EMPOWERING MEDICAL WRITERS: ONWARDS AND UPWARDS FROM THE GROUND-BREAKING VALUE OF MEDICAL WRITING WORKSTREAM

The 2021 AMWA working group survey aimed to gain an understanding of how Regulatory Agencies perceive the value of medical writing.

Survey responses showed that:
- Document quality is extremely important for regulatory reviewers
- Poor document quality can hamper the ability of the reviewer to provide an assessment (delaying the drug approval process)
- Regulatory reviewers understand the role of medical writers, believe that they increase the quality of documents, and make the job of the regulatory reviewer easier

The survey also identified key factors affecting document quality that negatively impact application approval.

In 2022, work has continued to build on the survey results:

- Higher quality regulatory submissions
- Identify main document quality problems affecting submissions
- Identify how medical writers can help to solve the problems identified by the survey
- Produce a toolkit to educate and empower medical writers
- Empower medical writers to develop more effective authoring teams

TOOLKIT

This workstream is continuing the survey, and developing a toolkit based on Regulatory Agency survey results, describing best practices.

The goals of the toolkit are:
- Train medical writers to deliver succinct documents with clear and concise reporting of results and messaging, while achieving timelines
- Educate teams on how professional reviewers review documents
- Empower medical writers to act as strategists and key drivers of the documents
- Provide a slide deck that can be used at kick-off meetings with authoring teams

Lisa Chamberlain James1, Julia Forjanic Klapproth1, Rona Claire Grunspan1, Wayne Beazley3, Brian Bass1, Joan Affleck5, Julia Cooper6, Caroline Lilley7, and Amy Wollish8

1 Trilogy Writing and Consulting, Cambridge, UK and Frankfurt, Germany
2 Medical Writing, ICON, Leawood, Kansas, USA
3 Medical Writing, Astellas, Northbrook, Illinois, USA
4 Bass Global Inc, Fort Myers, Florida, USA
5 Medical Writing, Merck and Co., Inc, Rahway, New Jersey, USA
6 Global Medical Writing Services, Parexel International (IRL) Limited, Dublin, Ireland
7 Regulatory Writing, Amgen, Thousand Oaks, California, USA
8 Medical Writing, Jazz Pharmaceuticals, Raleigh, North Carolina, USA

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