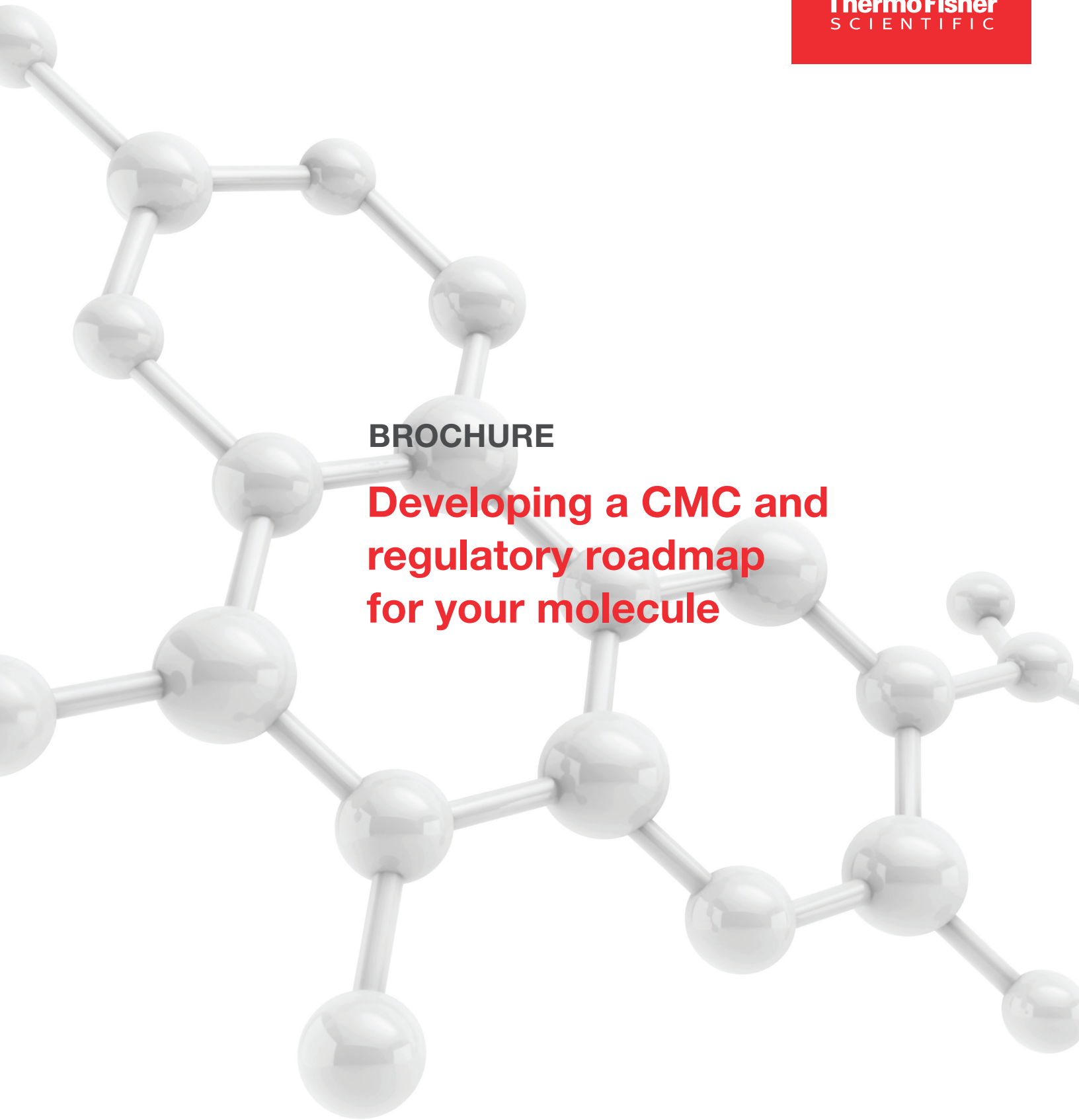
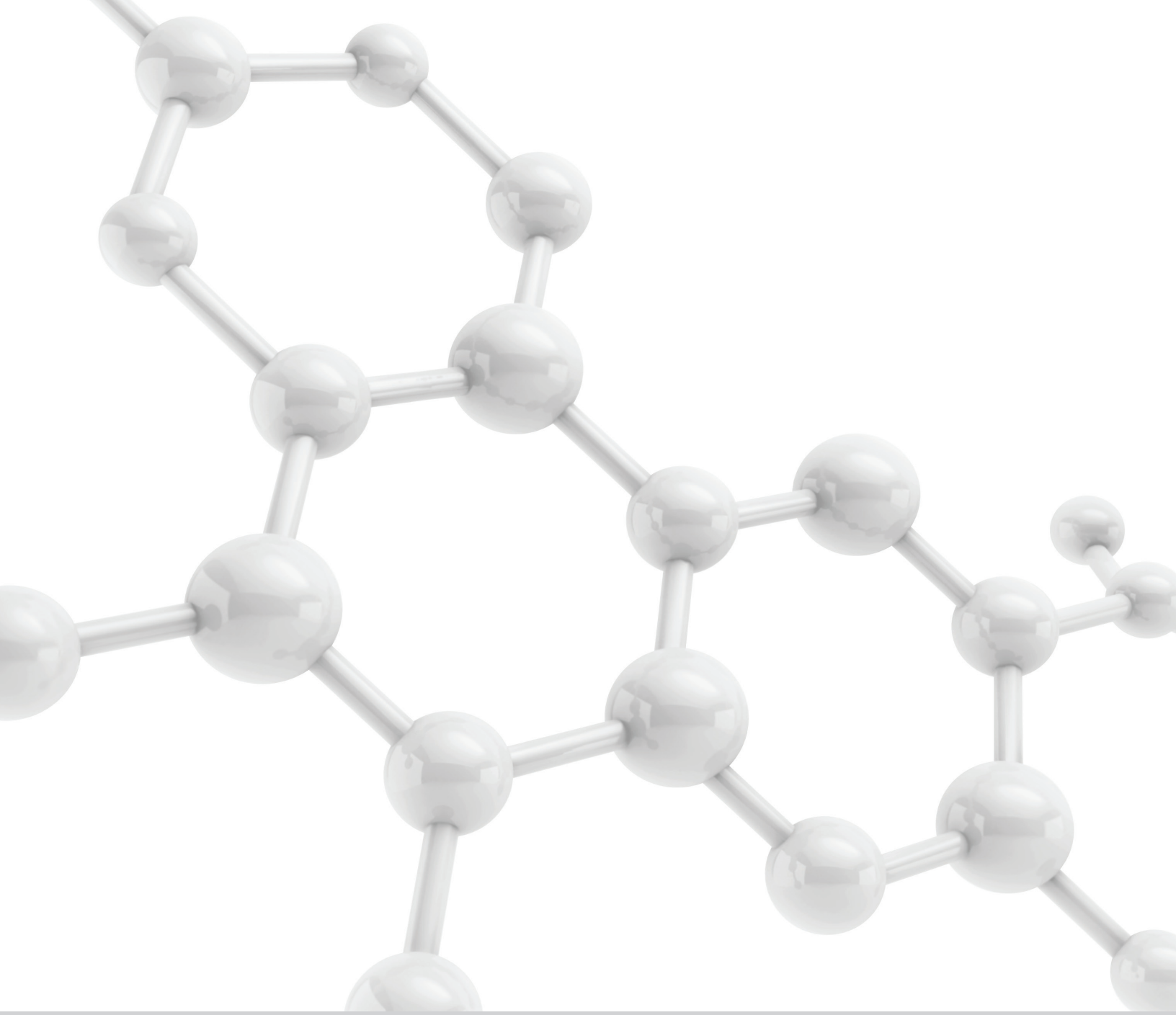


BROCHURE

Developing a CMC and regulatory roadmap for your molecule



Gain access to CMC and regulatory services from drug development through to commercialization

Navigating a complex regulatory environment is vital to the success of your molecule's lifecycle. Thermo Fisher Scientific has managed regulatory submissions in over 180 countries. We provide a range of flexible regulatory solutions that can help easily address your molecule's unique needs and challenges, while being backed by a global network and seasoned regulatory experts.

Thermo Fisher Scientific has an integrated global network of sites comprising regulatory, technical, quality, QP (EU buyer), and customer engagement teams—each team can help support and solve complex challenges through every step of your molecule's lifecycle. Our regulatory solutions for **oral solid dose** and **steriles** span across our global network.

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Document preparation
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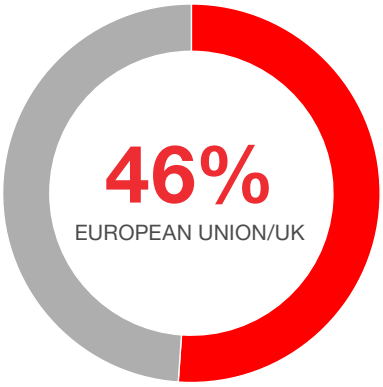
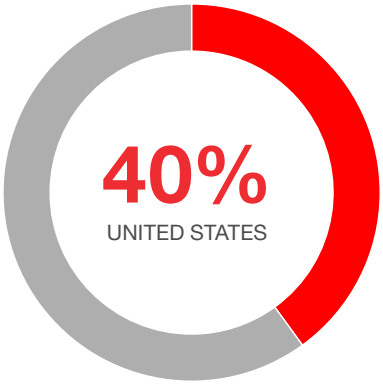
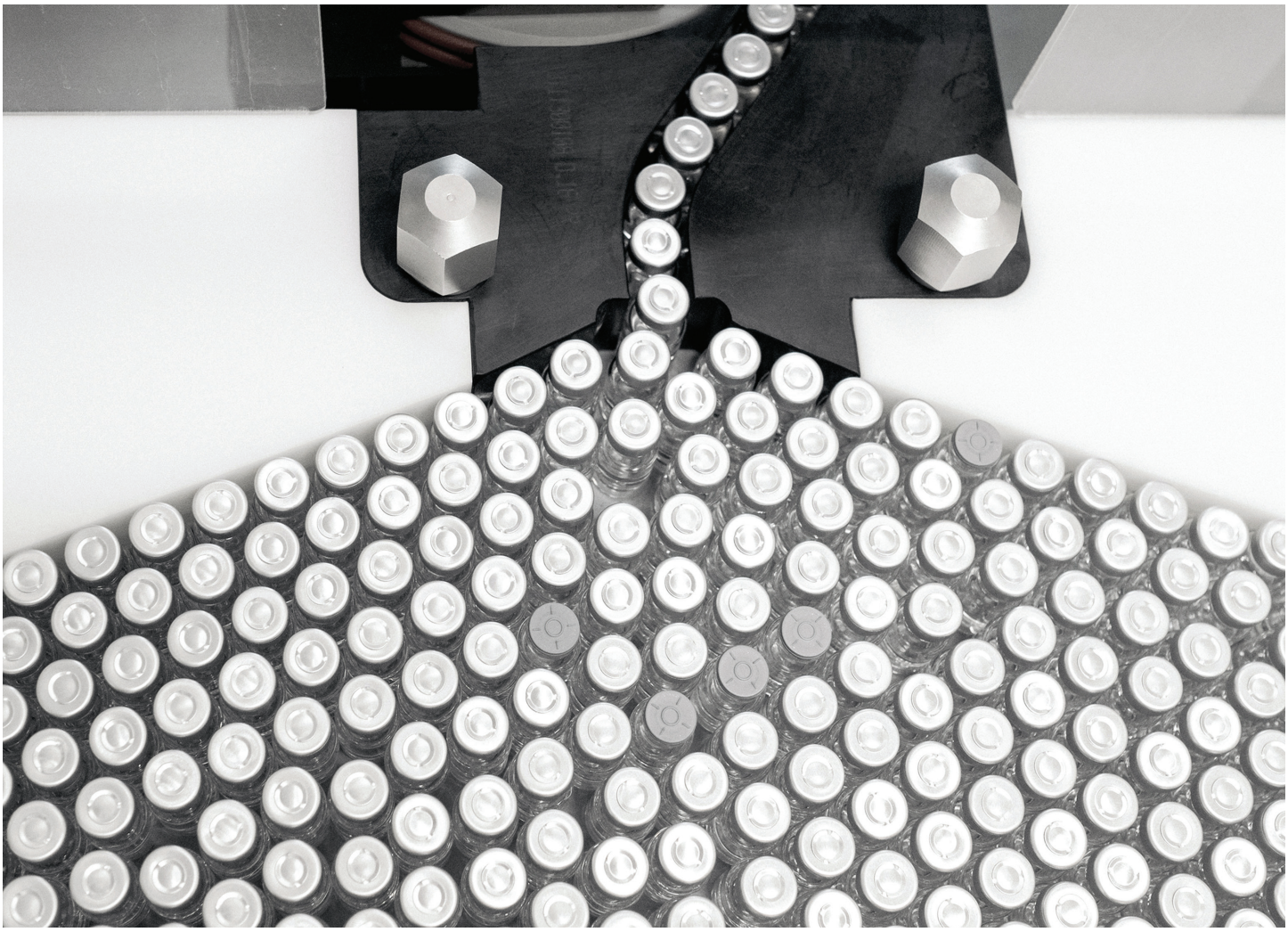
Regulatory expertise

Our regional support and expertise from 2020-2023

We provided regulatory services on 477 dossiers (writing and review), related to 185 products.





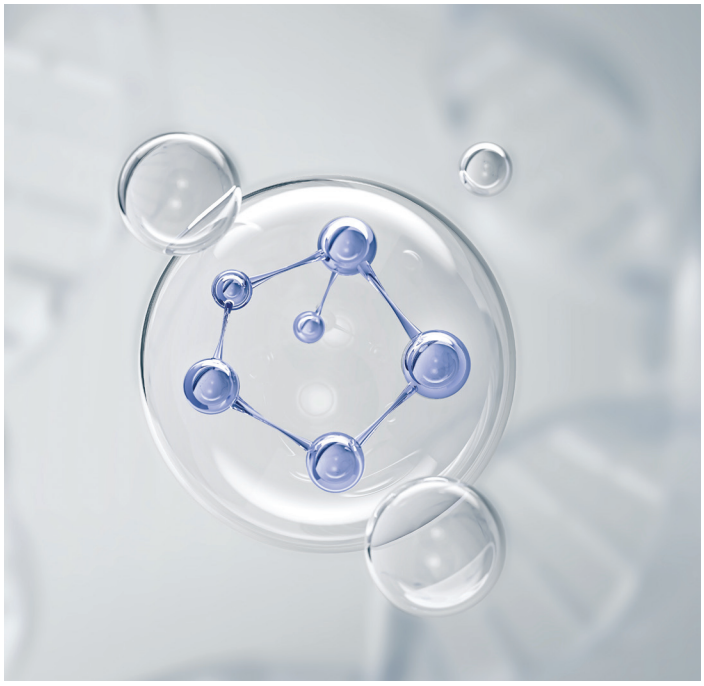


CMC strategy development

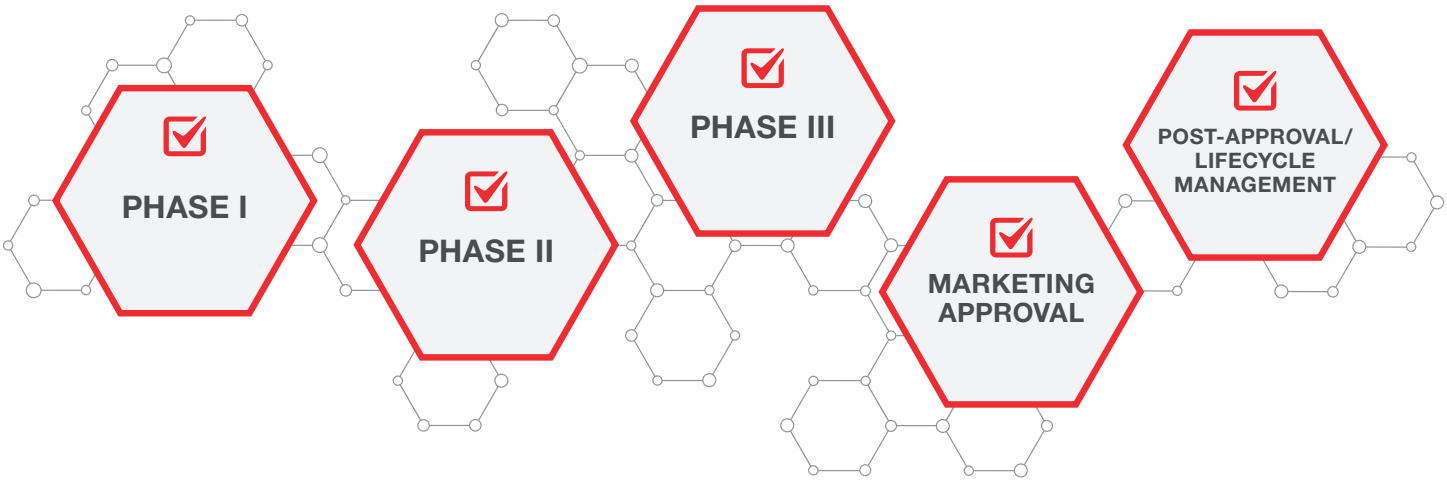
Avoid rework and costly delays by getting your regulatory strategy right from the start

In a recent study amongst new and emerging and large pharma, leveraging a CDMO with regulatory experience was an important attribute. We understand that getting **your CMC strategy** right from the start of your 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-term and long-term
- Outline your options, so you can make the best decision for your project
- Understand and evaluate trade-offs to ensure they align with your goals and strategy
- Plan best practices for your product's lifecycle
- Optimize your submission to help you get to the next phase with efficiency



Supporting you every step of the way



Business continuity and supply chain

Address your regulatory needs and challenges with proactive planning and problem solving

Proactive planning is critical for setting your short-term and long-term strategy and prioritization. To drive efficiencies, here are some key considerations we can work with you on:

- **Planning:** Establish a realistic timeline that fits into the scope and vision of your project. If you plan your program early on, you'll know what data you need to be collecting without putting your next target submission at risk of delays.
- **Supply chain:** The movement of product is critical to the success of your project. It's important to be prepared for the import/export of your drug product.

Prioritize initiatives and enhance strategic decision making by conducting a gap assessment

Trying to navigate the regulatory process of drug development can be complex and challenging. It's common to focus on the high-level, current tasks at hand, without thinking more holistically about the regulatory process and your molecule's lifecycle. With a high-level approach, important steps and milestones are often missed, which can cause lengthy timelines or add additional costs to your project. Our regulatory experts will help with a comprehensive, phase-appropriate gap assessment of your data to the most current regulatory standards to identify those milestones.

PRO TIP

We often see delays because of reactive planning vs. proactive planning, which can also increase costs. For example, not anticipating site license changes and valid GMP certificates in some jurisdictions or EU QP dispositions for product release to the market may substantially impact timelines.

PRO TIP

More data can enhance strategic decisions and your submissions. However, it takes time to generate data. Therefore, it's important to strike the right balance between generating additional data to better understand/control the manufacturing process, while not unnecessarily delaying your project from getting to clinic or commercialization. In addition to this, there are innovative approaches such as **QbD** (Quality by Design) and **continuous manufacturing** to help strengthen your process.

Data: Access to the right type, quantity, and forms of data can help enable strategic decisions and ensure you have the data that is necessary for your submissions. Our experts will help guide you on:

- Data requirements at each stage of the development process for your global submissions
- What tests to include in the regulatory specifications
- How to best justify your specification
- When method validation should be completed
- What compatibility studies are required with your container closure, device, and for dilution of reconstituted product
- What stability data is needed at what stage of development
- How much stability is needed under what conditions
- How many pilot/commercial scale batches
- Specific requirements to be considered for certain dosage forms/product types
- What process validation data needs to be submitted

Global and regional launches

Holistically planning about your global and regional launches

Even if right now you are only considering a regional - or country-specific launch, it's important to look at it from a global perspective. Evaluating your strategy at a global scale can help save rework, unexpected barriers, and costs.

PRO TIP

Even if you are years away from thinking about global markets, building it into your regulatory strategy from the start can enable you to proactively make strategic decisions. Here are some common challenges we often see:

- **Specifications:** In many circumstances, teams are only focused on the first country/market's specifications. Later, when people start thinking about global scale, they can discover that those specifications might not be suited for the next market.
- **Processes:** Sometimes the process you use to sample a product in testing can have different requirements from country to country. When customers don't account for this, there is a lot of rework that needs to be done.

Please note that you don't have to have every piece of information and detail figured out for these future markets; however, taking some time to think globally and holistically can save you time, money, and resources.

"The team has always been willing to extend itself to meet our timelines and provide for the patient."

— Midsize drug development company, USA

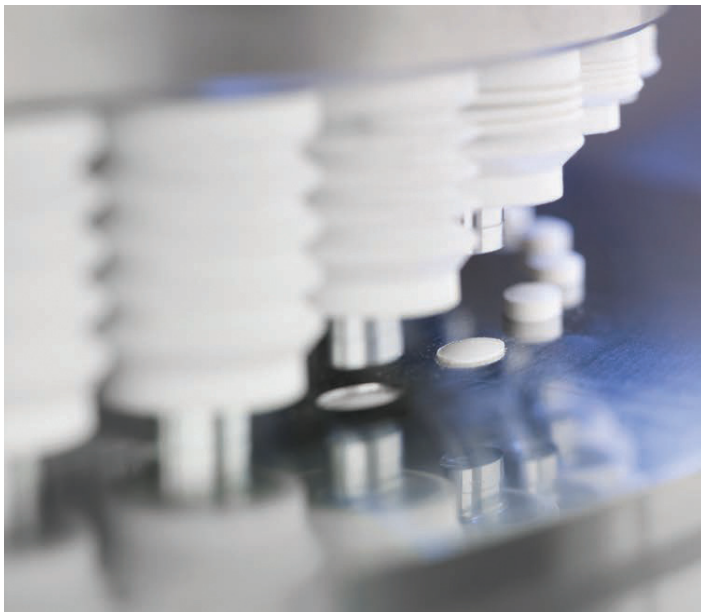
"Great communication and document turnaround."

— Large pharma company, USA

Integrated regulatory solution
Shorten timelines with fewer intermediaries

Moving through each phase with speed and agility is critical to the success of your small or large molecule. Our regulatory experts are here to connect and support every step of your project and network. Leverage our integrated regulatory solutions to:

- Access a range of CMC regulatory services for all product types manufactured across sites.
- Support ICH Common Technical Document (CTD) Quality/Module 3 for clinical and commercial applications and lifecycle maintenance.
- Support multi-jurisdictions such as USA, EU, and Canada, as well as international/Rest-of-World (RoW) registrations.
- Provide deliverables that are in alignment with the latest regulatory standards.



Document preparation[1]

ACTIVITIES	DESCRIPTIONS
Complete CMC dossier sections [Module 3.2.S, 3.2.P, 3.2.A 3.2.R]	• Preparation of complete or partial, publishing-ready, Drug Substance (DS), Drug Product (DP) and/or Appendices modules, including authoring, review rounds (internal and costumer), and comments integration • Authoring and review of responses to agency questions
ICH regions[2]	**Clinical trial applications (CTA Phase 1, 2, and 3):** • USA Investigational New Drug Application (IND) • EU Investigational Medical Product Dossier (IMPD) • Related amendments **Marketing application:** • USA New Drug Application (NDA) • USA Biological License Application (BLA) • USA Abbreviated New Drug Application (ANDA) • EU Marketing Authorization Application (MAA) **Post-approval changes:** • USA Prior Approval Supplement (PAS) • USA Change Being Effective (CBE)/(CBE30) • USA Annual Report (AR) • EU Type II variation • EU Type IB variation • EU Type IA variation
Non-ICH regions	Authoring, editing, and assessment of dossiers case-by-case

[1] In English, with the possibility of technical report translation
[2] End-to-end dossier preparation of all modules available on request

Document review

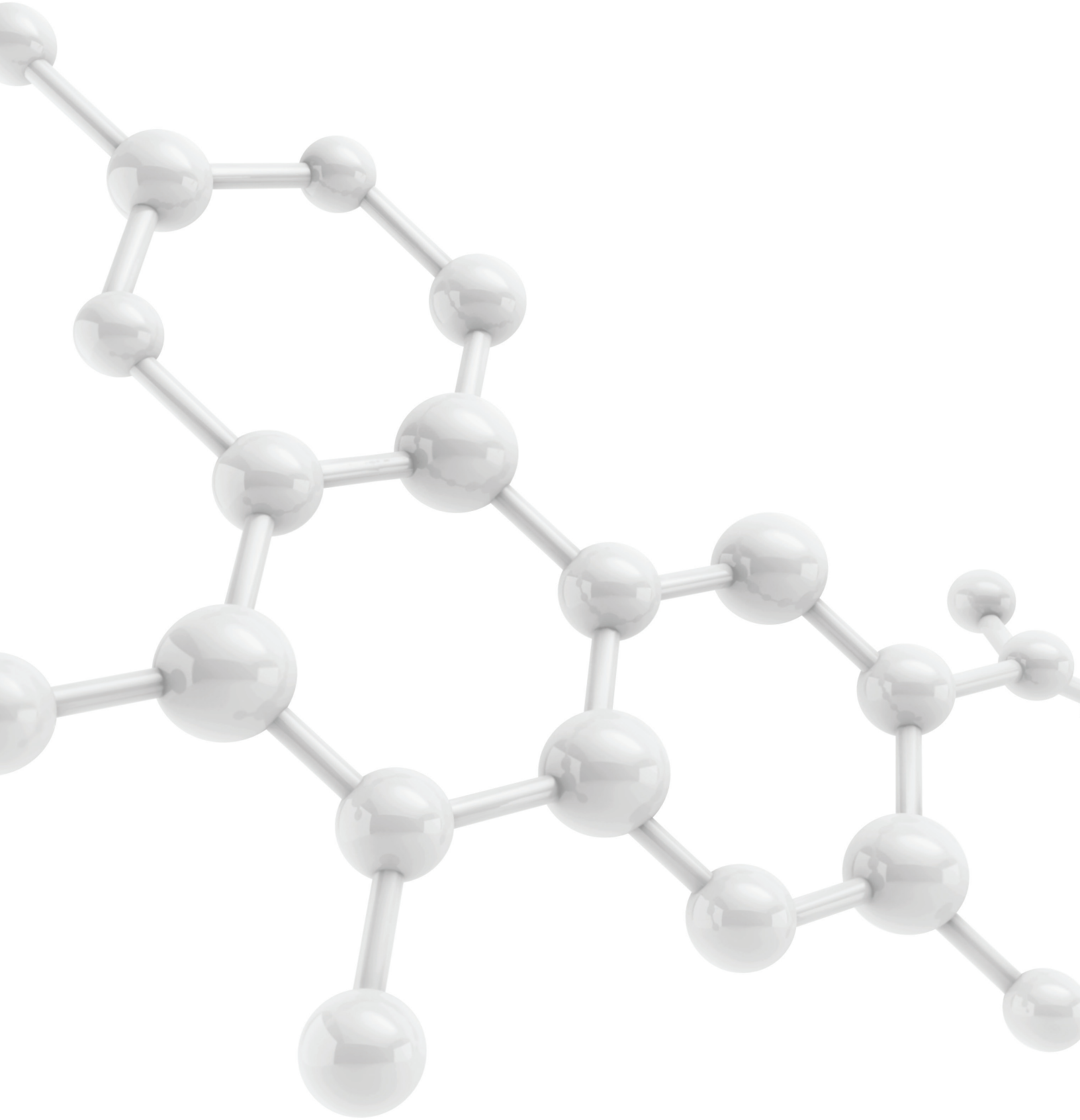
ACTIVITIES	DESCRIPTIONS
CMC dossier review	• Assessment of customer's submission drafts for consistency with current Thermo Fisher Scientific site practices and regulatory standards • Gap analysis summary report of current dossiers, in support of technology transfers and product inspection preparedness, per CTD granularity

Regulatory expertise

ACTIVITIES	DESCRIPTIONS
Project regulatory liaison	Participation in customer's routine project team and/or milestone meetings
Regulatory consulting and strategy	Provision of ad hoc regulatory consulting and strategies across product life-cycle per customer request
	Assistance in regulatory agencies meetings (e.g. requests, briefing books, minutes)
Regulatory training/ workshop	Preparation and delivery of customer-specific training on applicable regulatory topics, frameworks, procedures, GMP, and trends

At Thermo Fisher Scientific, our regulatory experts will do more than write the narrative for your approval. We will work hand-in-hand with you to build a robust and flexible regulatory strategy and proactively address problems.

Need help filing your submission and developing your regulatory strategy?
Contact us now.



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