## **Speaker: Simone Otto, PhD**

## **By Melissa Growney**

At the intersection of innovation and compliance lies a crucial role for medical writers: crafting Clinical Evaluation Reports (CERs) and Clinical Evaluation Plans (CEPs) for medical devices. During a recent presentation for the 2025 AMWA Carolinas Chapter Conference, Dr. Simone Otto, PhD illuminated the growing importance of regulatory writing in this evolving space, highlighting how medical writers are essential in translating complex technical data into documents ready for regulatory assessment and opinion.

As Dr. Otto explained, a foundational understanding begins with a simple question: *What is a medical device?* From contact lenses to implantable defibrillators, as well as drug-device combinations, the range and complexity of medical devices continue to expand. Regulatory writers must stay abreast of how these devices are defined and classified under regional guidelines, such as the Food and Drug Administrations’ (FDA) Code of Federal Regulations (CFR).

Dr. Otto emphasized that writing CEPs and CERs is far more than box-checking; it is a rigorous process that requires a clear narrative, evidence synthesis, and critical appraisal of clinical data. Medical writers are tasked with demonstrating that a device is not only safe and performs as intended but also offers a clinical benefit that outweighs any risks. These evaluations rely on a blend of literature reviews, post-market surveillance data, risk assessments, and real-world evidence. It is a discipline that demands precision and scientific fluency.

She also introduced the memorable concept of the “Grandma test”: *Would you feel comfortable giving this device to your own grandmother?* This question underscores the ethical responsibility of ensuring devices meet the highest standards of safety and efficacy - fulfilling the standard general safety and performance requirements in addition to setting a standard for post-marketing safety protocols for risk management. Regulatory bodies depend on CERs and CEPs to inform their decisions on product validation and market authorization.

The field of regulatory writing is evolving alongside the devices themselves. Advances in biomedical engineering, wearable tech, Artificial Intelligence-powered diagnostics, and combination products push the boundaries of traditional evaluation frameworks. As innovation outpaces regulation, medical writers are often the first to confront ambiguity and interpret new guidance documents.

What does this mean for emerging medical or regulatory writers? For those seeking to enter or grow within regulatory writing, the demand is high for individuals who can critically analyze data, interpret regulatory requirements, and create documents that satisfy both scientific rigor and regulatory expectations. Training in systematic literature review methodologies, familiarity with developmental standards, and awareness of global harmonization efforts are invaluable assets.

Ultimately, writing CERs and CEPs is about bridging science and policy, as well as innovation and safety. As the regulatory landscape continues to shift, medical writers are poised to lead the way through clear, thoughtful, and evidence-based documentation.

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