

Top strategic tips for filing a successful IND with speed and efficiency

The road to filing your IND can be arduous and cumbersome. Building the right strategy coupled with the right team can not only drive efficiencies within your process, but also enable you to get to market quicker.

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Balance how to generate more data without causing delays

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 and not unnecessarily delaying your project from getting to clinic or commercialization.



Look at your launch globally and regionally

Even if you are years away from thinking about global markets, it's important to look at your launch from a global perspective. Holistically evaluating your strategy at both a global and regional scale can help you avoid rework, unexpected barriers, and unnecessary costs. Most challenges stem from:

- **Specifications**—Teams often focus on the specifications of the first country or market in which they intend to launch. Later, when people start thinking on a global scale, they may discover that those specifications are not suitable for other markets.
- **Processes**—Sometimes the process you use to sample a product in testing can have different requirements from country to country. If this is not accounted for early on, it can require rework and delay your timeline.



Be prepared for unexpected roadblocks

Flexibility to adapt to the unexpected is critical. Creating a proactive strategy positions you to better navigate obstacles you may encounter throughout the IND process, ultimately avoiding unnecessary frustration, unaccounted delays, and additional costs. To ensure efficiency with filing your IND:

- Be realistic about how long activities will take
- Anticipate site license changes and valid GMP jurisdictions
- Understand EU QP dispositions for product releases
- Evaluate where current/potential bottlenecks are and monitor them



Create realistic timelines

Yes, it's important to file your IND as quickly as possible; however, underestimating how long this will take can lead to costly mistakes which can snowball into lengthy delays. As you set the scope of your project, setting timelines that are realistic and thorough will help you hit important milestones.



Conduct a gap assessment

A gap assessment is essential for setting your short-term and long-term strategy and prioritization. We can help you drive efficiencies by working with you on a number of key considerations, including the following:

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



Use fewer intermediaries to shorten timelines

If you need regulatory assistance, utilizing the regulatory services through your manufacturer, rather than a third-party service, can help prevent delays in IND filing. By leveraging the same team responsible for the daily management of your project, you benefit from the efficiencies of easier collaboration and faster responses to regulators' questions. And don't forget to include regulatory services in the scope of your project early on to prevent unexpected delays in the filing process.



Build a working project team

Establishing the right project team is important when bringing a drug to market. It provides a basis for broader and more collaborative discussions that help prepare your product for FIH studies. Including regulatory experts as part of this team can bridge gaps in regulatory knowledge, preserve timelines, and help mitigate risks when developing regional and global strategies.



Plan an effective kickoff meeting

Efficient and productive kickoff meetings define clear roles, responsibilities, and expectations of the project team while establishing detailed plans and alignment on timelines. By engaging the CMC content in the kickoff meeting, stakeholders can collectively outline the short- and long-term regulatory strategies and schedule multiple touchpoints for regulatory needs throughout the project.

Need help filing your submission and developing your regulatory strategy? Thermo Fisher Scientific's regulatory experts can assist you. [Contact us now.](#)