

Medical Affairs and Scientific Communications Forum

Primer: March 22 | Short Courses: May 5 | Forum: May 6-7



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Overview

As a direct and sole result of the outbreak of the coronavirus disease (COVID-19) and due to circumstances beyond our control, DIA announced has decided to change the format of the upcoming Medical Affairs and Scientific Communications meeting from “face-to-face” (in-person) to entirely virtual.

Originally scheduled March 23-25, DIA’s *Medical Affairs and Scientific Communications Forum* **WILL** continue on its new dates May 6-7 in an **entirely virtual meeting format**, with both speakers and attendees participating remotely via a digital platform.

Medical Affairs and Scientific Communications Forum will remain an interactive, multi-day event that brings together professionals from around the world to discuss how medical information managers, medical writers, and MSLS can best respond to the changing global regulatory and compliance environments. This year, DIA will accomplish that goal via a live, digital platform.

DIA’s *Medical Affairs and Scientific Communications Forum* is designed for medical affairs professionals, by medical affairs professionals. This forum provides a comprehensive understanding of the regulatory and compliance environment directly affecting the daily activities of medical affairs and scientific communication professionals. Made up of multiple general and breakout sessions within three tracks covering medical communications, medical writing, and medical science liaisons, you can pick and choose which sessions to attend and create your own unique forum.

Medical Affairs professionals continue to take on more strategic leadership roles within their organizations. This year the theme for this forum is “Navigating the Future”. The program will delve into how medical affairs – medical information professionals, medical writers, and medical science liaisons – can best respond to the rapidly evolving landscape and serve as a primary tactical leader in healthcare product development. Topics will cover how current technological, economic, and regulatory trends affect the vision, role, and influence of medical affairs.

Highlights

- Three Tracks: Medical Communications, Medical Writing, and Medical Science Liaisons
- Four Half-Day Short Courses *Additional fee required
- Cross-functional General Sessions dedicated to the future of medical affairs
- Two Poster Supplements highlighting original research from fellows, residents in training, and professionals
- Podium Pearl Poster Presentations

Who Should Attend

Professionals involved in:

- Medical Communications
- Medical Writing
- Medical Science Liaisons
- Medical Information
- Medical Call Center Environment
- Regulatory Affairs
- Clinical Research
- Professional Education, Training, and Development
- Document Management/ eSubmissions

Download the DIA Global App!

It is designed to enhance your meeting experience and provide valuable information in one place: agenda and speaker information, presentations, connect with attendees and exhibitors, participate in live session polling, and more!

- **Channels:** Keep the conversation going by utilizing these new Track Channels for MASC. It's a virtual discussion board for all the topics or questions you have regarding all the tracks at MASC. Select Channels on the App Menu to access all the track discussion boards.
- **Evaluations:** We value your feedback and are always looking to improve the MASC Forum. Access the evaluations by selecting General Information in the App Menu. From General Information select the Evaluations button.



Download today by searching
"DIA Global" in your app store.

SAVE THE DATE! Medical Affairs and Scientific Communications Forum

March 22-24, 2021
Loews Royal Pacific Resort,
Orlando, FL



Schedule At-A-Glance

Track* Key: **Track 1:** Medical Communications | **Track 2:** Medical Writing | **Track 3:** Medical Science Liaisons *See track descriptions on page 4.

DAY ONE | TUESDAY, MAY 5

12:00-3:30PM	Short Course 1: Medical Communications: Compliance in 2020 *Additional Fee Required
On Demand	Short Course 3: Pubs Planning (3.25 hours) *Additional Fee Required
	Short Course 4: Lean Authoring (2 hours) *Additional Fee Required
	Short Course 5: MSL 101: Fundamentals for New and Aspiring MSLs (2 hours) *Additional Fee Required

DAY TWO | WEDNESDAY, MAY 6

10:00-11:00AM	Opening Keynote Panel: The Future of Medical Affairs
11:15AM-12:15PM	Medical Communications 2020 and Beyond
12:30-1:30PM	Empowering Medical Writers
1:45-3:00PM	Future-Proofing Your Medical Affairs Organization
3:15-4:15PM	Hot Topics
4:30-5:45PM	It's All Part of the Plan: Preparation and Planning for a Series of Submissions

DAY THREE | THURSDAY, MAY 7

10:00-11:15AM	The Patient Journey—Ensuring an Optimal Customer Experience Through MI Contact Center
11:30AM-12:45PM	Amplifying Field Success Through Internal Partnerships
1:00-2:00PM	Breakthrough Designation and Expedited Approvals
2:15-3:15PM	Building Effective Field Medical Team Partnerships: Best Practices and Case Studies for Aligning HEOR Liaisons and MSLs in Support of External Stakeholder Needs
3:30-4:30PM	Closing Keynote Address: Headlines vs. Trendlines: How to Innovate in a World of Uncertainty
On Demand	Professional Development Workshop - Self Branding for Social Media
	A Whole New World: Real World Evidence (RWE)
	Changing Paradigm: Evolution of the Patient in the Information Era
	AMCP Format and Dossiers
	Podium Pearls
	Branded Communication

The PMTA Submission: How Clear Safety Reporting is Important

Evolution of Medical and Device Writing

The Mysterious Regulatory Landscape in China: A Medical Writer's Perspective

Improving the Efficiency of Medical Writing with Artificial Intelligence and Automation Technologies

Is Sub-Specialization an Option or A Necessity for The MSL Role?

Sharpening Your Skills to Overcome the “Wi-Fi, MyFi, and Hi-Fi” Challenges in Your MSL Role

Track Descriptions

Track 1: Medical Communications Track

Medical Information/Communications departments are evolving to meet customers' needs. Hear how some of these functions have evolved. Gain tangible insights on how to improve customers' experience while they engage with pharmaceutical/biotechnological companies via various touchpoints, when and how to successfully partner with suppliers. Explore the patient journey and how to communicate with patients and/or their caregivers. Further understand how real world evidence may be used in communications with customers based on recent guidances. Apply these learnings to refine content creation and dissemination to meet our evolving customer needs. The last session will weave in all three tracks to highlight change management and how to successfully navigate change.

Track 2: Medical Writing

Network and learn from your Medical Writing and Communications colleagues. Independent industry experts will share the latest approaches in medical regulatory and publication writing. The topics on tap include the scientific theory behind new therapies, empowering tactics for medical writers, the evolution of medical writing into the future, the process and practice of breakthrough and expedited drug approvals, regulatory submission writing in China, planning a series of submissions, and how automation in medical writing is the path to the future of our craft. Attend the Medical Writing track for an exciting and informational look into the challenges and emerging opportunities in Medical Writing.

Track 3: Medical Science Liaison Track

This track is appropriate for current or prospective Field Medical Professionals, including: Medical Science Liaisons (MSLs), MSL Supervisors, MSL Operations, HEOR Liaisons, and anyone else with interest in learning more about the issues impacting the Field Medical role. You will find a comprehensive and cohesive agenda that has been curated and peer-reviewed by recognized thought leaders from the global MSL and Field Medical community. The theme will be: Future-Proofing Your Role in Medical Affairs. The content is high-quality and non-biased, developed by Field Medical professionals for Field Medical professionals in the setting of DIA's neutral, global forum. This is your opportunity to network with and be a Medical thought leader!

Virtual Meeting May 6-7 - Continuing Education



DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This program is designated for up to 12 contact hours or 1.2 continuing education units (CEU's).

If you are claiming ACPE credit for this virtual meeting you must:

1. Complete a CE Verification of Attendance Form
2. Return it to NAEvents@diaglobal.org by May 14, 2020
3. Access your DIA account and select My Transcript to claim your ACPE credit, available on Thursday, May 21, 2020



**ACPE CREDIT REQUESTS
MUST BE SUBMITTED BY
FRIDAY, JUNE 19, 2020**

DIA is required by the Accreditation Council for Pharmacy Education (ACPE) to report pharmacy-requested CEUs through the CPE Monitor system. All ACPE-certified activity credit requests need to be submitted through DIA's My Transcript within 45-days post activity. If ACPE credit is not requested by Friday, June 19, 2020, the CEU request will not be transmitted through to the CPE Monitor. Pharmacists will need to provide their National Association of Boards of Pharmacy (NABP) e-Profile ID and date of birth (MMDD) to ensure the data is submitted to the ACPE and NABP properly.



Drug Information Association (DIA) is accredited by the International Association for Continuing Education and Training (IACET) and is authorized to issue the IACET CEU.

As an IACET Accredited Provider, DIA offers CEUs for its programs that qualify under the ANSI/IACET Standard. DIA is authorized by IACET to offer 1.2 CEUs for this program.

Participants must attend the entire virtual meeting in order to be able to receive an IACET statement of credit. No partial credit will be awarded.

If you would like to receive a statement of credit, you must attend the virtual meeting, complete the "CE Verification of Attendance" form, turn in your form to NAEvents@diaglobal.org by May 14, 2020, and claim CE via the online credit request process through DIA at My Transcript. Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests on **Thursday, May 21, 2020**.

TO ACCESS MY TRANSCRIPT

- Visit DIAGlobal.org
- **Sign In** with your DIA User ID and Password
- Select the Welcome Menu in the upper right hand corner (where your name appears)
- Select **My Account** from the menu
- Select **My Transcripts** then **Manage My Transcripts**

ACCESS PRESENTATIONS

- Visit DIAGlobal.org
- **Sign In** with your DIA User ID and Password
- Select the Welcome Menu in the upper right hand corner (where your name appears)
- Select **My Account** from the menu
- Choose **My Presentation**

Please Note: DIA User ID and Password are needed to access presentations. If you have forgotten your DIA User ID and Password, or this is your first time logging into the DIA website, please use our Login Reminder. **Presentations will be available for six months post conference.*

Primer: The Fundamentals of Medical Communications: Pharmacy 7 contact hours or .7 CEUs, IACET .7 CEUs

Live Virtual - UAN: 0286-0000-20-024-L04-P; Application

Short Courses

Short Course 1: Medical Communications: Compliance in 2020: Pharmacy 3.25 contact hours or .325 CEUs; IACET .3 CEUs

Live Virtual - UAN: 0286-0000-20-077-L04-P; Application

Short Course 3: Pubs Planning: Type of activity: Knowledge 3.25 contact hours or .325 CEUs; IACET .3 CEUs

On Demand - UAN: 0286-0000-20-027-H04-P

Short Course 4: Lean Authoring: Type of activity: Knowledge 2 contact hours or .2 CEUs; IACET .2 CEUs

On Demand - UAN: 0286-0000-20-028-H04-P

Short Course 5: MSL 101: Fundamentals for New and Aspiring MSLs: Type of activity: Knowledge 2 contact hours or .2 CEUs; IACET .2 CEUs

On Demand - UAN: 0286-0000-20-029-H04-P

Virtual Meeting Pharmacy Credit Breakdown

Opening Keynote Panel: The Future of Medical Affairs: Pharmacy 1 contact hours or .1 CEUs; IACET .1 CEUs

Live Virtual - UAN: 0286-0000-20-030-L04-P; Knowledge

Medical Communications 2020 and Beyond: Pharmacy 1 contact hours or .1 CEUs; IACET .1 CEUs

Live Virtual - UAN: 0286-0000-20-031-L04-P; Knowledge

Empowering Medical Writers: Pharmacy 1 contact hours or .1 CEUs; IACET .1 CEUs

Live Virtual - UAN: 0286-0000-20-032-L04-P; Knowledge

Future-Proofing Your Medical Affairs Organization Pharmacy 1.25 contact hours or .125 CEUs; IACET .1 CEUs

Live Virtual - UAN: 0286-0000-20-042-L04-P; Knowledge

Hot Topics: Pharmacy 1 contact hours or .1 CEUs; IACET .1 CEUs

Live Virtual - UAN: 0286-0000-20-049-L04-P; Knowledge

It's All Part of the Plan: Preparation and Planning for a Series of Submissions: Pharmacy 1.25 contact hours or .125 CEUs; IACET .1 CEUs

Live Virtual - UAN: 0286-0000-20-044-L04-P; Knowledge

The Patient Journey – Navigating an Optimal Customer Experience Through Contact Centers: Pharmacy 1.25 contact hours or .125 CEUs; IACET .1 CEUs

Live Virtual - UAN: 0286-0000-20-043-L04-P; Knowledge

Amplifying Field Success Through Internal Partnerships: Pharmacy 1.25 contact hours or .125 CEUs; IACET .1 CEUs

Live Virtual - UAN: 0286-0000-20-045-L04-P; Knowledge

Breakthrough Designation and Expedited Approvals: Pharmacy 1 contact hours or .1 CEUs; IACET .1 CEUs

Live Virtual - UAN: 0286-0000-20-051-L04-P; Knowledge

Building Effective Field Medical Team Partnerships: Pharmacy 1 contact hours or .1 CEUs; IACET .1 CEUs

Live Virtual - UAN: 0286-0000-20-052-L04-P; Knowledge

Closing Keynote Address: Headlines vs. Trendlines: How to Innovate in a World of Uncertainty: Pharmacy 1 contact hours or .1 CEUs; IACET .1 CEUs

Live Virtual - UAN: 0286-0000-20-056-L04-P; Knowledge

On Demand Offerings – Continuing Education

DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This program is designated for up to 23.5 contact hours or 2.35 continuing education units (CEU's).

ACPE Credit Requests



DIA is required by the Accreditation Council for Pharmacy Education (ACPE) to report pharmacy-requested CEUs through the CPE Monitor system. All ACPE-certified activity credit requests need to be submitted through DIA's My Transcript within 45-days post activity. Pharmacists will need to provide their National Association of Boards of Pharmacy (NABP) e-Profile ID and date of birth (MMDD) to ensure the data is submitted to the ACPE and NABP properly. If you need to obtain your NABP e-Profile, please visit www.cpemonitor.net.



Drug Information Association (DIA) is accredited by the International Association for Continuing Education and Training (IACET) and is authorized to issue the IACET CEU. As an IACET Accredited Provider, DIA offers CEUs for its programs that qualify under the ANSI/IACET Standard. DIA is authorized by IACET to offer up to 2.3 CEUs for this program.

Statement of Credit

If you would like to receive a statement of credit, you must complete all sessions in the desired, On Demand MASC track, complete the post-assessment and evaluation, and claim CE via the online credit request process through DIA at My Transcript. Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests on Thursday, May 21, 2020.

On Demand Sessions

Attendee must complete ALL On Demand sessions within the desired track to earn the applicable CE credits. Attendee can complete all four tracks for a maximum number of 23.5 credit hours.

Medical Communications Track:

UAN: 0286-0000-20-082-H04-P Type of activity: Knowledge
7 contact hours or .7 CEUs; IACET .7 CEUs

- Medical Communications 2020 and Beyond
- Hot Topics
- The Patient Journey – Ensuring an Optimal Customer Experience Through MI Contact Center
- A Whole New World: Real World Evidence (RWE)
- Changing Paradigm: Evolution of the Patient in the Information Era
- AMCP Format and Dossiers
- Podium Pearls

Medical Writing Track:

UAN: 0286-0000-20-083-H04-P Type of activity: Knowledge
9.25 contact hours or .925 CEUs; IACET .9 CEUs

- Empowering Medical Writers
- It's All Part of the Plan: Preparation and Planning for a Series of Submissions
- Breakthrough Designation and Expedited Approvals
- Branded Communication
- The PMTA Submission: How Clear Safety Reporting is Important
- Evolution of Medical and Device Writing
- The Mysterious Regulatory Landscape in China: a Medical Writer's Perspective
- Improving the Efficiency of Medical Writing with Artificial Intelligence and Automation Technologies

Medical Science Liaisons Track:

UAN: 0286-0000-20-084-H04-P Type of activity: Knowledge
5.25 contact hours or .525 CEUs; IACET .5 CEUs

- Future Proofing Your Medical Affairs Organization
- Amplifying Field Success Through Internal Partnerships
- Building Effective Field Medical Team Partnerships: Best Practices and Case Studies for Aligning HEOR Liaisons and MSLs in Support of External Stakeholder Needs
- Is Sub-Specialization an Option or A Necessity for The MSL Role?
- Sharpening Your Skills to Overcome the “Wi-Fi, MyFi, and Hi-Fi” Challenges in Your MSL Role

General Sessions:

UAN: 0286-0000-20-085-H04-P Type of activity: Knowledge
2 contact hours or .2 CEUs; IACET .2 CEUs

- Opening Keynote Panel: The Future of Medical Affairs
- Closing Keynote Address: Headlines vs. Trendlines: How to Innovate in a World of Uncertainty
- Professional Development Workshop – Self Branding for Social Media – No credit available

12:00-3:30PM

Short Course 1: Medical Communications: Compliance in 2020

**Additional Registration Fee Required*

Instructors

Monica Kwarcinski, PharmD, Vice President, Medical Affairs, Purdue Pharma L.P.

Mark DeWynngaert, PhD, Managing Director, Life Sciences, Deloitte & Touche, LLP

Gary Messplay, Partner, King & Spalding LLP

The compliance obligations within the pharmaceutical industry continue to increase each year. Now more than ever it is critical that medical communication departments have policies and procedures that address such things as medical inquiry and response documentation, staff training, and monitoring/audit programs. Whether you have been in medical communications for a few months or a few decades, this short course will provide an overview of what policies, procedures, and programs medical communications departments should consider implementing to help ensure compliance and mitigate risk. This will be an interactive course with opportunity for discussion and questions.

At the conclusion of this short course, participants should be able to:

- Discuss compliance hot topics in medical communications such as medical inquiry documentation, response development, review, and dissemination, Sunshine Act reprint reporting requirements, staff training, and sales force facilitated inquiries
- Discuss FDA guidances relevant to medical communications
- Describe what policies and procedures the Office of Inspector General (OIG) is requiring medical communications departments to have in place based on recent Corporate Integrity Agreements (CIA)
- Identify the factors to consider when developing, implementing, and maintaining QA, compliance, and training programs
- Describe how to mitigate risk in medical communications

On Demand

Short Course 3: Pubs Planning (3.25 hours)

**Additional Registration Fee Required*

Instructors

MaryKate Lesnevich, MS, CMPP, Associate Director, Global Scientific Communications, I&I, Celgene Corporation

Bhakti Kshatriya, PharmD, Founder, Publication Practice Counsel, Truposha, LLC

Publication of scientific and clinical research is fundamental in ensuring that findings are communicated to the scientific and medical community to ultimately help improve patient's lives. Scientific communication works to lead, organize, and develop the dissemination of quality and timely publications. The course will not only provide an overview of publication planning but also go into specific details on each element of the work process. You should have a good understanding of the core elements of publication development and a desire to expand your skill set relevant to strategic publication planning. This will be a highly interactive course with ample time for discussion and questions.

At the conclusion of this short course, participants should be able to:

- Discuss the role and responsibilities of scientific communications within the medical affairs organization
- Describe the components of the publication planning process which include: gap analysis, needs assessment, publication objectives, strategic publication plan, tactical publication plan, individual publication project planning, and development
- List the key activities, team members, and timing associated with the development of an individual publication project
- Identify the factors to consider when developing, implementing, and executing a publication plan
- Discuss the need for capturing documentation of reviews and approvals associated with each individual publication project
- Explain the industry standards for publications, such the International Committee of Medical Journal Editors (ICMJE) recommendations and Good Publication Practice (GPP3) guidelines as they relate to requirements for authorship, timeliness of publication, ensuring scientific rigor, and fair balance of content

On Demand

Short Course 4: Lean Authoring (2 hours)

**Additional Registration Fee Required*

Instructors

Ruggero Galici, PhD, Associate Director, Medical Writing, Pfizer, Inc.

Elizabeth Brown, PMP, Managing Medical Writer, Merck & Co., Inc.

Kimberly Jochman, PhD, Senior Principal Medical Writer, Merck & Co., Inc.

In today's regulatory environment, authors are routinely faced with writing numerous regulatory submission documents involving highly complex studies with overwhelming amounts of data. It is therefore imperative to develop documents that clearly convey the intended key messages to facilitate agency review. This short course will provide an overview of lean authoring, with discussion on the benefits and challenges of this approach. Hands-on activities will offer practical solutions to reduce content redundancy and to improve clarity of regulatory documents, with a focus on key messages. Strategies to help lean authoring succeed at your organization will also be discussed.

At the conclusion of this session, participants should be able to:

- Discuss the benefits of implementing a lean, message-based approach to authoring
- Apply techniques for introducing and highlighting the key messages
- Author documents with the needs and expectations of the target audience in mind
- Identify strategies for implementing lean authoring at their organization

On Demand

Short Course 5: MSL 101: Fundamentals for New and Aspiring MSLs (2 hours)

**Additional Registration Fee Required*

Instructors

Ed Cunningham, PharmD, Senior Director, Neurology Medical Science Liaison Lead, Sunovion

Angela Kodsi, PharmD, Rare Neuroscience Medical Affairs Director, Pfizer, Inc.

This short course will provide new and aspiring MSLs an understanding of the foundational principles for success in an MSL role. Topics will be wide-reaching and will include:

- Thought leader identification techniques and relationship development skills
- How to build strong, compliant internal partnerships
- Tips for effective scientific exchange
- Basic MSL business acumen skills ranging from territory management, adapting to evolving customer needs, working with other field colleagues, and managing administrative tasks

At the conclusion of this short course, participants should be able to:

- Describe the potential challenges MSLs face early in their new career
- Examine best practices for MSL success, including thought leader identification, territory management, and partnering compliantly with internal colleagues
- Discuss skills and techniques that are foundational for a successful MSL career
- Identify competencies that are necessary for growth within and beyond an MSL role

DAY TWO | WEDNESDAY, MAY 6

10:00-11:00AM

Opening Keynote Panel: The Future of Medical Affairs

Moderator

Rebecca Vermeulen, RPh, Vice President Strategy Lead Patients and Society, Hoffman-LaRoche, Ltd.

Medical Affairs continues to forge a new role as a strategic pillar for healthcare product and innovation. Teams within medical affairs support critical aspects of the drug development lifecycle. With these new responsibilities, challenges emerge. This keynote panel will highlight perspectives on how medical affairs will change the landscape for drug development. Panelists will provide insights on how medical affairs will continue to impact patients' needs, while providing recommendations for engaging global scientific experts to drive product development.

At the conclusion of this opening keynote panel, participants should be able to:

- Discuss the evolution of the medical affairs role and its impact in the drug development landscape
- Identify the role medical affairs plays in impacting the needs of patients
- Identify ways in how to engage globally with scientific experts to help drive the development of products

Alexandra Zemp, PhD, Partner, McKinsey & Company, Inc., Switzerland

Kirk Taylor, MD, Senior Vice President, North American Medical Affairs, EMD Serono

11:15AM-12:15PM

Medical Communications 2020 and Beyond

Session Chair

Dannis Chang, PharmD, Senior Director, Medical Communications & Operations, Myovant Sciences

For the past several years, Medical Affairs is increasingly recognized and have been held accountable to support critical success factors across the business to meet the needs of the medical community and the patients. With a growing number of challenges related to medical knowledge and information due to an information revolution in the digital space, policy changes, and evolving pipelines, a changing healthcare landscape is placing new demands on the life sciences industry. With the drive for greater demand of deep scientific information across the medical community and patient organizations, pharmaceutical companies are tackling these shifts through the expertise of Medical Affairs, specifically Medical Communications (MC) function. In the bio-pharmaceutical industry, the role of MC is to provide product-related medical information to healthcare professionals and consumers worldwide, as well as conveyance of knowledge to internal stakeholders and other relevant departments. With recent changes to regulatory and marketing practices, safety surveillance, and delivery of information conveyed to the medical communities, the traditional MC paradigm has shifted to a leadership function with decision-making entity, with anticipation of new and emerging responsibilities to enhance the work in Medical Affairs.

At the conclusion of this session, participants should be able to:

- Explore the recent changes in healthcare landscape
- Identify new emerging roles and responsibilities of the MC functions from a team structure perspective
- Discuss how the function of medical communications can optimize critical paths

A Vision to Optimize Customer Experiences and Outcomes

Stacey Fung, PharmD, Senior Director of Medical Information, Gilead Sciences

Optimizing MedComm Teamwork in 2020 And Beyond: A Perspective

Tony Lin, PharmD, RPh, Head of Scientific Communications, Medical Review and Knowledge Management, Pharmacyclics

12:30-1:30PM

Empowering Medical Writers

Session Co-Chairs

Andrea Meyers, Vice President, Medical Writing, Syneos Health

Dan Benau, PhD, Director, Biomedical Writing Programs, University of the Sciences

Medical writers are professionals in the therapy development and promotion fields. Although respect for this profession has increased over the past two decades, there are still islands of prejudice that inhibit the accomplishment of quality production and timeliness of document creation and publishing. This session will explore these problems and propose solutions to allow negotiating those obstacles. The session will also explore ways in which the medical writer can identify and properly handle discoveries of potential site fraud or misconduct, giving the writer the tools to identify it and how to deal with it while meeting deliverable timelines and ensuring GCP compliance.

At the conclusion of this session, participants should be able to:

- Maintain confidence as a professional in the field
- Recognize obstacles that prevent writers from keeping to schedules
- Avoid risky shortcuts that undermine quality

Empowerment is a Strategy, Not a Fist

Andrea Meyers, Vice President, Medical Writing, Syneos Health

Empowering Female Writers

Nancy Katz, PhD, President and Principal, Medical Writing Consultant, Illyria Consulting Group, Inc.

Future-Proofing Your Medical Affairs Organization

Session Co-Chairs

Kevin Appareti, MBA, Senior Director, Global Medical Science Liaisons, Royal Philips

Robin Winter-Sperry, MD, Head, Global Field Based Medical Excellence, Sanofi Genzyme

Healthcare continues to transform at a rapid pace across the globe. In many ways it is a perfect storm of change. There are profound trends that are driving change from global resource constraints to aging populations and the rise of chronic illnesses, to increasing consumer engagement, to broad technology disruption and innovation. The strategic imperative for healthcare providers and industry alike, is to navigate the ecosystem effectively and with purpose to drive better patient outcomes while maintaining a viable economic foundation. Healthcare industry organizations, whether it be pharmaceutical, medical device, diagnostics, or others, will survive and indeed “win” when they not only understand the dynamic ecosystem but use their science and technology acumen to drive innovations in partnership with key customers to inform the solutions that ultimately get delivered to patients. Medical Affairs teams are in the perfect position to lead this change and be an integral part of the strategic infrastructure of a company bringing medical/scientific data-driven value to the company’s success.

At the conclusion of this session, participants should be able to:

- Identify the major trends and drivers in Healthcare affecting Medical Affairs Organizations
- Translate the implications of these trends to Medical Affairs Organizations
- Apply a strategic planning process to support the value of Medical Affairs Organizations

Kate Chavez, MBA, Associate Partner, McKinsey & Company

Sameer Lal, MBA, Senior Vice President, Business Development, Indegene

Hot Topics

Session Chair

Hanady Elhadidy, PharmD, Global Medical Customer Engagement Lead, Bristol-Myers Squibb

This session will touch on three hot topics trending in the industry that may shape how we work in the future. These topics are: Gamification of Training to Enhance Adult Learning, and Congress Booth Effectiveness & Innovation, and creative ways of supporting activities given budget restrictions. Guest speakers from three companies will review some of the cutting edge work they are doing around these topics. The format of this session will be informal and audience questions are encouraged.

At the conclusion of this session, participants should be able to:

- Discuss innovative approaches to Gamification and congress booth effectiveness
- Think creatively about solving resources constraints for Medical Affairs staffing around company launches/growth
- Consider emerging trends in technology and their impact on Medical Communications.

Use of Gamification in Medical Training

Stacey Mont, PhD, Medical Communications, Bristol-Myers Squibb

Congress Booth Effectiveness & Innovation

Sejal Patel, PharmD, Vice President, Medical and Regulatory Affairs, Sprout Pharmaceuticals

Creative Thinking: An Example of Obtaining the Elusive Staffing Approvals for Medical Support of Launches

Christi Marsh, PharmD, Director, Medical Engagement and Communications, GlaxoSmithKline

It's All Part of the Plan: Preparation and Planning for a Series of Submissions

Session Chair

Ann Winter-Vann, PhD, Senior Writer and Manager, Whitsell Innovations, Inc.

When you are faced with a staggered series of submissions to different regulatory agencies or simultaneous submissions for different indications or both, the challenges increase exponentially. We will discuss how to plan for consistency with the careful reuse and revision of text between documents and across a team of writers. We will also present strategies to map out timelines that are feasible and keep team members involved but not exhausted.

At the conclusion of this session, participants should be able to:

- Assess the challenges involved in sequential submissions
- Employ best practices for the reuse and revision of text across related documents
- Construct timelines for a staggered series of submissions

Submission to Multiple Regions

Lima Chutkan, PhD, RAC, Associate Director, Medical Writing, Alnylam Pharmaceuticals, Inc.

Multiple Indications, Line Extensions and Formulation Changes

Kirsten Helmcke, PhD, RAC, Associate Medical Writing Program Director, Astellas Pharma Global Development

DAY THREE | THURSDAY, MAY 7

10:00-11:15AM

The Patient Journey –Ensuring an Optimal Customer Experience Through MI Contact Center

Session Co-Chairs

Robert Tamburri, PharmD, MBA, Director, Medical Information Communication Channel, Janssen Scientific Affairs, LLC

Amy Van Sant, PharmD, MBA, President, Medical Affairs, Ashfield Healthcare, LLC

In recent years, the channels of medical information available to different stakeholders have proliferated to elevate contact centers and take a more holistic approach to reach customers. In this session, we will explore factors that impact the patient journey when interacting with medical information contact centers. You will hear about how the evolving landscape plays a critical role in identifying customer preferences related to how they want to engage with medical information contact centers. You will also learn more about current approaches related to interaction platforms and interactive content being developed to enhance customer engagement.

At the conclusion of this session, participants should be able to:

- Discuss the concept of the “patient journey”
- Describe the current landscape of the customer journey and customer engagement preferences
- Identify examples of Omni channel offerings for medical information contact centers and items to consider when enhancing contact center capabilities and innovative content

Medical Communications of the Future

Alba Garcia, MD, PhD, Engagement Manager, McKinsey & Company

Engaging the Modern Customer Through Interactive Content

Leena Jindia, PharmD, MS, Content Strategy and Innovation Leader, Janssen Scientific Affairs, LLC

Enhancing the Customer Experience with a Multichannel Offering

Robert Tamburri, PharmD, MBA, Director, Medical Information Communication Channel, Janssen Scientific Affairs, LLC

11:30AM-12:45PM

Amplifying Field Success Through Internal Partnerships

Session Chair

Lori Mouser, PharmD, Global Head, Medical Customer Engagement, Roche

Working effectively with internal business partners can accelerate the opportunities for field medical teams to make an impact. This session will provide an opportunity to discuss useful approaches that can improve collaboration across the organization. Role clarity, external alignments, and appropriate internal exchange are common areas where teams can focus to improve field engagements.

At the conclusion of this session, participants should be able to:

- Identify two key internal partnerships that can accelerate opportunities for field medical teams
- Discuss two new collaboration forums and networking tools that can ease organizational communication

New Communication Platforms to Foster Collaboration

Lori Mouser, PharmD, Global Head, Medical Customer Engagement, Roche

Aligning on External Field Engagement

Brooke Hollands, PharmD, Head Medical Engagement Capabilities and Enablement, GlaxoSmithKline

Getting Your Voice Heard – Organizational Engagement

Jason Wicklund, PharmD, Global Medical Director, Rheumatology Medical Affairs, Gilead Sciences

1:00-2:00PM

Breakthrough Designation and Expedited Approvals

Session Chair

Lisa Ambrosini Vadola, PhD, Senior Writer and Associate Manager, Whitsell Innovations, Inc.

FDA offers several expedited approval programs to facilitate rapid and effective review of New Drug Applications for therapies treating serious medical conditions that represent an unmet need. Introduced in 2013, Breakthrough Therapy Designation (BTD) is the most recent addition to FDA's expedited approval pathways and has since been highly sought after by sponsors for therapies across a variety of serious conditions. In this session, we will present an overview of BTD and other expedited approval pathways and you will learn best practices for crafting successful applications for these designations.

At the conclusion of this session, participants should be able to:

- Define FDA's expedited approval pathways and their application
- Recognize the requirements in a BTD application
- Employ medical writing best practices in the drafting of a BTD application

Lima Chutkan, PhD, RAC, Associate Director, Medical Writing, Alnylam Pharmaceuticals, Inc.

Karen Moretti, MS, MSc, RAC, Oncology Therapeutic Area Lead, Medical Writing Submissions, Pfizer, Inc.

2:15-3:15PM

Building Effective Field Medical Team Partnerships: Best Practices and Case Studies for Aligning HEOR Liaisons and MSLs in Support of External Stakeholder Needs

Session Chair

Ed Cunningham, PharmD, Senior Director, Neurology Medical Science Liaison Lead, Sunovion Pharmaceuticals, Inc.

The evolving healthcare landscape continues to drive the need for demonstrating value and tailoring scientific information to the individual needs of a growing diversity of external stakeholders. Alignment of expertise and resources among Field Medical teams (MSLs and HEOR liaisons) is critical to an organization's success in this ever-changing environment. This session will discuss best practices and review case examples of partnerships among Field-Facing Medical teams to demonstrate value and optimize fulfillment of external stakeholder needs.

At the conclusion of this session, participants should be able to:

- Recognize the unique competencies and areas of focus for a variety of Field Medical teams
- Describe how Field Medical teams can be aligned to meet the needs of specific external stakeholders (e.g. payers, providers, and patients)
- Assess how the individual case examples discussed apply to their organization's capabilities and individual customer needs

Ed Cunningham, PharmD, Senior Director, Neurology Medical Science Liaison Lead, Sunovion Pharmaceuticals, Inc.

Robert Jaramillo, PharmD, RPh, Senior Director, Head of Field HEOR, Sunovion Pharmaceuticals, Inc.

3:30-4:30PM

Closing Keynote Address: Headlines vs. Trendlines: How to Innovate in a World of Uncertainty

Gautam Gulati, MD, MBA, MPH, Co-Founder and CEO, Well PlayedThe health industry is on a reverse path from great to good. The pace of innovation is exceeding our ability to keep up because most leaders believe innovation is about chasing the next shiny new object. As a result, we are facing our 'oh no' moment in health. We need to stop chasing headlines and start recognizing trendlines by challenging old assumptions and breaking free from mediocre thinking. We need to find new ways to inoculate ourselves against the status quo.

At the conclusion of this closing keynote address, participants should be able to:

- Compare the importance and difference between headlines versus trendlines in today's world
- Identify forward-thinking methods to recognize trendlines in the health industry
- Identify how to stand out and innovate effectively

On Demand

Professional Development Workshop - Self Branding for Social Media

How you are seen by others is important. You are your own brand. If one doesn't manage one's brand, it will be created for them by others. Through this workshop we intend to demonstrate to attendees what this means, how it manifests itself and how it can positively or adversely affect your career success. Forum attendance is its own unique social media. From the time you arrive at the airport through the end of the forum, your brand is being seen. The various social media outlets will be discussed and appropriate use of them from the business perspective will be presented.

At the conclusion of this session, participants should be able to:

- Recognize the importance of self-branding
- Differentiate social media tools for career support versus sharing life with friends
- Discuss the role your brand plays in your everyday life

Chris Matheus, MBA, President, Matheus BD Connections, LLC

Medical Communications Track

On Demand

A Whole New World: Real World Evidence (RWE)

Session Chair

Donna Booth, PharmD, Director, Field Medical HTA and Policy, GlaxoSmithKline

RWE plays an increasing role in healthcare decisions. Medical Information Departments vary in their understanding and approach to the dissemination for RWE based on guidance documents issued by FDA. As the US healthcare system continues to seek value for patients, it is increasingly important to have strategies for incorporating RWE into materials provided across the continuum of decision-makers (Regulators, Payers, Providers, and Patients). *Note: Audience participation will enhance the learning experience from this session.

At the conclusion of this session, participants should be able to:

- Recognize the importance of RWE to the decision-making process
- Discuss the FDA guidance documents that regulate the dissemination of RWE
- Propose strategies for dissemination of RWE by sharing examples utilized by various Medical Information Departments that demonstrated success as well as areas for improvement

Collaborative Discussion on the Use of RWE based on Recent FDA Guidance

Donna Booth, PharmD, Director, Field Medical HTA and Policy, GlaxoSmithKline

Ellen Whipple, PharmD, Director of Medical Communications, Med Communications, Inc.

On Demand

Changing Paradigm: Evolution of the Patient in the Information Era

Session Chair

Alexandra Kantar, PharmD, Associate Director, Specialty Global Medical Communications, AbbVie, Inc.

As patients continue to become more informed and resourceful about their health and medicines, their questions and demands from the pharmaceutical industry become more complex and harder to navigate with existing guidances. This session explores emerging patient needs, innovative approaches to engaging patients, assisting them with their medical information inquiries, and enhancing their patient journey while staying compliant and not interfering with the patient/physician relationship.

At the conclusion of this session, participants should be able to:

- Describe the applicable guidances related to interacting with patients and the areas of highest uncertainty
- Illustrate innovative approaches such as new technologies or social media outlets in engaging with patients
- Identify tools to assist in writing in a more patient-centric fashion

Bringing the Patient's Voice into Medical Information

Kelly Pincus, PharmD, Director, Medical Information, Specialty, GlaxoSmithKline

Embedding a Culture of Patient-Centricity Within an Organization – How Can We Lead the Way?

Michelle Quinlan, PharmD, Associate Director, Medical Information, Pfizer, Inc

AMCP Format and Dossiers**Session Chair**

Ivy Chang, PharmD, Principal Medical Science Director, Medical Affairs, Genentech, Inc., A Member of the Roche Group

The Academy of Managed Care Pharmacy (AMCP) developed the AMCP Format for Formulary Submission as a template and guidance that has become one of the most widely recognized standards for requesting and receiving clinical and economic evidence from manufacturers. The Format is used to evaluate the value of pharmaceutical products, tests, and devices and can help healthcare decision-makers make population-based, formulary, coverage, policy, and reimbursement decisions. In late 2019, AMCP's Format Executive Committee released the sixth revision of the AMCP Format: Version 4.1. This update aligns with the June 2018 final guidance from FDA on manufacturers' communication of information about unapproved products and unapproved uses of approved products to payers, formulary committees, or other similar entities. This session will provide a brief historical perspective on the AMCP Format with a focus on the recent updates proposed in Format Version 4.1. In addition, the session will discuss common challenges faced by manufacturers in the development of product dossiers.

At the conclusion of this session, participants should be able to:

- List the type of information that may be included in a dossier for an unapproved product and an unapproved use of an approved product
- Discuss why product dossiers developed according to the AMCP Format is important to formulary decision makers
- Identify three challenges that manufacturers face in the development and communication of product dossiers within their organizations

Iris Tam, PharmD, Senior Director, HEOR, Patient Access and Value, Coeus Consulting Group

Podium Pearls**Session Chair**

Maureen Feeney, MBA, PharmD, RPh, Vice President Scientific Communications, US Medical Affairs, Takeda

Medical communications professionals will be presenting their successes, challenges, and “pearls of wisdom” on various topics through podium presentations.

At the conclusion of this session, participants should be able to:

- Discuss and share best practices, experiences, and innovative processes for medical communications topics related to content innovation and digital channels, customer needs, advisory boards, readability access, and global scientific content.

Content Innovation and Digital Channels: Results from a Live-Virtual Medical Information Advisory Board

Truc Dinh, PharmD, Manager, Medical Information, Gilead Sciences, Inc.

Findings From Two Interactive, Virtual Advisory Boards – A Best Practice Example for Gaining Healthcare Provider Feedback

Amy Ruffolo, PharmD, Senior Manager, Medical Information, Abbvie

The #MII Hashtag Experiment: Capturing Insights in Real Time

Sraddha Wadhwa, PharmD, Associate Director, Medical Information, Pfizer, Inc.

A Digital Solution to Advance One Medical Voice by Increasing Visibility, Awareness, and Access to Global Scientific Content

Reeti Sethi, PharmD, Merck & Co., Inc.

Expanding Beyond Product Support to Meet Customer Needs: A Collaboration Between Medical Information and Field Medical

Michelle Quinlan, PharmD, Associate Director, Medical Information, Pfizer, Inc.

Readability Assessment of Clinical Trial Information on Pharmaceutical Product Websites Intended for Patients and Caregivers

Robin Watts, PharmD, Program Manager, Principal Medical Writer, Evidera

Medical Writing Track

On Demand

Branded Communication

Session Chair

Jennie Jacobson, PhD, Medical Director, Syneos Health

Most medical writing meetings deal with regulatory writing, publications, and continuing education. As for promotional/branded writing, few sessions include other branded materials produced by medical writers. This session will include writing training materials for sales representatives involved in medical advertising, publications, and promotion. Some medical writers consider medical advertising to be beyond actual medical writing, but if their output is regulated by the FDA's OPDP, that position is hard to defend.

At the conclusion of this session, participants should be able to:

- Differentiate between branded and unbranded medical education output
- Identify promotional and nonpromotional aspects of publications
- Evaluate the different promotional vehicles used in medical advertising
- Synthesize the regulatory environment that directs output in the above genres

Promotional Aspects of Publications

Jennie Jacobson, PhD, Medical Director, Syneos Health

Medical Advertising

Dan Benau, PhD, Director, Biomedical Writing Programs, University of the Sciences

Creating Sales Representative Training Materials

Deborah Anderson, PhD, MSc, MT, Medical Writer, Instructional Designer, DGA Medical Communications

On Demand

The PMTA Submission: How Clear Safety Reporting is Important

Session Chair

Dave Meats, Associate Director, Global Submissions, PRW, Synchronix

The Pre-Market Tobacco Products Application (PMTA) is a new and potentially controversial regulation issued by the FDA governing a wide scope of potentially health-harming products that consumers purchase. The FDA regulation will become effective for these products in the middle of 2020, and regulatory writers may be requested to apply their skills to these applications. This session will describe the scope and purpose of the new PMTA regulation the types of products for which a PMTA submission is required, how regulatory writers are involved, why they are important, and what hurdles need to be surmounted to complete these applications.

At the conclusion of this session, participants should be able to:

- Describe the scope and purpose of a PMTA submission
- Describe what regulatory writing skills can be utilized when completing these submissions
- Describe the importance of these applications to further the knowledge of potential adverse effects of these products

Premarket Tobacco Product Applications (PMTA) - How Did We Get Here, What is the Present Status, and Where Are We Going?

Ian Fearon, PhD, Director, Whatif? Consulting, Ltd

Structure, Process, and Content for Submission to the Center for Tobacco Products (CTP)

Steve Sibley, MS, Vice President, Global Submissions and Submissions Leadership, Synchronix

On Demand

Evolution of Medical and Device Writing

Session Co-Chairs

Sarah Ellinwood, PhD, Associate Analyst, Medical Writer, VERGE Scientific Communications

Dan Benau, PhD, Director, Biomedical Writing Programs, University of the Sciences

Since the inception of formalized regulatory medical writing in the 1980s, the medical and pharmaceutical communication industries have changed dramatically. Next-generation technologies have produced massive

datasets giving us a more holistic view of how a therapy, whether drug, biologic, or device, behaves. The problem is that this might have created possible information overload for HCPs and especially for patients. What have been some of the key inflection points in the history of medical writing and what can we expect moving forward? The speakers in this session will share their experiences and insights on the past, present, and future of medical writing with respect to the regulatory, promotional, and educational genres.

At the conclusion of this session, participants should be able to:

- Discuss the history of medical and device writing and how the fields have changed in response to evolving scientific understanding, trends, and technologies
- Identify and embrace opportunities to prepare for future trends and challenges in the field
- Initiate productive interactions with different medical writing audiences

Rita Francis, PhD, PMP, Adjunct Professor, Biomedical Writing Program, University of the Sciences

Dan Benau, PhD, Director, Biomedical Writing Programs, University of the Sciences

On Demand

The Mysterious Regulatory Landscape in China: a Medical Writer's Perspective

Session Chair

Ruggero Galici, PhD, Associate Director, Medical Writing, Pfizer, Inc

This session will provide an overview of the dynamic regulatory environment to support the clinical development of pharmaceutical products in China. Preparation of common and unique medical writing documents to support regulatory submissions will be discussed.

At the conclusion of this session, participants should be able to:

- Discuss the Chinese regulatory environment for pharmaceuticals
- Recognize common and unique requirements for regulatory submissions to the Chinese National Medical Products Administration (NMPA)
- Identify specific clinical documents for submissions to the NMPA

The Mysterious China Regulatory Environment: Considerations in Clinical Development, Regulatory Submissions, and Medical Writing in China

Hongbo Zhu, PhD, Director, Head of China Medical Writing, Pfizer, Inc., China

On Demand

Improving the Efficiency of Medical Writing with Artificial Intelligence and Automation Technologies

Session Chair

Ruggero Galici, PhD, Associate Director, Medical Writing, Pfizer, Inc.

The session will describe key concepts of artificial intelligence (AI), machine learning, and natural language processing. The relevance of these concepts to medical writing and the challenges typically encountered when developing AI platforms will be discussed. Current capabilities and limitations will be presented to set realistic expectations for potential users. We will close with a Q&A session with the audience.

At the conclusion of this session, participants should be able to:

- Identify core AI concepts and examine their relevance to medical writing
- Discuss current state of the art and limitations

Getting Artificial Intelligence to Deliver in Medical Writing

Anand Kiran, MPharm, MBA, Executive Vice President, Global Operations, Medical Solutions, Indegene, Inc., India

Artificial Intelligence Assisted Medical Writing

Carsten Eickhoff, PhD, MSc, Assistant Professor of Medical and Computer Science, Brown University

On Demand

Is Sub-Specialization an Option or A Necessity for The MSL Role?

Session Chair

J. Lynn Bass, PharmD, RPh, Senior Director, Head of Medical Science Liaisons, Mesoblast Limited

A subspecialty is a narrow field of professional knowledge and skills within a specific profession and is most commonly used to describe an increasingly more diverse role. Is the MSL role poised to undergo a phase of sub-specialization? Who/What is driving this sub-specialization of MSL roles? External stakeholders? Internal Stakeholders? The evolving healthcare system? Will sub-specialization dilute the MSL role or strengthen the profession for decades to come? This session is intended to address these questions and provide examples of current diversification and sub-specialization in the MSL role.

At the conclusion of this session, participants should be able to:

- Describe the current scope of MSL roles and predict future trends
- Explore implications for expansion of MSL Sub-Specialization
- Develop an understanding of how to implement potential changes within their MSL organizations

Ann Westra, MD, Senior Medical Knowledge Expert, McKinsey & Company

James Siano, PhD, MS, MBA, Chief of Staff and Head, US Medical Affairs Oncology Field Alignment, Merck & Co., Inc.

On Demand

Sharpening Your Skills to Overcome the “Wi-Fi, MyFi, and Hi-Fi” Challenges in Your MSL Role

Session Chair

Angela Kodsi, PharmD, Rare Neuroscience Medical Affairs Director, Pfizer, Inc.

This session will address how MSLs can sharpen their listening and communicating skills during their careers to successfully address the “Wi-Fi, MyFi, and Hi-Fi” challenges in today’s digital age. Whether you’re an MSL manager or an MSL, this session will provide examples of skills and real-life examples of their use in practice and their impact that MSLs can bring to their own careers. And the presentation will describe how MSL managers need to think differently to recruit, onboard, train, and maintain MSLs who can successfully demonstrate these skills. Hear from a manager who has more than 25 years’ experience in building, managing, and leading Medical Affairs and field medical teams and groups of all sizes and in all therapeutic areas and in all types of business conditions.

At the conclusion of this session, participants should be able to:

- Identify forces impacting today’s MSL labor and put into practice strategies you need to adopt to be successful in hiring or seeking MSL opportunities
- Implement strategies to employ to effectively successfully onboard, engage, and develop MSL talent
- Develop strategies to demonstrate even greater leadership and medical impact whether you are a manager of MSLs or an individual contributor

Timothy Hylan, PhD, Internal Medicine Field Medical Director Group, Pfizer, Inc



The banner features a green background with a blue gradient on the left. On the left side, there is an illustration of a laptop, a tablet, and a smartphone, all displaying a logo of a lightbulb inside a head profile. Below the laptop, the text "NOW VIRTUAL" is written in white. On the right side, the text "DIA 2020" is prominently displayed in white, followed by "GLOBAL ANNUAL MEETING" in a smaller font. To the right of this, "JUNE 14-18" is written in a large, white, sans-serif font. At the bottom right, there is a white rounded rectangular button with the text "JOIN US ONLINE" in green.