

P13 - Preparation is Key to Success: Use of the Document Content and Messaging Summary (DCAMS) in Authoring Regulatory Submission Documents

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INTRODUCTION

Appropriate planning of content and messaging ahead of the writing stage of a submission document is essential to ensure strategic alignment with key stakeholders and streamline document development. Early alignment on messaging reduces late-breaking critical comments and prevents the need for significant rework, that can add additional reviews and delay document finalization.

Here, we present our Document Content and Messaging Summary (DCAMS) for regulatory submission documents and how use can facilitate team alignment, engage stakeholders, and improve efficiency.

METHODS

A DCAMS is a short tabular document that identifies key messaging, supportive data, and possible risks. This living document should be developed prior to authoring the intended document and undergo review cycles, and therefore, should be built into the overall timelines.

RESULTS

Use of a DCAMS was well received by senior reviewers as a proactive time-saving approach that reduced reviewer burden during critical periods. We found it effectively facilitated discussion to allow the larger team to agree on the messaging, content, and data of the individual document prior to authoring. It also served as a concise summary for key stakeholders to review the team's plan, ensuring early agreement for the individual document. Critically, we observed it provided writers with a clear direction for efficient document development

CONCLUSIONS

While adding time for strategic development before document authoring begins may be a hard sell, the DCAMS has proven to be an effective tool for alignment within the team and management, ultimately saving time overall and smoothing the authoring and review processes.