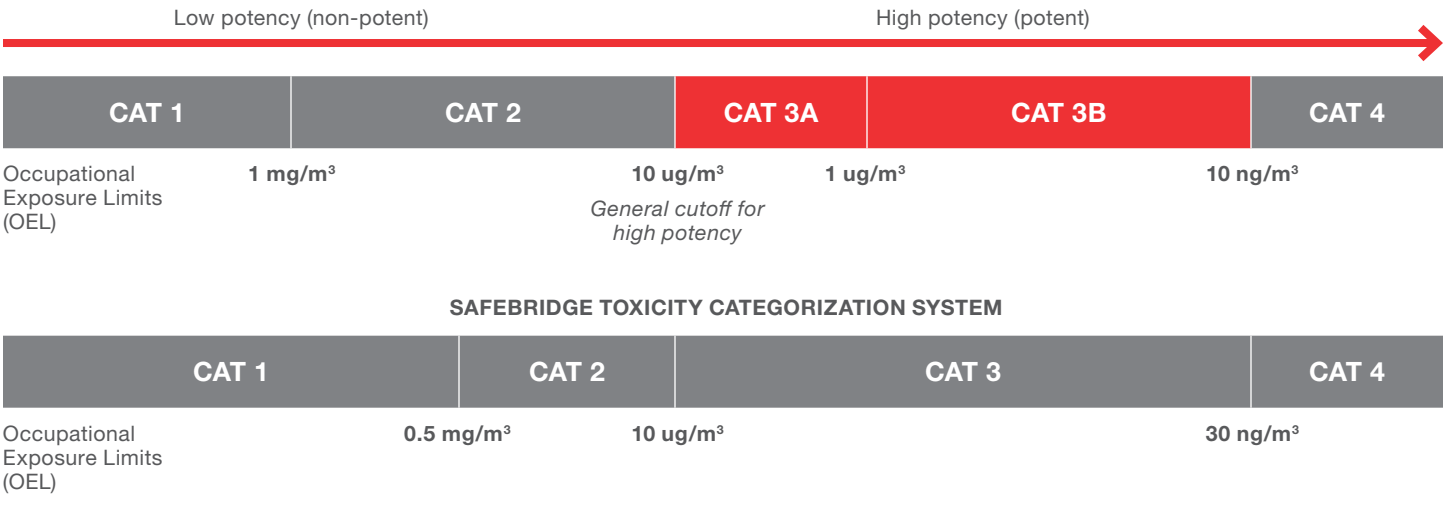
Since about 60% of all HPAPIs are being developed for cancer, a high-potency strategy is critical to the safety and success of your oral solid dose.[1] At Thermo Fisher, we ensure that the environmental health and safety (EHS) risks related to the products we manufacture are minimized and appropriately managed. The most effective way to do this is to have a robust EHS management system in place that can anticipate hazards before a process is introduced, recognize any existing hazards, and evaluate and control the risks associated with the presence of the hazard. Our categorization bands will ensure that your oncology program is being developed and manufactured to meet safety standards.

High potency: Pharma services categorization bands

CATEGORY 1	CATEGORY 2	CATEGORIES 3A AND 3B	CATEGORY 4
Compounds are typically very well studied; have minor, reversible effects; and are generally innocuous.	Compounds typically have more serious, reversible health effects, which occur at moderate to high doses.	Compounds have serious toxic effects at lower doses and include sensitizers, teratogens, carcinogens, and drugs with irreversible health effects. Based on the lack of sufficient data, drugs under development may be included in the category by default.	Compounds have exceptional toxicity and often cause severe, irreversible effects with very small exposures.

Capabilities to support growth of highly potent products

The number of highly potent molecules in the development pipeline is growing.



Solving your high-potency needs for API, drug product, and clinical services.

1 Switzerland joins major players as home to high containment API manufacturing facilities, GlobalData Healthcare, July 25, 2019
Note: Illustration not to scale
Source: Pharma Services Strategic Business Intelligence Pipeline Analysis August 2019; likely potency determined by Patheon EH&S, J. Galati (2019)

Solve solubility and bioavailability challenges before they become long-term issues

Poorly soluble compounds often demonstrate lower bioavailability, which can reduce the efficacy of the drug substance or product. Our solutions will ensure that your oncology product isn't hindered by these common challenges.

The need to quickly provide life-saving cancer drugs to patients doesn't correlate with a trial-and-error approach to formulation that is time-consuming and costly. Our **Quadrant 2™** program is an in-silico formulation development approach that saves time and reduces cost by avoiding the more traditional, empirical trial-and-error approach. This model analyzes the molecular structure and the physical and chemical characteristics of a compound, and then predicts the solubility enhancement technology and excipient combination that are most likely to succeed based on:

- API chemical structure
- Physicochemical properties
- Full-scale molecular modeling
- Exclusive excipient descriptor database developed by Thermo Fisher

We have analyzed 250+ molecules using Quadrant 2 for bioavailability challenges

We have extensive expertise and experience in spray drying thermodynamics, having spray-dried 120+ molecules

Spray drying is a strategic solution that addresses the bioavailability and crystallization challenges that are common across many drug substances and drug products. Thermo Fisher provides spray drying strategies that can be leveraged from early development to commercialization.

> ***"Technical strength in spray drying solid dispersion."***
>
> —Emerging biopharmaceutical company focused on autoimmune diseases, USA

Hot melt extrusion (HME) is a strategy for manufacturing amorphous solid dispersions (ASDs). Leveraging Thermo Fisher's HME solutions results in solvent-free processing, reduced cost of goods (COGs), and continuous manufacturing.

- Throughput rates from 20 g/hr up to 2.5 kg/hr
- Throughput rates of 5 to 25 kg/hr

> ***"Reliable, responsive, transparent. They always deliver and do not promise what they cannot deliver."***
>
> —Emerging biotechnology company focused on rare diseases, USA

Gain access to a broad range of dosage forms to meet your molecule's unique needs

Access to a wide range of conventional and specialized dosage forms, both simple and complex, can create an integrated drug formulation program that is customized to your oncology drug product's unique properties. We will work with you to ensure that your oncology discovery has a proof of concept with built-in speed and efficiency to accelerate your molecule's journey to FIH studies. When working with Thermo Fisher, you'll have access to a broad selection of dosage forms and release profiles.

Accelerate time to phase I clinical trials with Quick to Clinic™

Quick to Clinic for small molecules is an integrated approach that can expedite your product to phase I milestones and lay the groundwork required for phase II. Our comprehensive early development solutions solve complex molecule challenges by creating the most efficient route for your small molecule to reach FIH trials. Quick to Clinic allows you to save time, simplify your supply chain, and make investments for future milestones to deliver life-saving oncology products to patients quickly.

Fast

- Qualified Person (QP)–released product to the clinic in as little as 14 weeks from API receipt
- Phase-appropriate formulation
- Seamless manufacture, packing, and QP services

Flexible

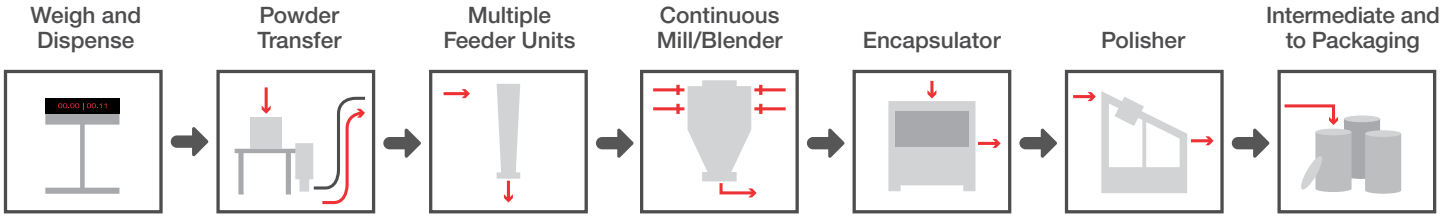
- Range of dose forms
- Seamless project management
- Technical expertise, fast problem-solving
- Reactive scheduling

Full

- One-month IND/IMPD stability
- QP release to clinic

Continuous manufacturing: Reduce API usage and total cost of supply

Encapsulation



Continuous manufacturing is an innovative solution providing flexibility and cost savings within your oncology drug manufacturing program by:

- Minimizing API usage
- Shortening development timelines
- Improving quality and consistency of products
- Reducing total cost of ownership
- Increasing control over manufacturing parameters
- Requiring a smaller manufacturing footprint
- Increasing process control for higher yields and less batch rejection

Optimize your regulatory process

The demand for oncology products today is high, so you don't have time to waste filing your IND. In a recent study of newly emerging and established pharmaceutical companies, leveraging a CDMO that has regulatory experience was an important attribute. We understand that getting your CMC strategy right from the start of your oncology molecule's journey can help save time and money as you advance through each phase and proceed to commercialization. Our regulatory experts will help you:

- Build a robust and flexible regulatory strategy for the short and long term
- Outline your options so that you can make the best decisions for your project
- Understand and evaluate trade-offs to ensure that they align with your goals and strategy
- Plan best practices for your product's lifecycle
- Optimize your submission to help you reach the next phase with efficiency

Technology transfer: Strategic investment for long-term advantage

Whether it's for scaling up or moving to another facility, **technology transfers** are part of the normal course of business. Our dedicated global experts ensure:

- Process validation is in accordance with regulatory and cGMP guidelines
- Speed and agility so that your project stays on track and your product supply is preserved
- Seamless execution for right-first-time (RFT) delivery
- Access to a robust system to manage the product lifecycle
- Insight to all stage gates required for each phase
- Access to stability studies, analytical data, release testing, and other regulatory documentation

In 2019, we successfully completed

119

technology transfers

44	60	15
commercial	drug substance	development

Commercial packaging provides assurance and simpler logistics in your supply chain

Thermo Fisher offers you flexible, integrated, end-to-end solutions and technical expertise in clinical and commercial packaging combined with other important value-added services.

Our breadth and depth of capabilities are designed to accommodate both small and large volumes to ensure that your product can be packaged in the most cost-effective way possible. Our commercial packaging can help:

- Simplify your logistics
- Provide reliable service levels and focus on quality
- Enable flexibility for both small and large volumes
- Streamline timelines with an end-to-end solution from development to commercialization
- Allow flexibility for changes in capacity for product growth or contingency planning

"Knowledgeable, flexible, understood the needs of a small biotechnology company, experienced scientists."

—Small biotechnology company focused on rare diseases, USA

Clinical trial solutions: Optimize your chances for approval

Thermo Fisher offers experience, reliability, and a broad range of fill/finish commercial capabilities. We have an enviable record of success in oral solid dose commercialization.

Leveraging our commercial production and **clinical trial** solutions will give you access to our extensive network of global technical experts as well as supply chain and transportation capabilities. Our solutions span:

- **Global clinical trial packaging and storage**
- **Clinical supply optimization**
- **Clinical labeling**
- **Distribution and logistics**
- **Global clinical ancillary management**

Contact us to learn more about how we can help you get your oncology therapy to patients with speed and agility.

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