Reference Management Process

By Rebecca Burnett
Executive Director, Strategic Services

By Nicole McCourt
Senior Advisor, Strategic Services

framework solutions
Pharmaceutical & Life Sciences

Introduction

Now more than ever, organizations are realizing the importance of having a well thought out and constructed process in place to manage their cloud-based content. This includes the management of References used to support and substantiate claims or statements made about a medical product or medical device. This is particularly true for emerging companies that are preparing for a product or device launch. Due to evolving regulations governing the Pharmaceutical industry, the expanded use of digital content, and the shift in how Content is being utilized, Late Stage companies benefit from establishing a Content Management Process earlier in the drug development lifecycle.[1] An important component of a well-designed Content Management Process is a Reference Management Process (RMP). The efficient and compliant management of cloud-based data is the key to delivering high-quality marketing Content to the end user. The absence of a process to do so can lead to associated risks and an increase in incurred costs.

In a recent survey of our current clients, the majority saw at least a 25% increase in digital Content over the last several months where digital Content now makes up approximately 80% of the average organization's Content[2]. With this recent surge in Content delivered digitally, driven by the impacts of COVID-19 and the way in which organizations now interact with their internal teams as well as their consumers, it is even more important for organizations to establish an RMP. Given how important an RMP is to operating a truly robust and efficient Content Management Process, it should be operationalized with as much oversight and rigor. An established RMP provides guidance to the entire organization as to what constitutes an acceptable Reference and a process by which References are reviewed and approved for use as substantiation. When well designed, an RMP provides a holistic solution to support all stakeholders in efficient submission, review, and approval of Content.

For the purposes of this paper, an RMP is inclusive of three pillars: 1) the creation of Acceptable Reference Guidelines, 2) a Reference Approval Process, and 3) ongoing Training, Monitoring, and Execution of the RMP. This white paper will explore each of the three pillars in more detail.

Three Pillars of RMP

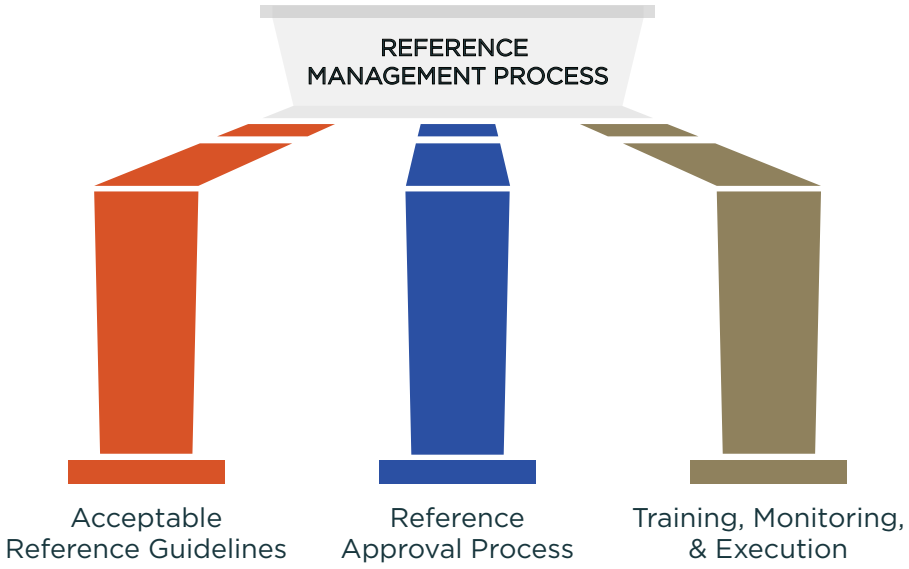
Acceptable Reference Guidelines

Establishing Acceptable Reference Guidelines is an important first step for an organization as it sets the foundation for what types of documents are considered as acceptable References for the substantiation of core statements and claims. The Guidelines also clearly articulate what types of documents can and cannot be used as substantiation. Often these Guidelines provide direction differentiated by Material Audience (e.g., consumer vs professional) as well as availability of the information (e.g., publicly available vs data on file). The Guidelines establish a basis from which to deploy an ongoing RMP Training, Monitoring and Execution program.

Reference Approval Process

Once the Acceptable Reference Guidelines have been written and agreed to, the next step in establishing an RMP is to outline the Reference Approval Process (RAP) – starting with the identification and collection of the References. There are several cloud-based solutions available to facilitate the Content Review Process, most of which associate metadata and workflows to the uploading of singular Reference documents. Organizations should carefully consider what data is critical to associate with each Reference and ensure the information is consistently captured for all References.

Establishing a document taxonomy that will support the types of References an organization has identified as acceptable, as well as a naming convention for the References, are two additional key components of this pillar. The creation of a Reference naming convention will ensure consistency as References are added to the library. This increases the utilization and searchability of the Reference Library for all users.



The next step in designing an RMP is to identify the role in the organization responsible for designating References as Approved for Use. Often that responsibility is assigned to the Medical Reviewer, as they are generally the one associated with the acquisition of the Reference or have historically had the training to determine if the Reference is Acceptable per the Acceptable Reference Guidelines. However, over the last 12 months there has been a shift in the assignment of this task to a Reference Librarian. This new role has been established as a procedural expert and one that can utilize the Acceptable Reference Guidelines to determine whether the Reference can be designated as Approved for Use. The Reference Librarian plays a large role in the ongoing Training, Monitoring, and Execution of the RMP, further supporting this 'Approval' designation to the Reference Librarian. The Reference Librarian confirms that all required data has been associated with the uploaded Reference and that the Reference meets all requirements per the Guidelines. The Reference Librarian performs this task for all References that are uploaded to the cloud-based Content Management System (CMS).

Training, Monitoring, and Execution

Once the Guidelines and process for reviewing and approving References have been established, stakeholders are trained on the execution of the RMP. Ongoing training is vital to the successful deployment and execution of an RMP. Proper training can help to ensure organizational compliance with the policies and procedures identified as critical to the success of the RMP and overall Content Management Process. The Reference Librarian is responsible for providing initial and ongoing RMP training. A recent survey found that only one third of organizations with an existing RMP reported consistent execution[3]. This speaks to the importance of ongoing training, monitoring, and execution support from the Reference Librarian to enforce and ensure compliant RMP execution.

After the initial deployment of the CMS, the Reference Librarian monitors the Reference Library on a go-forward basis. This routine monitoring is executed on a set frequency and cadence and is instrumental in ensuring that the Reference Library is up to date as well as free of duplicates or unacceptable References. The Reference Librarian pulls reports providing activity information on Reference usage and the frequency in which References are associated with Content that is created. In addition to these reports, the Reference Librarian completes a manual audit of a proportionally representative sample to ensure the quality and process adherence of the uploaded References. This helps the organization determine how claims and statements are substantiated and whether the data and References in utilization are current. As an additional data point, the Reference Librarian monitors the ratio of References to Content. While this ratio will differ from organization to organization based on the product and/or therapeutic area, as well as the lifecycle of the product, a major shift in the ratio should serve as an indicator that a more thorough audit should be performed to identify any potential issues. Typically, organizations with a well-executed RMP report a lower Reference to Content ratio indicating ongoing monitoring of the Reference Library[3].

Industry Observations & Trends

While ensuring each of the three pillars outlined above are part of the RMP, an RMP can and should be tailored to the needs and structure of an organization. It is important to ensure the RMP establishes a strong foundation to meet the immediate needs of the organization and allows for scalability to support future growth. Organizations tend to approach establishing an RMP in one of two ways.

1. One common approach is the deployment of an open access process in which all users have the ability to upload References and advance them to an approved state as long as they adhere to the Acceptable Reference Guidelines. The Reference Librarian's responsibilities in this scenario are to focus on the Training, Monitoring and Execution pillar.
2. Recent shifts in industry trends suggest the adoption of a more formalized Reference Approval Process. As discussed above, this approach is inclusive of a review by a designated user to confirm alignment of the Reference with the Acceptable References Guidelines. While historically this responsibility fell to the Medical Reviewer, the industry trend is now shifting toward the role of the Reference Librarian in completing this review to ensure alignment with the Guidelines and accuracy of the metadata completion. The Reference Librarian's responsibilities in this scenario are inclusive of both the RAP and Training, Monitoring, and Execution pillars.

Case Study

A recent client of Framework Solutions found themselves with a large and unwieldly Reference Library with References outnumbering the amount of promotional Content in their CMS by over 30%. Reference utilization was inconsistent leading to Content Review and Approval Process inefficiencies and wasted hours both during the creation of the submission for review as well as during the review. Their agency partners and internal Project Owners were spending time uploading duplicative References and creating new document links. An evaluation of their Reference Library found that more than 15% of their total Reference Library could be identified as 'duplicates' – meaning that the content was the same but the metadata, image of the content, or Reference name differed slightly which resulted in multiple uploads of the same Reference. Additionally, Reviewers were utilizing live Content review meeting time to discuss the appropriateness of the References. This led to additional rounds of review to allow new References to be reviewed. Not only did this increase review time and duration, but our estimates found that it increased the financial cost to the organization by nearly $5,000 per incident as it impacted multiple key stakeholders and, in many instances, resulted in the additional acquisition of already purchased References.

During the engagement, we partnered with the organization to deploy an RMP that established all three pillars: 1)Acceptable Reference Guidelines, 2) Reference Approval Process and 3)Training, Monitoring, and Execution.

The organization chose to establish a formalized review and approval process in which, upon upload of a Reference document, the Reference Librarian reviewed the Reference for adherence to the Guidelines and metadata accuracy. A Reference could not be utilized for substantiation until reaching an Approved for Use state in the CMS. The document hierarchy used within their CMS was updated to align with the types of References the organization would be utilizing for substantiation and a naming convention was established to increase the ease of navigating the Reference Library. Prior to RMP deployment, stakeholders were provided with training and resources to support consistent execution of the RMP. A monitoring and execution program was also deployed to ensure ongoing governance was performed by the Reference Librarian.

With a robust RMP in place, this organization gained efficiencies and consistency in Reference utilization. It was also found that the time allocated by the Reference Librarian to manage the RMP led to a significant reduction in the time spent in meetings discussing the acceptability of References. Further, the organization realized a reduction in the overall annual cost associated with their Reference Library by over $50,000. The introduction of the RMP and the deployment of a Reference Librarian was widely viewed as a cost-effective success throughout the organization.

Conclusion

A Content Management Process lacking a formalized RMP has far reaching implications for process efficiency, compliance, and cost. Absence of a well-executed RMP causes stress on the Content Management Process by potentially delaying submissions creating the need in some cases for shortened reviews to ensure business needs are met as well as at the same time necessitating additional rounds of review to further vet References. In addition to the associated cost of the increased hours stakeholders spend on Content submission, review, and approval, these process inefficiencies can lead to delays in Content's time to market which incurs additional associated costs.

An overwhelming majority of clients in a recent survey, approximately 90%, reported deployment of an RMP process to address identified gaps or inefficiencies in their Content Management Process.[3] It is clear that the proliferation of Content has put a focus on the quality of the References that are being used to substantiate claims and core statements. Creating a strong and robust RMP ensures the efficiency and compliance of the Content Strategy. Investing in the establishment of an RMP helps to protect the organization from future compliance issues or losses in process efficiency.

A robust RMP:

1. Ensures data used for substantiation is accurate and current;
2. Increases process efficiency by saving time at upload and Content submission preparation as well as during review;
3. Ensures utilization of only those References that have been Approved for Use;
4. Increases ease of utilization of References within the Reference Library by decreasing duplicative documents; and
5. Enables faster recall and Content updates when new data is released.

All three pillars play a crucial role in deploying an RMP and while the Guidelines and Reference Approval Process set the foundation, long-term success and scalability of an RMP requires strong oversight by a Reference Librarian. As the trend in the industry is showing, this new role is quickly becoming one that is vital to the success and efficiency of an RMP.

Early investment in the planning and execution of a Content Management Process, inclusive of an RMP, has proven to be part of the path to a successful commercial product launch.[1] Proactive establishment of Guidelines and a Reference Approval Process will ensure organizations are operating efficiently and reducing the need for major future Reference Library clean-up efforts. Organizations should invest the time to establish a well-designed RMP that will meet not only the current needs but will also scale to meet future growth. The time is now for organizations to ensure an RMP is part of their Content Management Process.

Now more than ever, organizations are realizing the importance of having a well thought out and constructed process in place to manage their cloud-based content.

About Framework Solutions

For over 10 years Framework Solutions has been working with pharmaceutical and life science companies to provide insight and analytics that ensure quality, efficiency, and compliance of their Content Review Processes. As leaders in the promotional and medical review and approval process, Frameworks works closely with clients to help find the right solutions for their needs. Visit https://framesol.com/ to learn more about Framework Solutions and the services offered.

About the Authors

Rebecca Burnett

Rebecca Burnett provides strategic advisory and consultative services to Late Stage Pharmaceutical companies that want to establish an efficient and high-functioning Content Management Process. With over 20 years of experience in the industry, Rebecca was an early adopter of harmonizing the People, Process, and Technology involved in the Content Management Process and has led dozens of process and system implementations and brings a wealth of knowledge on how to evaluate and optimize Content Strategy and the Content Management Process. She maintains a high profile, leading panel discussions and speaking at industry events focused on topics related to Medical and Promotional Content including conferences sponsored by the Drug Industry Association (DIA), the Food and Drug Law Institute (FDLI), ExL Pharma, and Dynamic Global Events (DGE). Her focus is on improving clients' quality, efficiency, and compliance in operations through customized solutions. As Executive Director of Strategic Services for Framework Solutions, Rebecca is responsible for the strategic direction, growth, and success of client engagements within the Pharmaceutical and Life Sciences industry.

Nicole McCourt

Nicole McCourt is a senior member of the Strategic Services team at Framework Solutions. With over eight years of Marketing Operations experience within the Pharmaceutical and Medical Device industries she is recognized as a subject matter expert in the field of Content Management Strategy. Nicole has successfully supported over 30 late stage and commercial organizations in the design and deployment of Content Management and Reference Management Processes. In her current role as Senior Advisor, Strategic Services at Framework Solutions, she applies her unique insights as she works with client teams to identify tactical solutions designed to optimize and increase the quality, efficiency, and compliance of Content Management Processes.

References

[1] Source: "Establishing a Content Management Process as a Late Stage Company," Framework Solutions, May 2020 (https://framesol.com/establishing-a-content-management-process-as-a-late-stage-company/).
[2] Source: "Impacts of COVID-19 on Content Review and Approval Survey." Framework Solutions, 2020.
[3] Source: "Reference Management Process Data Report." Framework Solutions, 2020.