
Evolving Roles for Submission Managers



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Executive Summary

The field of submission or dossier management has changed significantly in recent years. New electronic submission requirements, new technologies and varied agency implementation schedules for eCTD (electronic Common Technical Document) have added complexity and confusion to the submission management process. These factors have also changed the role of the submission manager and the skill sets required to be successful at submission management. This paper will discuss the changes that have occurred and how they impact the operational aspects of good submission management.

Submission and Data Standards

On September 28th, 2006, the U.S. Food and Drug Administration's Center for Drug Evaluation and Research published a notification in the Federal Register that three electronic submission guidances were being withdrawn. The agency listed eCTD as the preferred format for electronic submissions. In December, the agency held a Part 15 Meeting where the topic was the costs and burden associated with transitioning to eCTD. Though many large pharmaceutical organizations have already begun to submit in this format, many small to mid-size organizations were taking a "wait and see" approach to transitioning to eCTD. In most cases, this format represents process and technology changes for an organization and introduces a need for training on the new standard and new submission deliverables. For the purposes of this discussion, we will focus on the eCTD as the preferred format for electronic submissions since it is a global standard and has the greatest impact on submission management.

On the data side, the CDISC (Clinical Data Interchange Standards Consortium) has been making progress with several data models including the SDTM (Study Data Tabulation Model), which is the standard for electronic clinical data being submitted to the US FDA. Since the 1999 electronic submission guidances have been withdrawn, the agency has named SDTM as the preferred format for submission of electronic clinical study data.

Process and Technology Changes

The eCTD format requires process changes that affect all contributors to the submission. The eCTD format defines a level of granularity for submission documentation that is unprecedented in the electronic submission world. Instead of one large pdf being submitted, a clinical study report may consist of 24 individual components, as well as an XML-based study-tagging file in addition to file specific meta data that is incorporated into the overall submission index files in xml format. This scenario represents the merging of the traditional document lifecycle with the submission lifecycle. It also underscores a significant process change because submission compilation is no longer a "black box" activity that is completed at the end of the process. It requires the creation of "electronic submission-ready" components by contributing functions. This shift requires new collaboration and knowledge transfer between Regulatory Operations and other functions within R&D. For example, in most cases, the majority of the quality section of the application can be finalized while waiting for stability data that is usually the last document in the module that is received. Individual component documents can be processed in advance and once the last document is received, the module level activities can be immediately initiated. This change requires submission managers to be "submission

champions", monitoring statuses of individual components and developing strategies that use resources most efficiently.

This also impacts the role of Regulatory Operations personnel. Ten years ago this was a clerical position that required copying, binding and quality checking of multiple paper copies. Today, the regulatory operations professional must have a strong understanding of the business requirements as well as the supporting technologies (XML, PDF, and various submission management, content management and publishing technologies). The critical knowledge requirement is the application of the various technologies in the context of the submission lifecycle. If you don't understand *why* a specific attribute is being used as meta data as well as *how* meta data is compiled to assist navigation across the submission, submission management will be an extremely difficult task. Having this combination of business and technical understanding will also assist an organization in selecting appropriate tools to automate the process.

The Submission Manager must also have an understanding of organizational and industry standards and how they are applied to a technology and process environment. Standards such as file naming conventions, folder structures and linking strategies should be documented to maintain consistency across submissions teams, therapeutic and functional areas. It is typically part of the submission manager's job to participate in the development, deployment and enforcement of such standards. This individual is usually the force that facilitates transitioning an organization to new standards such as eCTD. Frequent and accurate functional area communication is required for this position since submission development teams usually span the entire R&D organization. Communicating standards, project statuses and issues is of paramount importance to the success of the submission team.

Keeping abreast of new technologies and standards is only part of the equation. Successful submission managers must also understand conversion processes such as rendering and scanning of paper legacy documents. These time-consuming processes are critical to the production of the submission and require attention to details noted in agency guidance documents and specifications. Often, these documents exist in multiple, global locations so the submission manager usually becomes the project manager for conversion work. Conversion processes must include quality-checking steps so that any reformatting or resizing occurs sooner rather than later. The application of navigation aids such as bookmarks and hyperlinks should be standardized and based on agency requirements. Logistics around such projects require management of resources (people and conversion tools (hardware and software) and may require vendor management if the work is outsourced. At all times the submission manager is held accountable for status and quality of the final submission deliverable. It should be noted that the agencies prefer text based PDF documents to scanned documents because reviewers can search across submission components more easily. The submission manager is often the point person leading the project to identify the location and retrieve electronic versions of legacy documents.

One important aspect of submission management is the production of supporting datasets. This tends to be an area where typical organizations have the most process issues requiring rework. Submission managers must champion the effort to train contributing functions on all submission requirements, including data set standards such as SDTM.

Required Skill Sets

Submission Management today requires expertise in project and resource planning, process management, and electronic submission strategy.

Paper World	Electronic Submission World
Clerical tasks (binding, copying, etc.)	Publishing, adding navigation aids (bookmarking, hyperlinking, etc)
Understands consistent "appearance" of documents	Understands consistent appearance, format and structure of documents
"Black Box" operational view of tasks	Cross-functional approach to process
Trained on paper QA processes	Trained on process, technology and new deliverables
Knowledge of print strategy was key	Knowledge of electronic submission strategy is key
Reg Ops resources work at end of process	Cross-functional, integrated processes require resources management throughout process

Project planning aspects of submission management are critically important when a major submission is in the works but can be equally essential when managing the smaller, more frequent activities supporting maintenance of multiple submissions. Managing the receipt and processing of submission components usually requires collaboration across departments. It may also require interactions with external partners such as CROs, medical writers, quality consultants and preclinical specialists.

Resource planning is an essential capability for submission managers. Because the electronic submissions require a unique combination of business and technical expertise, it is important to have the right resources deployed to a project at the right time. Resource planning often requires good negotiating skills since additional resources are often required in the submission process. Getting good representation from contributing areas and being able to manage skilled resources under very tight timelines requires a great deal of patience and skillful evaluation of available resources.

Process management involves the management and control of complex processes (i.e. submission development) that span functional areas and organizational boundaries. Submission management requires process management in order to connect workflows and operational tasks to the larger submission goal. As task are completed, it is important to capture process metrics so that the organization can learn from experience and incorporate lessons learned to improve processes. Good submission managers often take a lead role in managing these processes and collecting appropriate metrics for management reporting. Since an original marketing application is so critical to the organization, these multi-tasking professionals are often asked to interact with all levels of management to provide updates on the progress of the submission and any obstacles that may risk meeting a specified date.

Submission Managers today must also have an understanding of issues, potential issues and the lifecycle of identifying and resolving issues in a timely manner. Most

companies spend 30-40% of their time addressing issues (unplanned events that stall a process and require effort to address). Tracking issues and managing them efficiently is a new aspect of submission management that did not exist a few years ago because there was no visibility into a process. Well-planned processes and new technologies now provide visibility into issues and smart submission managers are becoming more adept at using these tools to identify and track issues through to resolution. This inevitably leads to longer-term process improvements that provide strategic benefits to the organization.

Strategic Responsibilities

Submission managers are often faced with the challenge of an overwhelming pipeline of submissions and limited resources to support those projects. Today, there are options for addressing this imbalance. Submission managers typically must evaluate outsourcing, insourcing and partnering strategies to support the development of internal capabilities, the execution of specific functions such as quality checking or the compilation of an entire submission. The appropriateness of each of these strategies will depend on the size of the organization, the submission pipeline, existing internal capabilities and submission deadlines. Submission managers often act as a champion or in a more consultative role to ensure that the best strategy (or combination of strategies) is selected. In all strategies, knowledge transfer is a key to investing in organizational expertise and the savvy submission manager will make training/education a high priority.

The submission manager must be a “jack of all trades” when it comes to engaging the organization in submission standards and processes but also has to have the knowledge of a specialist when it comes to important concepts such as document granularity and life cycle management. A submission manager differs from a project manager because the role requires content knowledge and technical skills in addition to traditional project management responsibilities. The submission manager also has critical communication responsibilities to liaison with all stakeholders including outsourcing partners, product development team, information technology support, technology providers, functional area authors and submission staff

Variables to Consider	Submission Manager Roles	Submission Strategies
Size of Organization	Project Champion	Outsourcing Partnership
Internal Capabilities	Project Manager	Insourcing Agreement
• Submission Expertise	Partner Liasion	Develop internal Capabilities
• Technology Infrastructure	Management Communicator	Combination Strategy
• Process Infrastructure	Organizational Educator	
Submission Pipeline	• Processes	
Existing Submission Deadlines	• Technologies	
Knowledge Transfer Plan	• Deliverables	

The transition to eCTD is a strategic move for any organization and the submission manager plays the key role in pushing such initiatives forward successfully. There may be many operational tasks that the individual is managing but the impact of a good submission manager provides strategic benefits to the organization through improved processes, recurring efficiencies and decreased costs.