

P9 - From Complexity to Clarity: The Power of Lean and Deductive Medical Writing

Maria Wendt - Merck Healthcare KGaA, Darmstadt, Germany

Michael Gyulay - EMD Serono Research & Development Institute, Inc., Billerica, MA 01821, USA

INTRODUCTION

Deductive writing and lean writing techniques are essential in the regulatory environment, where clarity and efficiency significantly impact the review and approval process. Deductive writing emphasizes presenting conclusions upfront, followed by supporting details, ensuring that critical information is immediately accessible. Lean writing eliminates redundancies and focuses on delivering concise content, saving reviewers' time, and facilitating swift data extraction. Here we report on the steps taken to implement these writing styles in our company.

METHODS

We collected and evaluated different approaches, tools and training materials that were used in our company to see which were most successful and why. We also examined the impact of these writing techniques on clarity, efficiency, and stakeholder engagement and identified best practices.

RESULTS

To promote the adoption of deductive writing among stakeholders, it is essential to emphasize its advantages, such as improved document clarity and reduced review times, while addressing potential drawbacks like perceived rigidity and resistance from stakeholders accustomed to more traditional writing styles. By providing tools such as training sessions and practical examples, stakeholders can be convinced of the benefits of deductive and lean writing in regulatory contexts. Consistent training is crucial especially within high turnover teams.

CONCLUSIONS

Implementing deductive and lean writing techniques is pivotal in optimizing the regulatory review process. By prioritizing clarity and brevity, these methods enable reviewers to locate critical data efficiently, reducing overall review timelines and enhancing decision-making. However, implementing these techniques requires a combination of structured training, practical tools, and active stakeholder engagement.