DELAWRITER

The quarterly newsletter of AMWA-DVC

Late Winter, 2025

Bridging Borders: The International Standardization of Regulatory Submissions

by Rouletta A. Blowers

Globalization of the pharmaceutical and biotechnology industries has created demand for the international standardization of regulatory submissions. These documents play a key role in ensuring that life-saving therapies reach those in need. Previously, each country or region had its own set of submission requirements, which resulted in a complex web of documentation and related requirements. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) has been at the forefront of standardization efforts and has created the Common Technical Document (CTD), the gold standard for regulatory submissions. It includes modules covering administrative information, summaries, quality, safety, and efficacy data.

The electronic CTD (eCTD) builds on the foundation laid in the CTD by digitizing the submission process. An enhanced format allows for a living document by incorporating updates and changes more efficiently. It also simplifies the updates necessary to adhere to regional differences in requirements and preferences, allowing for quick, transparent communication between regulatory bodies and sponsors.

Advantages of eCTD v4.0

The latest version of the eCTD, v4.0, has been released. The United States Food and Drug Administration (FDA) began accepting regulatory applications in eCTD v4.0 on September 16, 2024. This updated version offers more support and compatibility with Health Level 7 (HL7) and other regulatory standards, allowing for the exchange of healthcare data from other drug applications, veterinary medicine, medical devices, cosmeceutical, and more.

Version incorporates several key benefits, including:
1) **Content Reusability**: In previous versions, sponsors could only reference sections within a submission unit. Adding unique identifiers allows references to carry through to future submissions or across several applications, without resubmitting the refereed section. This benefit is key to lean-authoring practices, streamlining updates, life cycle management, and reducing inconsistencies and compliance risks.
2) **Enhanced Life Cycle Management**: The updated version introduces a "Context of Use" (CoU) concept. CoU manages documents based on their CTD section or context, and coupled with keywords, facilitates life cycle management at the contextual rather than the document level. This approach allows for additional flexibility while maintaining life cycle traceability.

Context Groups are now based on CoU concepts and keywords. The study tagging files from Modules 4 and 5 are now obsolete.
3) **Improved Metadata Correction**: Keywords allow for simple changes to the metadata without having to resubmit the physical files. The correction of typos or name changes are facilitated by submitting a new value in place of the original erroneous value.
4) **Harmonized Submission Unit**: eCTD v4.0 consolidates Modules 1 through 5 into a single message (XML) schema in eCTD v 4.0, reducing the overall submission complexity. Previous versions used separated messages for Module 1 and Modules 2 through 5.
5) **Controlled Vocabularies**: Adopting certain controlled vocabularies from authoritative regulatory sources, eg, ICH, HL7, and others, ensures consistent, structured, traceable, and reusable information. Sponsors can also define their own terminology, standardize values across outcomes and registrations, expand overall data governance, and provide some explanation of the relationships between certain terms, e.g., Application, Submission, Submission Unit.
6) **Flexibility for Future Updates**: ICH and the partner agencies added these features for flexibility and to allow for more data-centric submissions. It is believed the new format is also key to expeditious updates to the eCTD structure in the future.

Regional Agency Standardization Efforts

There are still challenges to achieving complete global standardization of regulatory submissions, progress is being made. While differences in regional regulations and varying levels of technological infrastructure pose ongoing obstacles, international collaboration and strategic investments in infrastructures are paving the way toward more unified global standards. Besides the efforts by the ICH, regional agencies are also developing their own standardization initiatives.

The FDA's Knowledge-aided Assessment and Structured Application (KASA) initiative defines the organization and develops the governance of data collected during the product life cycle. This program is expected to enhance the overall quality and format of submissions while enabling increased risk identification, mitigation, and computer aided evaluation of content.

Presently, KASA focuses on Module 3 pharmaceutical quality, manufacturing, and control information. The FDA and European Medicines Agency are also prioritizing stronger collaboration on medicines to further inter-agency cooperation and efficiency. Adopting standardized submission processes and interregional collaboration will allow sponsors to develop more efficient allocation of resources and the ability to target multiple markets in a similar timeframe. In the meantime, the regulatory medical writing team can ensure consistency and simplify future updates using lean authoring.

Actionable Strategies for Global Regulatory Alignment

Other practical steps companies can take to prepare for global regulatory alignment include:
1) Invest in a **Regulatory Information Management (RIM) System** for alignment. RIM systems save time by centralizing data and automating document tracking. This gives regulatory and medical writing teams access to accurate, real-time information, streamlining multiple compliance processes.

When a commercial RIM system is not practical, a system composed of spreadsheets and related templates using notes and links, as needed, can denote:

- what data are needed
- where the data are stored

- when the data were updated/submitted
- who submitted/updated the data
- other relevant details

The major elements are being able to track what is updated versus what needs to be updated and what has been submitted. Tracking should be sufficient for various rounds of submission and review and can also include post-approval correspondence and reporting.

2) Implement **Responsive Compliance Practices for Regulatory Adaptability** in the ever-changing climate of global regulatory alignment, where companies must adapt quickly to new requirements. A flexible working environment enables companies to adapt and respond to changes, reducing disruptions in the regulatory timeline.

3) **Cross-Functional Teams** should be developed to facilitate global compliance, enabling prompt responses to the ever-changing regulatory climate and cross-border compliance. The team helps in several key areas: identifying key markets, providing regional training, developing a compliance framework, and handling other important tasks.

4) **Partner with Regulatory Agencies**. By fostering strong relationships with regulators, companies can expedite approvals, enhance their grasp of local regulations, and meet global standards.

5) A **Patient-centric Approach to Compliance**, which advocates faster approvals and prioritizes high-impact treatments. By incorporating real-world evidence, sponsors can strengthen their standing with regulators and gain more data on treatments for unmet medical needs. Collaboration with patient advocacy groups helps companies gain a deeper understanding of patient needs and design data collection methods which fit those needs. Ensuring compliance and strengthening future submissions is achievable through post-market surveillance and data collection plans.

The international standardization of regulatory submission documents is pivotal to optimizing global pharmaceutical and medical device distribution. The alignment of regulatory standards and format for submission will reduce barriers to innovation, enabling efficient comparison and evaluation of submissions, and expediting the approval process. With this collaborative effort, life-enhancing discoveries that transcend borders and significantly improve global health outcomes are expected in the future.

Rouletta Blowers has a Bachelor of Science in Civil Engineering Technology from Fairmont State University. Rouletta is an entrepreneur and founder and operates Technical Technique*, a technical writing and editing business. A writing enthusiast, she specializes in crafting technical documents which are easy to digest and tailored to the intended audience.*

Beyond Clickbait: How Science Communicators Can Reclaim the Narrative and Fight Pseudoscience

by Tim Rinehart

The hosts of the Unbiased Science podcast, Drs. Andrea Love and Jessica Steier, held a webinar for AMWA members this past year. Their podcast focuses on dispelling common misconceptions and disinformation in medical topics.

This webinar provided guidance for combatting misinformation and disinformation about science topics, as this issue has increased in visibility via social media and news channels. Recently, the topic of the health benefits of raw milk has trended over social media, but there are many other opinions that are also being rebranded as fact, despite evidence of the contrary.

Love and Steier stated that the Trump administration's Secretary of Health nominee, Robert F. Kennedy, Jr., promotes misinformation in many spheres of science and medicine, including the disproven notion that the MMR vaccine causes autism. The difficulty lies in rebutting and explaining the truth to the public when trust is low.

Who is more trustworthy with science news: journalists, non-governmental organizations, government leaders, technical experts, scientists, or peers? The public ranked scientists and peers the highest and both ranked at the same level on the trustworthiness scale. This points to a need to write for the layperson in a communicative, simple style.

To address the challenge of gaining the public's trust, Love and Steier advised educating individuals with a multi-pronged approach using multiple formats. While not everyone will listen to a full podcast about a topic, some individuals will instead read an email newsletter and infographics on social media. Adapting to different learning styles is key, and the wider the reach of your message through multiple communication platforms, the more likely it is that individuals will absorb the message.

Love and Steier also recommended that instead of using complex jargon in conversation, try "meeting a person where they are" in terms of science literacy. Only 28% of Americans are science-literate, indicating a need for plain, familiar language. The low basic literacy and education of the public in the United States needs to be kept in mind when drafting materials for them. While writing, it can help to keep an audience in mind, such as a

friend with a minimal science background.

Communicating effectively to the public can leave a lasting impact. Love and Steier presented a case study where they were approached to provide education about influenza vaccination. After a campaign that reached 1.3 million people across multiple channels, Love and Steier were able to directly convince approximately 11200 individuals who had never had a flu shot to get their first shot. In the age of vaccine denialism and skepticism about simple concepts like germ theory, this accomplishment in science education demonstrates the significance of clear communication.

Overall, the strategies discussed at this informative webinar empower science communicators to strive to appeal to the average person while fighting disinformation. Many of the flaws that Love and Steier pointed out throughout the presentation concern communication gaps that can be bridged between science and health communicators and the public. All it takes is simple alterations in information presentation and knowing how to reach the target audience through multiple communication platforms. Science communicators have a talent that can be harnessed to encourage critical thinking and help stem the tide of misinformation that will continue to grow.

Tim Rinehart has an MS in Communication from Drexel University. He has worked as a medical writer for over 5 years, most recently with the National Comprehensive Cancer Network (NCCN).

AMWA-DVC Midwinter Warm-Up Networking Dinner

By Shalini S Kumar

On the chilly night of February 6, 2025, over 10 souls braved the winter to meet at the Chevys Fresh Mex Restaurant in Linden, NJ. It was a great place to cozy down and network on what may otherwise have seemed like a dreary evening outside. The participant mix included new and existing members, as well as non-members who wanted to get a taste of what the AMWA-DVC chapter is like. As a non-member, I was excited to bring a fresh pair of eyes and later share my experience by contributing my perspective to the Delawriter.

From the get-go, the environment was warm and friendly, and every member was genuinely interested in learning about each other. This experience was quite refreshing; this was my first time at a networking event where I got the opportunity to strike up a conversation with every participant present. I have hosted many events in the past in New Zealand

and India, but I have never left an event thinking, “Well done, Shalini! You spoke to everyone in the room!” From a Project Manager’s perspective, it is a brownie point to see the whole team's participation. Medical Writers are assumed to be introverted and shy, but the friendly AMWA-DVC participants and newcomers helped us all shine.

The participants included established Medical Writers with several decades of experience, junior medical writers who have been in the field for a few years, and new participants who decided to dip their toes into this vast field. This was an ideal mix for a networking event. Those new to the field were able to better understand the progression of a medical writing career and easily visualize themselves in a similar role. Program Chair Laura Sheppard, MBA, MA, briefly discussed and introduced the AMWA-DVC Chapter and its President - Jennie Jacobson, PhD, CMPP, and President-Elect - Suzanne Bujara, BA, MBA. She briefed us about the upcoming events:

- The 23rd Annual Freelance Workshop, “Staying Competitive in a Crowded Marketplace: Building Your Freelance Business”, Saturday, March 8, 2025, and its pre-dinner networking event on March 7, 2025.
- The 28th Annual Princeton Forum (Virtual), Saturday, May 3, 2025

This briefing was followed by Jennie informing us about past activities and calling for volunteers who play an integral part in supporting these events. If you are keen to get some action yourself, please contact jennie@jacobsonmedicalwriting.com for available volunteering opportunities.

The networking dinner was a treat, it was delicious and sizzling, followed by mouthwatering sweet treats. The host for our night was an amazing lady, who would magically appear to hand us cups of water as though she had the power to read our minds. This restaurant is highly recommended — thanks, Laura, for selecting a great choice! All participants left with warmed hearts and nourished selves after having clicked a group picture and making sweet memories. Have I convinced you enough to join us at our next event?

AMWA-DVC Midwinter Warm-Up Networking Dinner, 2025

Shalini S Kumar, Ph.D., PMP, is a Scientist by training and Project Manager by profession. She recently moved to New Jersey from New Zealand and is open to building connections in the USA. With over 12 years of experience as a Researcher and Project Manager, she is looking for opportunities in the Project/Program/Portfolio Management space in Life Sciences and AgriBiotech.

Staying Competitive: Insights, Tips, and Networking at the 2025 Freelance Workshop

By Lori De Milto, MJ

Staying competitive as a freelance medical writer or editor is getting tougher. Participants will learn how to stand out in a crowded marketplace during the 23rd Annual Freelance Workshop hosted by AMWA-DVC in King of Prussia, PA on Saturday, March 8, 2025.

Whether you are just starting out or you have been freelancing for years, there is something for everyone, including presentations on how to:

- **Live your dream.** Sophie Ash will share how to avoid burnout while growing your business and building a freedom-focused life.
- **Get good, steady, high-paying clients.** Brian Bass will show us practical ways to avoid mistakes that get in the way of your success so you can get good, steady, high-paying clients.
- **Explore opportunities.** Andrew Bowser will highlight how to break into CME writing.

Participants will network with other freelance medical writers and editors through our:

- Pre-workshop dinner on Friday, March 7
- Networking lunch and networking activity during the workshop
- Interactive roundtables on 8 freelancing topics like rates and favorite tools
- Jam sessions where you can share your experiences in a supportive setting.

Questions about future workshops? Email Lori at loriwriter@comcast.net.

Lori De Milto is a freelance medical writer who has been helping clients attract, engage, and motivate audiences through targeted medical content since 1997. As host of The Mighty Marketer, Lori also helps other freelancers get the steady, high-paying clients they deserve. Lori is the founder of the AMWA-DVC Freelance Workshop and a member of the AMWA Journal Freelance Forum.

CALL FOR VOLUNTEERS

Co-Chair Volunteer Opportunity for the Online Princeton Forum

The online Princeton Forum is coming soon this spring. The forum focuses on how to write different types of documents, such as regulatory documents, continuing medical education, publications, grants, and sales training. Dan Benau will be serving as the co-chair. There is a spot open for one additional co-chair.

Responsibilities include identifying topics and speakers, follow-up with presenters before the conference, advertising to colleagues, other chapters and the national organization, registration management, and online management on the day of the conference.

Interested in volunteering for the Princeton Forum or learning more? Email Dan Benau at dbenau52@gmail.com with "Volunteer for Princeton Forum" in subject line.

Quotes of the month:

"The greatest reward for a writer is not recognition, but the knowledge that one's words have made a difference." – Unknown

"Write with the door closed, rewrite with the door open" – Stephen King

Jokes for the Quarter:

"What do you call a biologist's self-portrait? A cell-fie" – Unknown

"My grandfather was told a joke about genetics. My dad didn't get it, but I did." – Unknown

Remember, Use Proper Plurals and Singulars!

Use "The criteria are clear" instead of "the criteria is clear"

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