 corpus callosum

The ONLY medical writing event dedicated to addressing the challenges of clinical and regulatory professionals

3rd Clinical Regulatory MEDICAL WRITING Forum

Understand how to navigate the changing regulatory landscape and effectively manage resources and timelines

FEATURED SPEAKERS:

Cathy Cummins
Global Head, Submissions and Documentation
NOVARTIS

Tadas Petrys, Ph.D.
Associate Director, Regulatory Disclosures
GENENTECH

Lawrence Giraudi
Manager, PD Regulatory Documentation
F. Hoffman-La Roche

Sulochana Gawande, Ph.D.
Head of Oncology Medical Writing
Eisai

George Allan, Ph.D.
Associate Director, Regulatory Medical Writing
JANSSEN PHARMACEUTICAL R&D

Aaron B. Bernstein, Ph.D.
Senior Director, Medical Writing
Shionogi Inc.

EVENT HIGHLIGHTS:

✓ Discuss the new EU clinical trials regulations, the challenges of preparing lay summaries and how to stay ahead of the curve
✓ Learn how your peers manage data sharing, redactions and the anonymization of patient data
✓ Determine how to prepare a risk management plan and safety documents for the different regional regulatory authorities
✓ Explore the challenges of preparing pediatric documentation
✓ Discover which tools and technologies can help expedite the medical writing process

ADDITIONAL KEY SPEAKERS INCLUDE:

✓ Carmen E. Aldinger, Ph.D., M.P.H., Program Manager, MULTI-REGIONAL CLINICAL TRIALS CENTER OF BRIGHAM and WOMEN’S HOSPITAL and HARVARD
✓ Vishal Soni, Head of Clinical Pharmacology Medical Writing, HIV Medical Writing Lead, Global Regulatory Medical Writing, TEVA PHARMAECUTICALS
✓ Darryl Z. L’Heureux, Ph.D. Medical Data Operations Medical Writer, Global Clinical Operations, BRISTOL-MYERS SQUIBB
✓ Sara Symons, Manager, Medical Writing, GILEAD SCIENCES
✓ Maha Saad, Ph.D., M.B.A., Associate Director, Global Medical Safety, JANSSEN PHARMACEUTICAL R&D
✓ Bhaskar Shenai, Ph.D., Senior Manager, Medical Writing, PFIZER
✓ Madhu Mawal-Dewan, former Senior Manager, Medical Writing, NOVO NORDISK
✓ Mary Ann F. Wojcik, M.S., ELS, MWC, Senior Submission Writer, Oncology Submission Management/Drug Regulatory Affairs, NOVARTIS
✓ Julia Forjanic Klapproth, Ph.D., Senior Partner, TRILOGY WRITING & CONSULTING

Sponsored by:

ExL Events certifies that this conference has been approved for 12 Regulatory Affairs Credits (RAC) by the Regulatory Affairs Professional Society (RAPS)
Dear Colleague,

Regulatory medical writers face quite the challenging prospect when preparing applications and documents for submission to global regulatory authorities. They must coordinate with various stakeholders to gather, organize and compile information on new products and processes, interpret the data from clinical trials, and present the findings in a clear and concise way. Their ability to communicate the results and outcomes of a product while maintaining a logical narrative and managing aggressive deadlines helps determine whether a new therapeutic or medical device is approved for commercialization.

In order to remain compliant and gain approval from regulatory authorities, documents have to be composed and prepared according to changing regulatory guidelines, which can affect the structure and content. Therefore, it is vital for medical writers to stay up to date with the latest regulatory developments and anticipate how their documentation processes might be impacted.

The 3rd Clinical Regulatory Medical Writing Forum is designed to provide attendees with the strategies and insights needed to efficiently compose clinical regulatory documents, manage in-house and external resources, effectively execute the writing process and understand the recent developments in regulations. Exclusive sessions for 2016 include:

- Panel: Recent Developments and Their Ramifications on Clinical Trial Disclosure and Data Transparency
- The CORE Reference: A Medical Writer’s Guide to Preparing CSRs in an Evolving Context
- Medical Writing Challenges Stemming from Recent Developments in Pediatric Regulations
- Guidance for Medical Writers for Returning Aggregate Results to Participants Using Lay Language
- Panel: Utilize Tools and Technology to Help Improve the Efficiency of Medical Writing
- Innovative Ideas for Improving Communication Between Sponsors and Vendors to Create the Best Working Relationships

We look forward to meeting you at this must-attend event in Philadelphia!

Sincerely,

Zohaib Sheikh
Conference Production Director
ExL Events

WHO SHOULD ATTEND:
This conference is designed for representatives from pharmaceutical and biotechnology companies with responsibilities in the following areas:

- Medical/Regulatory/Scientific/Clinical/Technical Writing
- Regulatory Submissions/Documentation
- Medical Affairs
- Global Medical Publishing

THIS CONFERENCE IS ALSO OF INTEREST TO:
- Medical Writing Service Providers and Consultants
- Clinical Research Organizations
- Document Application Suppliers
- Information Management Consultants
- Research Informatics
- Component Authoring Software Suppliers
- Bibliographic Software Suppliers
- eCTD Suppliers
- Regulatory Submissions Providers
- Structured Content Software Suppliers

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Do you want to spread the word about your organization’s solutions and services to potential clients who will be attending this event? Take advantage of the opportunity to exhibit, underwrite an educational session, host a networking event or distribute promotional items to attendees. ExL Events will work closely with you to customize a package that will suit all of your needs.

VENUE
Sonesta Hotel Philadelphia
1800 Market Street | Philadelphia, PA 19103

To make reservations, please call 1-800-SONESTA and request the negotiated rate for ExL’s July meetings. The group rate is available until June 20, 2016. Please book your room early, as rooms available at this rate are limited.

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Learn about a new and valuable resource that provides descriptive, implementation, and interpretation guidance.

Describe the different safety documents required during clinical development and post-marketing.

Explore the use of structured content management tools to improve the efficiency of medical writing.

Assess industry requirements for more robust pediatric pharmacology studies.

Outline the function of each document and understand how they are linked.

Consider different ways of structuring the general format of this section.

Understand key concepts that can be applied to proactively prepare CSRs for uses that require redacted personally identifiable information.

Gain an understanding of the key concepts around preparing and reviewing fit-for-purpose CSRs in the context of modern drug development.

An Overview of Safety Documents: Regulatory Requirements and Interdependence
- Recognize the importance and impact of safety data for regulatory reporting
- Describe the different safety documents required during clinical development and post-marketing
- Summarize the scope and timelines for documents such as IBs, RMPs and annual reports (e.g., PBRERs, DSURs)
- Outline the function of each document and understand how they are linked

Sulochana Gawande, Ph.D., Head of Oncology Medical Writing, EISAI

10:00 Explore the Best Ways to Present Pharmacokinetic and Pharmacodynamic Data in the Summary for Clinical Pharmacology Studies
- Determine critical aspects of study design and data analysis that should be included
- Prepare succinct narratives to highlight the results and outcomes of pertinent individual studies
- Explore the best ways to present data to compare and analyze the results of critical studies

Vishal Soni, Head of Clinical Pharmacology Medical Writing, HIV Medical Writing Lead, Global Regulatory Medical Writing, TEVA PHARMACEUTICALS

10:45 Networking Break

11:15 Outsourcing: Achieve Success with Offshore Medical Writing, Overcome Challenges and Optimize Results
- Understand the difficulties of managing a team of medical writers in India and overseas, and how to overcome them
- Identify the best approaches to optimizing outsourcing relationships
- Employ training practices with a focus on improving writing standards, quality, speed and efficiency

Madhu Mawal-Dewan, formerly Senior Manager, Medical Writing, NOVO NORDISK

12:00 Luncheon

1:00 Approaches to Presenting Clinical Laboratory Evaluations in the Clinical Study Report
- Consider different ways of structuring the general format of this section
- Discuss tailoring the general content to a particular patient population or therapeutic area (e.g., healthy patients, oncology, liver disease)
- Determine the critically essential information that must be included in this section

Sara Symons, Manager, Medical Writing, GILEAD SCIENCES

1:45 Medical Writing Challenges Stemming from Recent Developments in Pediatric Regulations
- Review the EMA guidance on the preparation of pediatric investigation plans
- Analyze the FDA guidance for pediatric study plans and the best approaches for preparing them
- Assess industry requirements for more robust pediatric studies and evaluations

Cathy Cummins, Global Head, Submissions and Documentation, NOVARTIS

2:30 An Overview of Safety Documents: Regulatory Requirements and Interdependence
- Recognize the importance and impact of safety data for regulatory reporting
- Describe the different safety documents required during clinical development and post-marketing
- Summarize the scope and timelines for documents such as IBs, RMPs and annual reports (e.g., PBRERs, DSURs)
- Outline the function of each document and understand how they are linked

Sulochana Gawande, Ph.D., Head of Oncology Medical Writing, EISAI

3:15 Networking Break

3:45 Success by Design: Strategically Managing the Writing Process for Submission Dossiers
- Highlight the pitfalls of individual document preparation and the implications each document's message can have on the overall storytelling of the NDA
- Examine the role of the medical writing lead and how they can encourage discussion, mitigate debates and steer the storytelling of the application
- Create an effective strategy for lead writers to consciously assess and successfully focus the input from cross-functional teams
- Evaluate approaches to ensure reviewers understand the full implications and potential of the product they are assessing

Julia Forjanic Klapproth, Ph.D., Senior Partner, TRILOGY WRITING & CONSULTING

4:30 Panel: Utilize Tools and Technology to Help Improve the Efficiency of Medical Writing
- Explore the use of structured content management tools to reuse content and reduce the effort required for document preparation
- Share tools and add-ons that help improve writing efficiencies
- Discuss tips for widely used applications and programs, and how to best utilize them

Cathy Cummins, Global Head, Submissions and Documentation, NOVARTIS
Vishal Soni, Head of Clinical Pharmacology Medical Writing, HIV Medical Writing Lead, Global Regulatory Medical Writing, TEVA PHARMACEUTICALS

5:15 Conclusion of Day One

“In our rapidly changing regulatory environment, this conference provides the opportunity for medical writers to meet, network and share solutions to problems we are facing on a daily basis.”

Cathy Cummins, Global Head, Submissions and Documentation, NOVARTIS
Understand registries, data portals and the new regulatory requirements
Streamline documentation resourcing by assigning writers
Ensure institutional readiness for transparency
Create models for working with vendors/contractors that can discuss clinical data transparency and how it’s the new do’s and don’ts for reviewing CSRs and learn how to best train reviewers to provide meaningful feedback at each round of review
Apply the use of technology to get the most out of every clinical trial disclosure and data transparency panel: recent developments and their ramifications on clinical trial disclosure and data transparency
Examine the recent EU clinical trial regulations and their implications for medical writers
Discuss clinical data transparency and how it’s the new industry-wide norm
Determine possible approaches to the preparation and submission of lay summaries
Analyze the benefits of having a medical writer as a strategic partner in document preparation and submission planning
Ensure that the development of key messages and planned statistical outputs support the approved regulatory strategy by the early inclusion of a writer on cross-functional teams
Streamline documentation resourcing by assigning writers to the same set of molecules in the therapeutic portfolio to further leverage experience within the documentation team
Build relationships between the medical writer and various cross-functional team members to help drive document development
Understand how to author concise and focused CSRs for a “writing in isolation” situation
Develop strategies for the successful planning and execution of a “speed filing” round of review
Review templates for communicating study results — including Phase 1, Phase 2 and Phase 3 studies and clinical trials that stop early — as developed by a multi-stakeholder work group
Discuss how to communicate various endpoints in simple language
Learn about using lay language to communicate summary results
• Review a successful case study of a medical writing team who prepared a “speed filing” submission of lay summaries
• Discuss challenges encountered and strategies implemented
• Critique the relevance of the case study in relation to “normal” NDA filings
• Examine lessons learned and leverage takeaway materials for use

1:00 Case Study: How a Hyper-Compressed NDA Timeline at Dyax Inspired Breakthrough Performance from a Medical Writing Team
1:45 Clinical Study Report Authoring and Review: Best Practices for Preparing High-Quality CSRs While Minimizing Review Cycles
2:30 Practical Considerations for Preparing Marketing Authorization Renewals
3:45 Integrated Documentation Teams: A Model for Maximizing Efficiency
4:30 Innovative Ideas for Improving Communication Between Sponsors and Vendors to Create the Best Working Relationships
5:15 Chairperson’s Closing Remarks and Key Takeaways
5:30 Conference Conclusion
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MEDICAL WRITING

3rd Clinical Regulatory Forum

Understand how to navigate the changing regulatory landscape and effectively manage resources and timelines.

July 11-12, 2016 | Sonesta Hotel Philadelphia | Philadelphia, PA

EVENT HIGHLIGHTS:

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