The premier medical writing event dedicated to addressing the challenges faced by regulatory writers

4th Clinical Regulatory MEDICAL WRITING Forum

Understand the impact of recent regulatory developments and leverage innovative strategies to increase the operational efficiency of your medical writing group

FEATURED SPEAKERS

Madhavi Gidh-Jain, Ph.D.
Senior Director, Head of Medical Writing, Clinical Documentation (US), **SANOFI**

Vishal Soni
Head of NTE, Early Development and Clinical Pharmacology Medical Writing, **TEVA PHARMACEUTICALS**

Barbara Kress
Executive Director, Clinical Data Disclosure and Transparency, **MERCK**

Deborah Collyar
President, **PATIENT ADVOCATES IN RESEARCH (PAIR);** *Research Summary Manager,* **HEALTH LITERACY MEDIA (HLM)**

Lisa Cloutier
Head, Outsourcing Operations for Regulatory Medical Writing, **JANSSEN**

Gretchen Griffin, M.S., *Director, Regulatory Strategic Writing,* **ABBVIE**

July 10-11, 2017 | Sheraton Philadelphia University City | Philadelphia, PA

CONFERENCE CHAIRPERSON

Bert Wagner
Associate Director, Regulatory Medical Writing
JANSSEN

TOP REASONS TO ATTEND

- ✓ Learn about the updated guidance on EMA Policy 0070
- ✓ Discuss innovative ideas for improving collaboration between sponsors and vendors
- ✓ Review process re-engineering and change management strategies for implementing transparency initiatives
- ✓ Explore the use of cost-effective tools and technologies to help improve the efficiency of document preparation
- ✓ Hear about effective mentoring programs to recruit, train and hire medical writers

75+ attendees

20+ speakers

50+ companies represented

15+ hours of educational content

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PRINCIPAL MEDVANTAGE

TRILOGY Writing & Consulting | REWRITING MEDICAL WRITING

4th Clinical Regulatory MEDICAL WRITING Forum

Dear Colleague,

If there is one thing most medical writers are familiar with, it's the ability to juggle a range of responsibilities at once. Medical writers are responsible for integrating myriad scientific knowledge into comprehensive communications and efficiently preparing compliant documents for a diverse group of stakeholders. In order to do this, they must interface with cross-functional team members to collate clinical and nonclinical data, work with physicians and clinicians to understand the positioning of information in a document, and help create a common narrative that is consistent across a submission dossier.

The field of medical writing is one that is constantly prompted to do more with less. Whether it involves leveraging technology solutions to streamline your document preparation process or finding innovative ways to manage internal resources, medical writers act as project managers and can expect to wear multiple hats to excel in their role. A big part of this involves and relies on collaborations and strong partnerships.

Most life science companies partner with vendors and CROs for their medical writing needs, which can lead to communication and quality challenges. In addition to leading internal projects and teams, medical writers are required to effectively manage the timelines and output of outsourced writers. It is important to maintain an open channel of communication to avoid isolating contract writers and to ensure the documents they prepare are consistent with the big picture for the whole submission. However, aggressive timelines can cause these initiatives to fall by the wayside, which is why it's important to have robust processes in place for your team to rely on when the pressure is on and specific deliverables are needed.

The **4th Clinical Regulatory Medical Writing Forum** will feature real-world insights from industry experts that will help you improve the efficiency of your medical writing operations. Join our esteemed speaking faculty as they share an effective blueprint for developing mutually beneficial working relationships with vendors, creative approaches for leveraging technology solutions to prepare specific documents, and innovative strategies for training and developing new medical writers.

I look forward to welcoming you to Philadelphia in July!

Sincerely,
Zohaib Sheikh
Zohaib Sheikh
Senior Conference Director
ExL Events, a Division of Questex, LLC

VENUE INFORMATION

Sheraton Philadelphia University City
3549 Chestnut St.
Philadelphia, PA 19104

To make reservations please call 888-627-7070 and request the negotiated rate for **ExL's July Meetings**. You may also make reservations online at http://bit.ly/2msoy3S. The group rate is available until **June 23, 2017**. Please book your room early as rooms available at this rate are limited.

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WHO SHOULD ATTEND

This conference is designed for representatives from pharmaceutical, medical device and biotechnology companies with responsibilities in the following areas:

- ✓ Medical/Regulatory/Scientific/Clinical/Technical Writing
- ✓ Electronic Submissions/Documentation
- ✓ Clinical Trial Disclosure
- ✓ Clinical Trial Transparency
- ✓ Clinical Documentation/Publication
- ✓ Clinical Operations/Development
- ✓ Clinical Research
- ✓ Medical/Scientific Communications
- ✓ Medical Publications
- ✓ Regulatory Affairs/Operations
- ✓ 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

SPONSORSHIP AND EXHIBITION OPPORTUNITIES

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.

8:00 Registration and Continental Breakfast

8:45 Chairperson's Opening Remarks

Bert Wagner, *Associate Director, Regulatory Medical Writing,* **JANSSEN**

9:00 **Effective Project Management Tips for Medical Writers**

- Learn about organization prior to and during the document process
- Forecast and efficiently manage timelines
- Plan and lead strategic meetings to effectively communicate with teams
- Initiate productive document reviews while consolidating and resolving review comments

Lynne Munno, M.A., M.S., *Associate Director, Medical Writing,* **DECIPHERA PHARMACEUTICALS**

9:45 **Review Process Re-Engineering: How to Achieve More Efficient and Valuable Document Review**

- Outline goals and the best practices of the top review processes
- Gain a proper understanding of the purpose of a document and learn how to ensure that reviewers understand and contribute to this rather than simply "marking their territory"
- Examine the reasons why most review processes do not achieve their goals and miss the opportunity to add value and streamline the document finalization process
- Explain tactical, focused and strategic reviews and their roles in providing quality to a document in a timely manner

Barry Drees, Ph.D., *Senior Partner,* **TRILOGY WRITING & CONSULTING**

10:30 Networking Break

11:00 **Address the Need for Streamlined Processes and Increased Awareness Among Global Regulatory Authorities Regarding eCTD Submissions for Legacy Products**

- Hear a brief overview of the current process for submission of NCEs (new chemical entities)
- Discuss potential gaps relating to appropriate documentation required for the submission of new registrations and renewals for legacy products
- Explore strategies for a path forward for the submission of legacy product renewals and registrations in emerging markets

Anil H. Vaidya, *Associate Director, Medical Writing, Cardiovascular/Metabolic/Rare Diseases,* **PFIZER**

11:45 **Understand the New FDA Guidance for Assessing the Abuse Potential of New Products**

- Review structural guidelines for preparing Module 1 and Module 2.7 summary documents
- Learn how to efficiently write these two documents
- Understand the impact of this new guidance and its implications for medical writers

Vishal Soni, *Head of NTE, Early Development and Clinical Pharmacology Medical Writing,* **TEVA PHARMACEUTICALS**

12:30 Luncheon

1:30 **Preparing the Investigator's Brochures with the Investigator in Mind**

- Gain an overview of general requirements and guidance on the investigator's brochure (IB)
- Learn from a site investigator poll and understand how much time is spent reading the IB, which sections are most important to investigators and how they use the IB
- Discuss approaches to incorporate what the investigator wants and needs with agency requirements

Rene A. Alvarez, *Director, Medical Writing,* **SUNESIS PHARMACEUTICALS**

2:15 **An Overview of Pediatric Plans: Medical Writing for the Evolving Pediatric Landscape**

- Describe the applicable pediatric regulations and associated documentation requirements in both the EU and the US, including Pediatric Investigation Plans (PIPs), Pediatric Study Plans (PSPs), Proposed Pediatric Study Requests (PPSRs), modifications/amendments and waivers
- Contrast the development of pediatric plans between regions and discuss strategies for preparing plans in both regions
- Examine the role of the medical writer as a strategic partner in preparing pediatric plans

Jennifer Rilstone, Ph.D., *Senior Regulatory Documentation Scientist, PD Regulatory Documentation,* **F. HOFFMANN-LA ROCHE**

3:00 Networking Break

3:30 **Writing Plain Language Summaries in Accordance with the New EU Guidelines**

- Review the new EU guideline's recommendations for summarizing clinical trial results for laypeople
- Learn how to return results consistent with the EU guidelines, utilizing the MRCT Center Toolkit and Guidance Document
- Apply health literacy, numeracy and readability standards to plain language summaries
- Weigh the benefits of planning for plain language summaries in the early stages and throughout the clinical trial

Carmen E. Aldinger, Ph.D., M.P.H., *Program Manager,* **MULTIREGIONAL CLINICAL TRIALS CENTER OF BRIGHAM AND WOMEN'S HOSPITAL** *and* **HARVARD**

4:15 **PANEL: A Year Into Implementation — Where Does the Industry Stand in Meeting the EU's Clinical Trial Disclosure and Data Transparency Requirements?**

- Discuss how to improve operational efficiencies to meet required expectations
- Ensure the effective preparation of plain language summaries for the people they are meant to benefit: patients
- Explore the future landscape and discuss the challenges of returning individual participant results/summaries

PANEL

Carmen E. Aldinger, Ph.D., M.P.H., *Program Manager,* **MULTIREGIONAL CLINICAL TRIALS CENTER OF BRIGHAM AND WOMEN'S HOSPITAL** *and* **HARVARD**

Deborah Collyar, *President,* **PATIENT ADVOCATES IN RESEARCH (PAIR);** *Research Summary Manager,* **HEALTH LITERACY MEDIA (HLM)**

Behtash Bahador, *Program Manager, Communicating Trial Results,* **CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION (CISCRP)**

Barbara Kress, *Executive Director, Clinical Data Disclosure and Transparency,* **MERCK**

5:00 Day One Concludes

8:00 Continental Breakfast

8:45 Chairperson's Recap of Day One

Bert Wagner, *Associate Director, Regulatory Medical Writing,* **JANSSEN**

9:00 **How to Sustain and Grow a Relationship Between a Sponsor and Vendor**

- Choose a vendor that matches the sponsor culture
- Learn how to optimize the partnership between sponsors and vendors
- Build a culture of innovation and process improvement

Rumina Sunderji, *Outsourcing Manager, Product Development Regulatory Documentation,* **F. HOFFMANN-LA ROCHE**

9:45 **PANEL: Innovative Ideas to Improve the Working Relationship Between the Sponsor and Medical Writing Service Providers**

PANEL

- Determine how poor communication can create a multitude of challenges for each party
- Develop a strategy to tackle the issues caused by team members writing in isolation
- Create a process for training a team lead that is then responsible for training the rest of the team on company standards and expectations

Lisa Cloutier, *Head, Outsourcing Operations for Regulatory Medical Writing,* **JANSSEN**

Mari Welke, *Director of US Operations,* **TRILOGY WRITING & CONSULTING**

Maha Saad, Ph.D., MBA, *Associate Director, Global Medical Safety,* **JANSSEN**

Gretchen Griffin, M.S., *Director, Regulatory Strategic Writing,* **ABBVIE**

10:30 Networking Break

11:00 **Structured Content and Information Design That Maintains Consistency and Turns Content Into "Data"**

- Explore authoring processes and tools that allow you to reuse content from protocol development to disclosure in a consistent manner
- Map your documents and content for information design
- Reduce potential review times and tackle change management

Mitzi Allred, Ph.D., EE, *Director, Clinical Operations,* **MERCK**

Vasu Ranganathan, *President,* **ARBORSYS GROUP**

11:45 **Creative Artificial Intelligence (AI): Teaching Computers to Be Medical Writers**

- Explore the use of Natural Language Generation (NLG) technology (a subfield of AI) as an opportunity to provide automated contextual drafting
- Build an AI engine to create well-written, meaningful narratives for clinical study reports
- Gain efficiency by reducing time to first draft and decreasing quality control (QC) requirements

Madhavi Gidh-Jain, Ph.D., *Senior Director, Head of Medical Writing, Clinical Documentation (US),* **SANOFI**

12:30 Luncheon

1:30 **Develop a Robust Onboarding and Training Process for New Medical Writers**

- Understand the current state of regulatory medical writing education and identify development needs of new writers
- Examine a training initiative for new medical writers
- Hear about effective approaches for onboarding global university and post-doctoral candidates
- Consider the benefits of a rotation program for new writers at various sites in different capacities, while gaining exposure to multiple therapeutic areas

Bert Wagner, *Associate Director, Regulatory Medical Writing,* **JANSSEN**

2:15 **Competency Models and Certifications That Can Help Medical Writers Succeed**

- Consider what content and knowledge is essential for developing a medical writing competency model
- Apply this competency model to career development activities for sponsor and vendor writers
- Gain an overview of different medical writing certifications, identify their link to competency and appraise their professional merits

Darryl Z. L'Heureux, Ph.D., *Senior Scientific Writer,* **BRISTOL-MYERS SQUIBB**

Eileen Girten, M.S., *Adjunct Assistant Professor of Biomedical Writing,* **UNIVERSITY OF THE SCIENCES**

3:00 **PANEL: Effective Mentoring Programs to Recruit, Train and Hire Medical Writers**

PANEL

- Discuss how millennials view the field of medical writing and explore its impact on the future hiring landscape
- Address the challenges of training contract and vendor writers to meet internal quality standards
- Examine the value of training and certification programs and their impact on the career development of medical writers

Bert Wagner, *Associate Director, Regulatory Medical Writing,* **JANSSEN**

Darryl Z. L'Heureux, Ph.D., *Senior Scientific Writer,* **BRISTOL-MYERS SQUIBB**

Eileen Girten, M.S., *Adjunct Assistant Professor of Biomedical Writing,* **UNIVERSITY OF THE SCIENCES**

3:45 Conference Concludes

"The quality of the presentations were excellent and even better than I hoped for — practical, firsthand insights and collegial. Very high quality across the board, both in terms of content and presentation."

—Medical Writer, **THE EMMES CORPORATION**

"The greatest benefit of attending this meeting was the discussion of current and relevant topics and learning what industry and vendors are doing to meet today's demands in medical writing."

—Senior Global Medical Writing Lead, Pharmaceutical Development, **ALCON**

"Outstanding speakers and content with valuable information sharing focused on medical writing."

—Associate Director, Medical Writing, **PFIZER**

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EARLY BIRD PRICING *Register by Friday, May 19, 2017*	$1,895
STANDARD PRICING *Register after Friday, May 19, 2017*	$2,095
ONSITE PRICING	$2,295

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