

P7 - Growing Role of Regulatory Medical Writers in Driving and Optimising Submissions

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INTRODUCTION

The role of medical writers (MWs) has evolved over the past decades from merely being scribes to "submission strategists". In today's world, MWs play a major role in driving and optimising submissions. MWs

contribute increasingly and creatively towards forging efficiencies through several innovative approaches. These creative approaches foster a collaborative environment, enhance communication, and streamline writing and review processes, ultimately contributing to more efficient and successful submissions.

METHODS

We collected insights from experienced MWs about their role in driving teams toward successful submissions and developing and promoting innovative approaches to optimize future submissions.

RESULTS

A The collected findings illustrate the significant role of MWs in developing and optimising submissions through the creation and implementation of innovative strategies, such as

- Optimised document development and delivery through early engagement, cross-functional collaborations, and strategic thinking.
- Development and implementation of efficient project management tools and resourcing strategies.
- Adaptive writing strategies, including lean writing, and risk assessment and mitigation strategies.
- Creative approaches to collaborative authoring and review leveraging technology.
- Facilitating a streamlined process to deliver high-quality documents and promote efficient and accelerated working methods.
- Focusing on continuous improvement initiatives, continually refining processes, identifying areas for improvement, and enhancing efficiency in future submissions.
- Developing and providing training to writers and cross-functional teams to ensure quality and compliance, and to promote effective teamwork.

CONCLUSIONS

MWs combine scientific and operational expertise with strategic contributions, leadership, and successful partnering with cross-functional stakeholders, and, as such, play a critical and fundamental role in driving teams toward successful submissions.