

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

The road to filing your IND/IMPDP can be dynamic and challenging. Building the right CMC strategy coupled with the right team can not only drive efficiencies within your process, but also enable you to get to clinic without unnecessary delays.

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Balance how to generate more data without causing delays

More CMC data can enhance strategic decisions and your submissions. However, it takes time to generate data. It's important to have a robust understanding of the CMC data required to enable clinical study and strike the right balance between generating must-have data and nice-to-have data. Maintaining a farther horizon for CMC activities helps to establish this balance early on.



Look at your global and regional filing plan

Even if you are years away from thinking about global markets, it's important to look at building your dossier 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. Challenges can stem from:

- **Materials specifications**—Teams often focus on guidelines and compendia of the first planned jurisdiction. Later, when thinking on a global scale, there may be data missing.
- **Processes**—Keeping up with not only guidelines but review trends on phase-appropriate process knowledge can prevent rework and delays.
- **Stability requirements**—Collecting stability data takes time. Mapping out jurisdictional differences in stability data requirements can provide a roadmap for triggering studies on time.
- **GMP evidence**—Ensuring you have the required evidence in hand prior to preparing dossiers for import/export can save months of time.



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 product lifecycle, ultimately avoiding unnecessary frustration, unaccounted delays, and additional costs. To ensure efficiency with your filings:

- Be realistic about how long activities will take
- Anticipate site license changes and jurisdictional GMP requirements
- 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 as quickly as possible; however, underestimating the CMC timeline can lead to gaps which can snowball into costly and 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 CMC 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 phase-appropriate 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 boost efficiencies in your dossier preparation. By leveraging the same team responsible for the daily management of your project, you benefit from the efficiencies of easier collaboration, more effective dossier drafting, 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 moving a drug through development. It provides a basis for broader and more collaborative discussions that help prepare your product for FIH studies and beyond. 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.](#)