The AMWA Executive Forum identified understanding and promoting the value of medical writers as a key initiative for the organization. Three separate working groups were formed to address various aspects of demonstrating the value of a regulatory medical writer. This subgroup focused on "Measures of Success and its Drivers".

A team of experienced regulatory medical writers leveraged their collective knowledge and expertise to do the following:

1. Define components of a successful document in the context of regulatory medical writing.
2. Identify best practices for adhering to timelines, working with teams, and outlining key metrics for assessing quality.
3. Plan and provide tools for AMWA members that will support their efforts to achieve and measure success.

**BACKGROUND**

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**METHODS**

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**PRODUCTIVITY**

Improve cost/resource utilization and increase volume of work a writer is able to yield.

**QUALITY**

Reduce errors by using quality review checklists, training materials for document reviewers, and other tools.

**EFFICIENCY**

Balance accelerating timelines while improving quality. Identify time wasters that drive up costs.

**SPEED**

Use industry-standard timelines to benchmark the time required to prepare key regulatory documents.

**TEAM ENGAGEMENT**

Follow best practices to get information and support from cross-functional team members in a timely manner and maintain collaborative relationships.

A high-quality document is consistent, cohesive, succinct, and includes the necessary content while adhering to company policies and applicable Agency regulations. The scientific rationale/purpose is clearly stated, data are presented in well-constructed tables/graphs (as applicable), and results are an accurate interpretation of the data. The document should be well-organized with correct formatting, style, spelling, and grammar, and give the reader the ability to navigate easily.

**DEFINITION OF A QUALITY REGULATORY DOCUMENT**

An interactive toolkit is being prepared that aims to provide AMWA members with access to industry standards for timelines that can be used for benchmarking, document templates, example QC checklists, best practice guidelines, practice scenarios, and other helpful tools from experienced writers.

**COMING SOON**

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This initiative addresses barriers that medical writers encounter when communicating success to key stakeholders.