



The Key to Finding a Trusted Regulatory Submission Management Partner

Vanessa Phillips
Shannon Heacock
Allison Steffen

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Executive Summary

Regulatory submission management is a vibrant collection of resources, practices and tools that are combined to support the regulatory submission lifecycle for a product, device or therapy. It demands regulatory knowledge, technical expertise, proactive planning, and operational excellence. A good submission management function is efficient, compliant, responsive, and flexible. The broad umbrella of submission management is complex and constantly evolving.

For these reasons, many R&D teams consider outsourcing their submission management capabilities. Outsourcing is a viable strategy that can simplify a costly and complicated process. Building and maintaining capabilities is time and resource-intensive and can be expensive. Obtaining these capabilities requires an ongoing investment in people, processes, and technologies that are continuously changing.

An outsourcing partner must offer comprehensive regulatory submission management capabilities while also monitoring industry initiatives that impact these capabilities. As new requirements emerge, they must have the ability to evaluate and implement new processes to meet changing standards. But their responsibilities don't end there. A good Regulatory Submission Management Partner (RSMP) offers enough expertise to protect their customer from the traditional chaos, trauma, and drama of a regulatory submission. Those aspects are no longer the necessary evils that they once were.

This paper outlines regulatory submission management capabilities, details the barriers to building capabilities and discusses the benefits of employing an outsourcing strategy to achieve them.

Overview of Regulatory Submission Management

The definition of Regulatory Submission Management continues to change. Emerging technologies, regulations, organizational structures, skill sets, and best practices have impacted submission management. Twenty years ago, the industry was learning how to implement the electronic Common Technical Document (eCTD). In large part, Regulatory departments operated as separate Regulatory Affairs and Regulatory Operations teams.

The Regulatory Affairs teams were responsible for liaising with the health authorities. The Regulatory Operations teams were responsible for understanding the technical requirements around document and submission publishing. Original new drug applications were expansive collections of documents that were submitted in bulk, instead of electronic applications that are built incrementally. Standards such as reference models were not yet widely accepted.

Today, the industry is experiencing a shift in the way we work. Submission-ready content is typically finalized in contributing functions and sent to Regulatory Operations. Development teams are taking advantage of more mature document management and submission publishing systems. As a result, regulatory submission management has moved away from being a discrete publishing function. "Regulatory Affairs Operations" is the term currently being used to describe the merged role. It now leans more toward regulatory project management that requires concrete skill sets and knowledge of technologies, regulations, and relevant standards.



Required Skill Sets

The unique set of skills required for regulatory submission management often creates barriers for teams that want to build internal capabilities.

A solid understanding of the underlying technologies and their application to electronic submissions is essential. It's also necessary to understand how contributing systems feed into the submission management process. Knowledge of document management, document and submission publishing tools, and submission viewing tools is essential to build an effective submission management environment.

A detailed understanding of technical requirements for electronic submissions is also essential. This level of knowledge provides a solid foundation for understanding the impact of new technical requirements and any changes needed to software, processes, and best practices.

Regional and country-specific regulations and requirements around the globe continue to change. A submission manager needs to understand the differences as well as the overlaps of various regulations so they can employ the most efficient strategies. They must also be able to interpret health authority guidances and assess their impact on current and future submissions.

These resources enable the organization to plan for and react to new needs. For example, emerging requirements appear to be moving toward a greater focus on structured data. Initiatives such as eCTD 4.0, electronic IND Safety reporting, and iCSRs require monitoring so the team can prioritize projects and make informed choices.



Compliance with various requirements also requires system qualification of the technology environment. Qualification is often a resource-intensive task that relies on user input and participation. As new versions of software become available, the submission manager will need to assess the changes, determine a practical qualification approach, and execute a plan before implementation.

A reliable process is also vital to a successful regulatory submission management capability. The submission manager must define standard operating procedures for compiling, publishing, and submitting a submission. They must also develop SOPs for quality checking, issue resolution, and escalation procedures.

The investment in RSM resources is significant. A good manager who brings all these skills and experiences to the table is tough to find. Because of the breadth of expertise required, a team may be more appropriate than a single resource.

An effective RSMP must have all these skill sets and experiences. If they don't, a Sponsor will likely encounter unexpected issues such as delays and missed deadlines. They will also experience the chaos that is traditionally associated with a major submission. Any last-minute changes to submission content will result in long hours and repetitive review cycles that are common among inexperienced teams.

An experienced RSMP understands the content enough to plan ahead and grasp the impact of last-minute changes. They also know their processes and tools well enough to implement strategies that minimize the impact while keeping the entire process moving forward. This is also where a Sponsor gets a real understanding of the RSMP's capabilities.



Technology and Process Considerations

Regulatory Submission Managers leverage technologies to develop efficient and compliant processes. The technology and the process go hand-in-hand.

A regulatory submission management capability requires a document management system or process. This system or process does not have to be elaborate; however, it must protect important R&D documents as they travel through the authoring lifecycle.

Tools for submission publishing, validation, and viewing are also required. Some publishing tools encompass all three; however, wide variations exist across different tools. This disparity further emphasizes the need for knowledgeable resources who can discern the difference between critical and non-critical issues.

Submission content authors should use document authoring templates to streamline the submission process. Though the authoring may occur within contributing functions or by various vendors, submission managers often become the "last line of defense" in troubleshooting document issues and maximizing the use of the templates.

All these tools play a role in regulatory submission management. As crucial components of a larger "system," they must be validated to ensure the integrity of the submission output.

A good RSMP has made the investment in reliable technology and processes that produce consistent output. To survive, RSMPs must be efficient AND compliant. Sponsors don't have the luxury of choosing one or the other.



Unique Challenges of Building Internal Capabilities

Cost, complexity, and commitment are the red flags associated with developing submission management capabilities.

Costs (Initial and Ongoing)

There are numerous costs associated with creating a regulatory submission management capability. Attracting the right talent and providing the right tools can be an expensive undertaking. Once you have them, there are also costs of maintaining the infrastructure. These include recurring fees for licensing and qualification of tools as well as training costs.

Complexity

As Regulatory Operations responsibilities shift toward regulatory submission management rather than strictly transactional publishing, team members need greater planning and organizational skills. These teams also need an understanding of comprehensive submission requirements from a technical and a content perspective. The depth and breadth of unique skills and knowledge reflect the complexity of the task. Managing resources, systems, and processes, monitoring health authority regulations, guidances, and standards, tracking new electronic initiatives, and evaluating and validating new technologies are all part of the typical submission manager's job. The complexity is constant.

Commitment

Developing these capabilities is a significant commitment. Regulatory submission management is a dynamic function. Tracking and participating in industry initiatives is resource intensive. Maintaining a team and staying abreast of relevant technical requirements means updating systems and processes. Ramping up a capability takes time.

Staffing at the appropriate level is essential because major submissions can quickly overwhelm a team. If two priority submissions overlap, the unpredictability of the workload can be challenging to manage. These challenges require continuing leadership support to ensure the retention of key talent.

Benefits of Outsourcing Regulatory Submission Management

The challenges listed have motivated many R&D teams to consider outsourcing regulatory submission management to a strategic partner. The strategy allows their team to focus on core competencies. The partner takes responsibility for maintaining the required systems, processes, and expertise and completes all submission management functions.



There are many benefits to this approach. Sponsors save time, effort, and money that would be used to build internal capabilities and maintain internal expertise. Outsourcing can help to normalize the peaks and valleys associated with major submissions while filling skill or resource gaps.

Outsourcing is also a preferred strategy for many small teams. They can take advantage of the capacity and experience of a submission management partner until the organization is ready to implement its internal capabilities. The internal regulatory team can learn from their partner while still moving regulatory applications forward.

In some cases, the current development pipeline and revenue may not warrant a large investment and lengthy implementation of submission management technologies and processes. And for many small teams who are planning for an early-phase exit, this type of investment will never make sense. Outsourcing offers quick ramp-up, capabilities, and capacity without requiring a long-term commitment.

Outsourcing all or parts of a regulatory submission management function can also eliminate the trauma and drama that are usually associated with sizeable regulatory submission projects. Access to the capacity and experience of the RSMP team allows greater flexibility in planning and resourcing such complex undertakings.

A New (Familiar) Look for RSMPs

There are numerous outsourcing vendors in the marketplace. The evolution of RSMPs seems to have come full circle.



In recent years, large, global service providers acquired niche vendors to offer 24/7 "follow-the-sun" capabilities.

Today, a new type of RSMP has arrived on the scene because requirements have changed. Rolling, electronic submissions have removed the requirement for massive numbers of resources to be at-the-ready.

Today, successful RSMPs offer the excellent customer experience of niche providers of the past. They have replaced large offshore teams with smaller, well-organized, trained, and experienced resources.

Today, RSMPs understand that customers want a frictionless partnership – from contracts to daily interactions. They "block and tackle" anything that stands between a Sponsor and getting a submission out the door. Today's RSMP is reliable, efficient, and compliant. They offer powerful capabilities with minimal fuss.

How to Assess an RSMP

As Sponsors contemplate an outsourcing strategy, evaluating potential partners is a priority. There are essential questions to factor into the discussion.

- What is the practical expertise of the partner team? Does their expertise complement the Sponsor team's existing skillsets?
- Are they a trusted advisor that adds value or a transactional vendor providing a commodity capability?
- Does the SMP have the systems, processes and expertise to minimize drama and maximize efficiency?
- What are the service level agreements? How responsive will they be?
- As a client, will you be a small fish in a big pond, or will you get the attention you need to be successful?
- Does the partner supply references from clients that are similar in size to your team? What are others saying about them?
- What kind of network does the partner team have? Can the partner help connect to other service providers (biostats and programming, medical writing, etc.)?
- Do you know in advance what the costs will be with no surprises? What is the fee for submission crunch time, elevated turnaround services (if any)?



Conclusion

The decision to outsource regulatory submission management capabilities is an especially good fit for small, growing, and early-stage teams. It offers easy and quick ramp-up and much greater agility to Sponsor teams. It also represents a reasonable investment. It helps to move a development product forward without requiring a significant investment in the people, processes, and technologies that are necessary for successful regulatory submission management.

Outsourcing can be a long-term or short-term solution. It affords flexibility and scalability to growing teams while delivering critical capabilities. If you outsource to the right regulatory submission management partner, they become seamlessly integrated into your process, and ultimately, help to achieve your submission goals in the most efficient manner.