COMMON REGULATORY SUBMISSION PITFALLS AND WAYS TO AVOID THEM

No matter your company size or phase of product development, regulatory submissions can be challenging. The process of creating a regulatory submission for approval involves numerous steps and potential opportunities for missteps. However, companies can control many of these challenges, and project managers experienced with regulatory submissions can help anticipate, avoid, mitigate, and overcome them.

Here are some common pitfalls, examples, and recommendations regarding regulatory submissions:

CHANGING REGULATORY REQUIREMENTS

Managing differing country-specific requirements for submissions—such as those for the United States, Europe, and Japan—can be daunting. Companies need to track global regulations carefully since they often change, and these changes could affect product submission requirements. Keeping a close eye on the ever-changing regulatory landscape is key to a smooth and successful submission outcome.

UNCLEAR REGULATORY STRATEGY

Developing a sound regulatory strategy depends on numerous factors related to your product and company's business plan, including target market, competitive landscape, opportunity for first-in-market, an unmet medical need, and initial target indication with a potential opportunity to expand into other indications in the future. Companies must define the appropriate strategy up front and conduct a pre-submission meeting with the target regulatory authority to help guide product development and identify required data to be included with the submission.

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LACK OF A COHESIVE PRODUCT POSITIONING STORY

From a regulatory reviewer's perspective, often companies do not adequately describe the whole picture and context for their product in the market. Providing the historical background for the unmet medical need, including a rationale for the scope of the data in the submission, and elaborating on future studies to elucidate product safety and efficacy creates a cohesive narrative explaining why the regulatory reviewer should approve your submission.

For instance, key messages for product positioning in the market should be threaded throughout the eCTD submission document. Multiple SMEs write different sections of the submission, therefore the cohesive storyline can be easily lost. A regulatory submission project manager can alleviate this issue and help ensure consistency throughout the submission.

UNDEFINED AND/OR UNCLEAR DOCUMENT CONTROL PRACTICES

Managing the multitude of documents required in a submission is critical. Having predefined templates helps ensure consistency across modules. Performing adequate data verification and having a process in place for updating late-breaking data can be another challenge for submission teams. Rigorous version control and adequately preparing for last-minute changes can reduce errors in the submission.

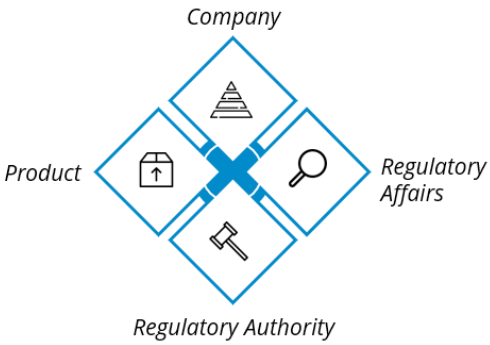
LACK OF OWNERSHIP

The company needs to identify an overall owner of the submission at the beginning of the project. Typically, this responsibility lies with the regulatory function. However, companies without in-house regulatory resources can give this responsibility to the program team leader/sponsor with assistance from the program manager. The submission leader is responsible for driving communication within the organization, striving for alignment within the team to ensure accountability, adhering to target timelines, and ensuring adequate resourcing to support the entire submission process.

LACK OF SUBMISSION EXPERIENCE

Companies are often challenged by identifying, acquiring, and retaining knowledgeable regulatory resources to manage their submissions. Changes in business strategy —such as adding a combination product to the pipeline — can result in a skills gap for regulatory employees. Proactively identifying the growth opportunities for regulatory and providing adequate opportunities for continuing education is key for adapting to product changes.

KEY SUBJECT MATTER EXPERTS (SMEs) IN HIGH DEMAND OR UNAVAILABLE



SMEs help guide the team's strategy based on their functional knowledge and prior experiences. SMEs who lack the time to dedicate to the project put the submission at risk. It's important for the company to identify the need for additional SMEs or to prioritize more time from a specific SME early in the process.

UNREALISTIC TARGET SUBMISSION DATE

When senior management sets aggressive target submission dates without consulting the submission team, it can result in unrealistic deadlines that increase risk. The project manager is responsible for working with the submission team to build a realistic timeline with documented assumptions to explain to senior management what is achievable within a given timeline. The team's morale and motivation improve when senior management recognizes and endorses an achievable target. The team then feels empowered to potentially accelerate the timeline. Adequate risk management and risk mitigation is key to keeping the submission project on track. Leveraging teamwork to identify opportunities to parallel track activities may help bring the submission in early.

NOT DELIVERING ON THE PREVIOUSLY AGREED-UPON TARGET SUBMISSION DATE

Submission dates can slip due to misaligned priorities or mismanaged deliverable timelines. Team members may not understand why certain documents need to be prepared early in the process due to cross-functional interdependencies between documents or difficulty in simultaneously reviewing a bolus of documents toward the end of the process. Project management can map out the key interdependencies between functional area deliverables to clarify how each activity affects another. Identifying opportunities to compress the timeline by parallel tracking activities may also help recover the timeline. Adequate risk management to anticipate and minimize potential delays is also helpful.

INEFFICIENT REVIEW PROCESS

Without careful prior planning, incorporating reviewer comments for each section of the submission can be painful. Sequential reviews that build on the previous person's comments are easier to reconcile than reviews conducted in parallel, which can result in direct conflicts of opinion. It is best to focus senior management reviews on the Module 2 summary documents and schedule their review after everyone else has had a chance to comment. Regulatory with relevant SME input should have the final say with buy-in from senior management. The person signing off on the submission is accountable for its accuracy and completeness.

BURNOUT FROM MULTIPLE SUBMISSIONS

The regulatory submission process is intense. People tend to work long hours under stress for many months to achieve a major submission. Years of hard work go into compiling the data needed to support product approval. Although a successful product portfolio can lead to exciting opportunities for the company, management must be sensitive to the risk of employee burnout that can accompany the desire of being first to market or getting to market as rapidly as possible. Professional project management can leverage resource planning to help accelerate project schedules while mitigating burnout.

YOU'RE NOT DONE UPON SUBMISSION!

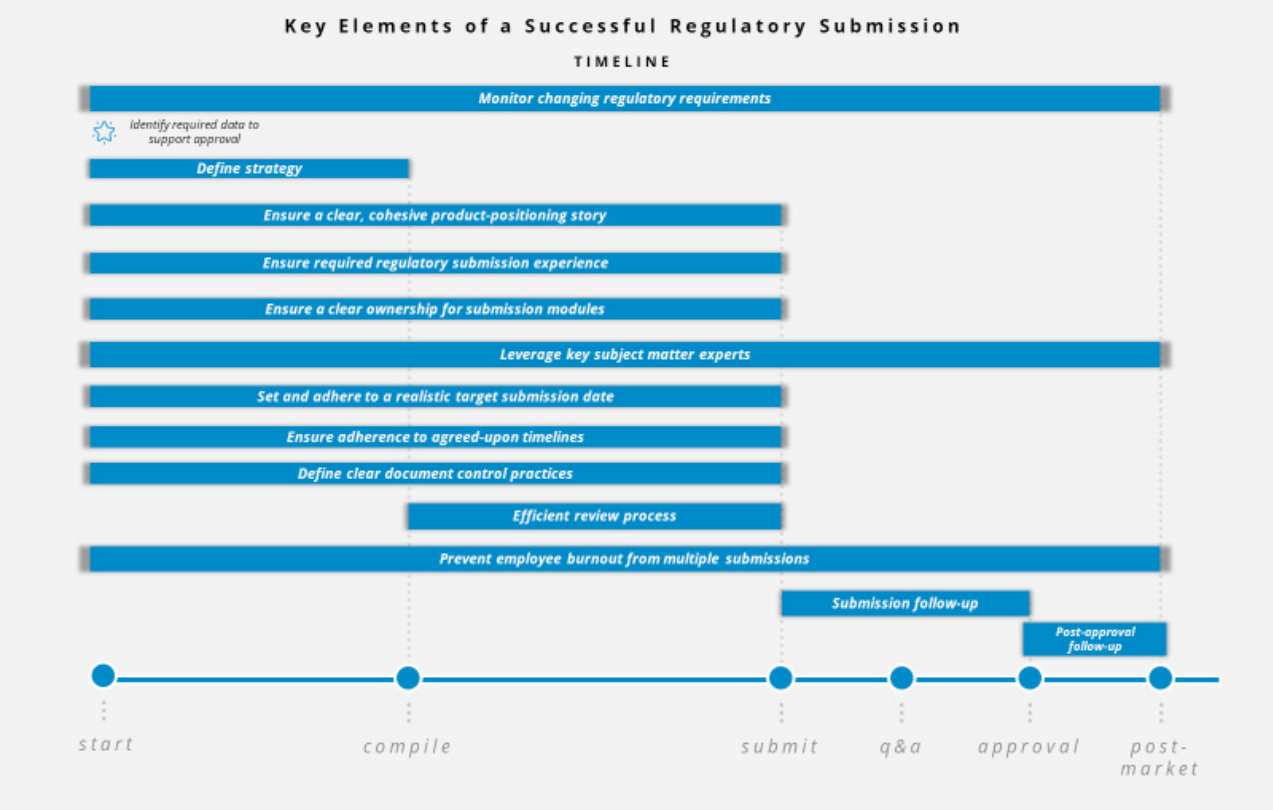
The submission team may mistakenly think once the submission is complete, they're done. Regulatory authorities routinely have questions that need to be addressed promptly after submission. The submission team should identify potential questions with accompanying responses and conduct a risk assessment with potential mitigation actions that can be invoked, if needed, once questions are received. In parallel, the program team needs to adequately prepare for pre-approval site inspections.

POST-APPROVAL WORK CAN BE TIME CONSUMING

Even after a product is approved and goes to market, the company may need to meet post-marketing requirements. Regulatory authorities are placing increased importance on post-market surveillance and vigilance. Companies may have heightened data requirements for conducting trend analyses to identify potential issues with the product post approval. After submission, companies need sufficient resources to address post-approval follow-up requirements and manage tight response timelines for inquiries from regulatory authorities.

Developing a regulated product suitable for commercialization is expensive and time consuming. Don't underestimate the importance of initiating the submission planning process before starting studies that provide key data to support product approval and prevent rework down the road. Delivery of a high-quality, on-time submission that meets regulatory requirements, stakeholders' interests, and company expectations demands excellent strategic and tactical planning and the focus of a dedicated and experienced regulatory submissions project manager.

A successful submission resulting in product approval achieves the ultimate goal of benefiting patients by improving quality of life or potentially saving lives.



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