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The Well-Rounded Medical Writer: It Goes Beyond Good Writing

AMWA 2023 Roundtable

27 October 2023

Who Are We?

Getting to know each other

My Background

- Pharmacist by education
- Clinical researcher by trade with 16 years experience
  - 14 years as a clinical trial manager
  - 2 years as a monitor/auditor
  - 3 years as a data manager/data scientist
  - 1+ year as a medical writer
  - No, that doesn't add up to 16
- All my experience is within clinical research at CROs

Your Background

- What is your education and professional history?
- How and why did you become a medical writer?
- What experience have you had outside of medical writing?

What Experience Is Most Helpful?

For My Clinical Research Writing:

- Data Management – Most helpful and applies to many documents on which I work (e.g., CSR, DSUR, IB)
- Clinical Trial Management – Useful for managing projects and herding cats
- Monitoring / Auditing – Good for protocol development

For Your Writing:

- What experience outside of medical writing has been most helpful?
- Interested in what differences, if any, there are between those working with regulated vs. non-regulated content.

How Do We Broaden Our Experience?

Within My Company

- Opportunities to help other functional areas with their tasks
  - QC SAEs for pharmacovigilance
  - Prepare CMC documentation with regulatory affairs
  - Somehow, I’ve become an unofficial blog editor
- The company offers access to skill-building programs

How Have You Done It?

- What opportunities are available to you?
- What are the challenges (few opportunities, time limitations)?
- Does anyone hold 2 positions concurrently (medical writing + _____)?
- Any favored educational resources?
- Any other avenues?