# Outsourcing Submission Management

Introduction

Navigating the complexities of global submission strategies for original and lifecycle applications is a major commitment for pharmaceutical, biotechnology, and medical device organizations. This capability demands attention to evolving global submission requirements, experience in understanding their implications, and tools to implement them. Many small companies choose to outsource their submission management activities, while larger companies build internal capabilities or augment their capabilities with various outsourcing strategies.

A balanced outsourcing model enables a cost-effective submission and efficient review process for electronic submissions and associated metadata management.

With an effective outsourcing submission management strategy, companies can use external vendors to either manage all agency submissions or augment their internal staff to assist with different responsibilities as they pertain to the publishing process. With that said, the submission management and publishing partner should be carefully selected; otherwise, the entire strategy can backfire, resulting in frustrated teams, increased costs, and submission delays.
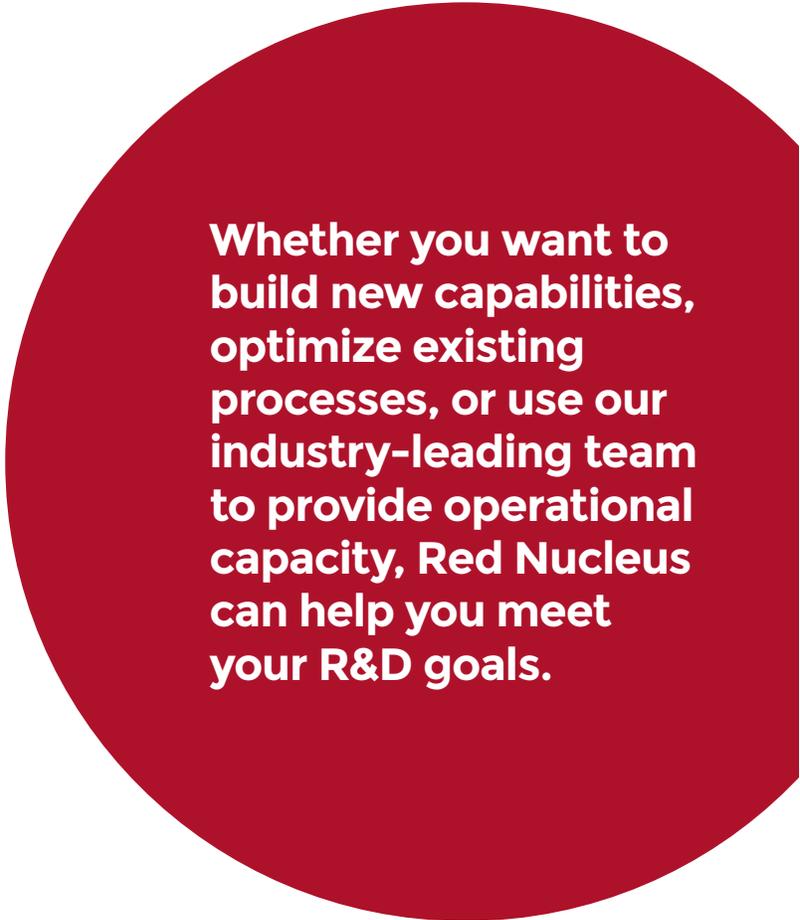
Whether you want to build new capabilities, optimize existing processes, or use our industry-leading team to provide operational capacity, Red Nucleus can help you meet your R&D goals.

It's not what we do; it's HOW we do it.

Red Nucleus R&D has attracted top talent from across the life sciences industry. Our experts are laser-focused on delivering R&D capabilities. We understand the complexities of R&D processes, the constant constraints, and the need to do more with less while still remaining compliant. We work with our clients to deliver the capabilities and customer experience that helps them meet their R&D goals in the most efficient way possible.

What to Look for in a Submission Management and Publishing Partner

In order to make the most of your outsourcing strategy, it is important to consider the specialty skill sets and capabilities that your organization needs. Some of the top knowledge/experience considerations include:

- Proficiency in leading global submissions (knowledge of global guidances)
- Leaders in content-based submission documentation strategy
- "Perceptive publishing"- document interpretation, guidance on authoring, and CTD placement
- Experts at global simultaneous original applications
- Experience with drug development and lifecycle application submissions
- Specialized publishers (Document QC, readiness, cross-referencing, hyperlinking strategies, etc)

Cost savings will come naturally if you select a qualified partner. However, selecting a partner based on cost alone will end up costing you more in the long run and result in submission delays. Submission management still isn't a commodity service. With the evolution of electronic submission document and data standards, perhaps it will eventually become more of a commodity, but it isn't there yet.

For example, as documents and data are turned over to an outsourcing partner for processing/management, some vendors require a spreadsheet to accompany the submission components. The spreadsheet includes metadata about the submission that the customer must complete for every submission, including routine, daily maintenance submissions.

The spreadsheet may not be difficult to maintain if you only have one product in development, but for multiple products or multiple submissions in one day, the spreadsheet quickly becomes cumbersome and time consuming. This means it also typically becomes the first source of failure in the process. Lack of understanding

of the metadata and how it is eventually used by reviewers leads to incorrect data entry, duplication of efforts, longer QC cycles, and loss of efficiency. Some submission management partners do not rely on the spreadsheet approach because of the widely understood shortcomings. If a customer doesn't want to waste time on additional manual tasks that don't add value to the submission, they should seek a submission management partner that is adept at "perceptive publishing." Perceptive publishing refers to the ability to receive submission components and compile submission documents and metadata without using the dreaded spreadsheet transaction. Well-versed publishing professionals can collect documents and review and organize the collection while using their existing knowledge of the product to compile metadata. They understand submission standards, how the metadata is used, and enough about the submission status to enter the correct metadata. This unique knowledge is something that comes with experience. It's what separates true submission management partners from commodity publishers.

Paying for Expertise

It is critical that companies are quickly and cost effectively able to complete and file their submissions without sacrificing quality. Therefore, when considering the submission management and publishing team, it is essential that the team is specialized in submission management. It is also essential that the team is able to rapidly understand the intricacies of the products and its applications and combine that with the requirements as defined in global guidances. Without this subject matter expertise, either speed or quality (or potentially both) will be compromised. In order to maintain such control and ensure high-quality deliverables and services, companies tend to develop these teams internally. That may not always be the right approach.

Demand for submission management and publishing services come in peaks and troughs. Maintaining a fully internal team means that (1) if the team is staffed for peaks then the company will carry a workforce that is not utilized during troughs, and (2) if the company is staffed for troughs then the company will be struggling to meet demands during periods of workload peaks and in many cases, will staff projects with underqualified members just to get the work done. This can be a source of significant hidden costs where rework, quality control, and staff overturn push costs higher.

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Partners who primarily use off-shore resources may initially seem attractive due to their "low cost." However, these types of commodity services ultimately result in higher costs and delayed submissions due to the amount of rework. The rework is often caused by lack of experience, lack of specialty knowledge, and/or a lack of understanding of the broader submission strategy. This commodity approach to submission management is typically not sustainable.

Internal Team or Submission Management Partner?

A typical employee will spend up to 20% of their normal work week completing general back office work like training, staff meetings, reviews, etc. Using a "qualified" submission management and publishing vendor can provide flexibility and knowledgeable specialists at any time, for any type of global application submission. An effective outsourcing model offers a company the flexibility to only pay for dedicated work from the partner as it is needed. The right submission management partner can reduce the costs associated with retaining internal knowledge, skill sets, and production environments that support efficient and compliant submission management.

Reduce, Re-use and Electronically Submit

Establishing electronic submissions allows for reuse of documents and metadata for global submissions. The development of a global electronic submission strategy allows for reduction of country-specific documents. Others have made the transition to eCTD but are not capitalizing on the efficiencies of a truly "global" submission strategy.

While electronic submission management systems are being implemented, business

processes can be established and implemented to ensure that efficiencies are realized. A strategic outsourced submission partner should not only be savvy in electronic submissions and eCTD but also have experience in simultaneous global submissions. Without this expertise, the customer will pay the cost (both $$ and time) for their inefficiencies.

## Agency Requirements: Electronic Submissions

There are multiple electronic submission initiatives that continue to evolve. A good submission management partner understands the nuances and challenges of the various standards, their strengths and weaknesses, and how they impact global filings. This type of partner invests in team-wide knowledge sharing and actively participates in industry activities that help to advance electronic submissions.

Red Nucleus R&D

Red Nucleus R&D takes pride in its successful delivery of global submissions, with unbeatable turnaround times and quality deliverables at a fair price. Much of our experience comes from forming and leading submission management teams internal to pharmaceutical companies. We have been in our customers' shoes and understand the challenges that they face.

We provide project management for the successful delivery of global original and lifecycle submissions. Our staff offers global submission guidance interpretation and document authoring support for paper, eCTD, and NeeS submission compilation, publishing, and delivery. The Red Nucleus R&D team is comprised of experienced regulatory operations professionals. We are not a commodity publishing service. We understand customer expectations and we deliver perceptive publishing, compliant quality deliverables, and an unmatched client experience.

Let us support you in leading your submission or technology implementation or validation project, facilitating document preparation, report publishing, and routine submissions to the agencies. Utilizing our R&D team is an effective strategy that enables your team to focus on core competencies while efficiently filing global submissions.

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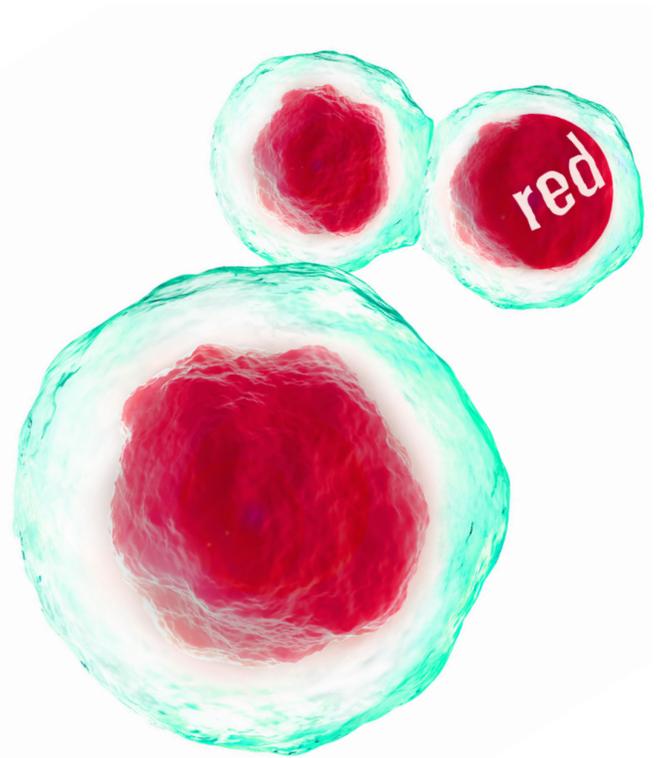
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