Medical and Scientific Communications 2013 Annual Forum

Core Curriculum: March 18, 2013
Preconference (PM) Tutorials: March 18, 2013
Conference: March 19-21, 2013

The Sheraton Wild Horse Pass Resort & Spa | Chandler, AZ

PROGRAM CO-CHAIRPERSONS

NATALIE GEARHART, PharmD
Associate Director, Medical Information Center
Jannsen Scientific Affairs, LLC

SARA DOSHI, PharmD
Manager, Global Medical Information Strategy
Eli Lilly and Company

DAVID CLEMOW, PhD
Senior Clinical Research Scientist
Lilly USA LLC

TOLU TAIWO, PharmD
Director, Medical Information
Horizon Pharma

REBECCA VERMEULEN, RPh
Senior Director, MSL BioOncology
Genentech, A Member of the Roche Group

RAMINEH ZOKA, MS, PharmD
Senior Director, Clinical Science Liaison, Medical Affairs
Janssen Services, LLC

WHO SHOULD ATTEND

Professionals involved in:

- Medical Information
- Medical Communications
- Medical Writing - Publications
- Medical Writing - Regulatory
- Medical Science Liaisons
- Medical Contact/Call Centers
- Industry, Academia, and Government

This program was developed by the **Medical Communications, Medical Science Liaison and Medical Writing** Special Interest Area Communities.

DIA WORLDWIDE HEADQUARTERS
Horsham, PA, USA
Washington, DC, USA

REGIONAL OFFICES
Basel, Switzerland I Beijing, China I Tokyo, Japan I Mumbai, India

Medical and Scientific Communications 2013 Annual Forum

A Forum for Medical Communication, Medical Information, Medical Science Liaison and Medical Writing Professionals.

PRECONFERENCE HIGHLIGHTS

Core Curriculum – This Medical Information workshop is specifically designed to meet the needs of individuals new to pharmaceutical based medical communications. Those who have been in this function for less than 1 year would gain the most from attending. This full-day program compliments training of individuals in medical information fellowships and residency programs.

Preconference Tutorials

Tutorial 1 - Instilling Quality in Promotional Materials via Medical Communications Input in 2013

Tutorial 2 - Medical Communications: Compliance in 2013

Tutorial 3 - Contact Center 101

Tutorial 4 - Medical Writing: Clinical Overview

Separate registration is required.

FORUM HIGHLIGHTS

The Medical and Scientific Communications 2013 Annual Forum is being developed by three DIA SIAC's (Special Interest Area Communities): Medical Communications, Medical Science Liaisons, and Medical Writing. At this forum, attendees will gain further expertise in their own area and/or learn about different functional areas. Attendees have the flexibilityto attend sessions from any of the tracks. In addition to professional development, this forum will also provide numerous opportunities for networking.

SESSION TOPICS

Topics include but are not limited to:

- Medical Communications Track:
  - Overview of Health Care Landscape
  - Review of Global Medical Information survey results
  - Gain an in-depth knowledge of the managed care world and customers
  - Update on the latest digital tools in Medical Communications
  - Discuss the latest thinking on responding to unsolicited requests and scientific exchange
  - Review outsourcing strategy case studies
- Medical Writing Regulatory and Publication Tracks:
  - Protocol Writing
  - Medical Writing Outsourcing and Partnerships
  - Responding to Regulatory Questions and Feedback
  - Medical Writing for Social Media
  - Publication Planning
  - Safety Writing
- Medical Science Liaisons Track (New this year):
  - Future MSL Trends
  - Creating and Communication MSL Value Proposition/ MSL Life Cycle
  - Emerging MSL Technology
  - MSL Productivity/Metrics and Management
  - Training, Career Development, and Building Your Brand

TABLETOP EXHIBIT OPPORTUNITY
For contact information, see Page 27.

CONTINUING EDUCATION

The Drug Information Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This program is designated for up to 20.5 contact hours or 2.05 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.

Corexcel is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

Corexcel designates this activity for a maximum of 23 contact hours.

Drug Information Association has been accredited as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 1760 Old Meadow Road, Suite 500, McLean, VA 22102.

As an IACET Authorized Provider, Drug Information Association offers CEUs for its programs that qualify under the ANSI/IACET Standard. Drug Information Association is authorized by IACET to offer up to 2.3 CEUs for this program. Participants must attend the entire program <core curriculum, tutorial, conference, if applicable> 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 conference, core curriculum, and/or tutorials, if applicable, scan your name badge at each session, core curriculum and/or tutorial you attend, and complete the on-line credit request process through My Transcript. To access My Transcript, please go to www.diahome.org, select "Login to My DIA" and you will be prompted for your user ID and password. Select "My Transcript" (left side bar) and "Credit Request" to process your credit request. 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, April 4, 2013.**

Please Note: *If you do not scan your badge at each session you attend, you will not be able to request continuing education credits for that portion of the program.*

DISCLOSURE POLICY

It is Drug Information Association policy that anyone in a position to control the content of a continuing education activity must disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and/or the educational activity, and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Faculty disclosures will be included in the course materials.

CONTINUING EDUCATION CREDIT ALLOCATION

Core Curriculum: Pharmacy up to 7.25 contact hours or .725 CEUs; Nursing up to 7.25 contact hours; IACET .7 CEUs

Tutorial 1 – Instilling Quality in Promotional Materials via Medical Communications Input in 2013: Pharmacy 3.25 contact hours or .325 CEUs, 0286-0000-13-053-L04-P, Type of Activity: Application; Nursing 3.25 contact hours; IACET .3 CEUs

Tutorial 2 – Medical Communications: Compliance in 2013: Pharmacy 3.25 contact hours or .325 CEUs, 0286-0000-13-054-L04-P, Type of Activity: Knowledge; Nursing 3.25 contact hours; IACET .3 CEUs

Tutorial 3 – Contact Center 101: Pharmacy 3.25 contact hours or .325 CEUs, 0286-0000-13-055-L04-P, Type of Activity: Application; Nursing 3.25 contact hours; IACET .3 CEUs

Tutorial 4 – Medical Writing: Clinical Overview: Nursing 3.25 contact hours; IACET .3 CEUs

Conference: Pharmacy up to 13.25 contact hours or 1.325 CEUs; Nursing up to 15.75 contact hours; IACET 1.6 CEUs

PHARMACY CREDIT BREAKDOWN

CORE CURRICULUM

Sessions 1 and 2: 3.75 contact hours or .375 CEUs, 0286-0000-13-051-L04-P, Type of Activity: Application

Sessions 3 and 4: 3.5 contact hours or .35 CEUs, 0286-0000-13-052-L04-P, Type of Activity: Knowledge

CONFERENCE

Opening Plenary – Session 1 – Politics, Policy and the First Amendment: What to Expect from Capitol Hill, HHS, FDA and the Courts During the Second Term of the Obama Administration: 1.25 contact hours or .125 CEUs, 0286-0000-13-056-L03-P, Type of Activity: Knowledge

Medical Communications Track 2A-B – Globalization: Smooth Ride or Bumpy Road: 1.5 contact hours or .15 CEUs, 0286-0000-13-057-L04-P, Type of Activity: Knowledge

Medical Communications Track 3A-B – Transformation Within Medical Information To Adapt to the Changing Health Care Environment: 1.5 contact hours or .15 CEUs, 0286-0000-13-058-L04-P, Type of Activity: Application

Medical Writing Publication and Regulatory Tracks 3C – Patient Reported Outcomes: 1.5 contact hours or .15 CEUs, 0286-0000-13-059-L04-P, Type of Activity: Knowledge

Medical Science Liaisons Track 3E – "A Paradigm-Shift": Navigating a New Path for the Future of MSLs: 1.5 contact hours or .15 CEUs, 0286-0000-13-060-L04-P, Type of Activity: Knowledge

Medical Communications Track 5A-B – Medical Communications for Managed Care: 1.5 contact hours or .15 CEUs, 0286-0000-13-061-L04-P, Type of Activity: Knowledge

Medical Science Liaisons Track 5E – Creating and Communicating the MSL Value Proposition throughout a Product's Life Cycle: 1.5 contact hours or .15 CEUs, 0286-0000-13-070-L04-P, Type of Activity: Knowledge

Medical Writing Publication and Regulatory Tracks 6C – Device, Diagnostic, and Biotech Submissions: 1.5 contact hours or .15 CEUs, 0286-0000-13-062-L04-P, Type of Activity: Knowledge

Medical Writing Publication and Regulatory Tracks 6D – Guidance on Guidelines: Understanding MOOSE and STROBE: 1.5 contact hours or .15 CEUs, 0286-0000-13-063-L04-P, Type of Activity: Knowledge

Medical Science Liaisons Track 6E – MSL Performance Appraisal Continuum for Both Management and Individual Contributors: Coaching Feedback, Communication: 1.5 contact hours or .15 CEUs, 0286-0000-13-071-L04-P, Type of Activity: Knowledge

Medical Communications Track 8A-B – Using Customer Input as a Key Source of Quality Improvement: 1.5 contact hours or .15 CEUs, 0286-0000-13-064-L04-P, Type of Activity: Application

Medical Communications Track 9A-B – Digital and Social Media: What Should You Know… And Be Thinking About It?: 1.5 contact hours or .15 CEUs, 0286-0000-13-065-L04-P, Type of Activity: Knowledge

Medical Communications Track 10A – Hot Topics in Medical Communications: 1.5 contact hours or .15 CEUs, 0286-0000-13-066-L04-P, Type of Activity: Knowledge

Medical Writing Publication and Regulatory Tracks 10D – Publication Safety Writing: 1.5 contact hours or .15 CEUs, 0286-0000-13-067-L04-P, Type of Activity: Knowledge

Medical Science Liaisons Track 10E – Considerations for the Development and Communication of MSL Metrics: 1.5 contact hours or .15 CEUs, 0286-0000-13-072-L04-P, Type of Activity: Knowledge

Medical Communications Track 11A-B – Current Legal and Regulatory Landscape Impacting Medical and Scientific Communications: 1.5 contact hours or .15 CEUs, 0286-0000-13-068-L03-P, Type of Activity: Knowledge

Continuing pharmacy education credits are **NOT AVAILABLE** for the following sessions:

- Welcome and Opening Remarks
- Breakout Sessions 2: 2C, 2D, 2E
- 2013 Medical Communications Workshop Networking Lunch Discussions
- Resident Session
- Breakout Sessions 3: 3D
- Breakout Sessions 4: 4A, 4B, 4C, 4D, 4E
- Breakout Sessions 5: 5C-D
- Breakout Sessions 6: 6A-B
- Luncheon/Professional Poster/Session 7/Roundtable Discussions
- Breakout Sessions 8: 8C, 8D, 8E
- Breakout Sessions 9: 9C, 9D, 9E
- Resident and Fellow Poster Reception
- Breakout Sessions 10: 10B, 10C
- Breakout Sessions 11: 11C, 11D, 11E
- Closing Remarks

Navigate the Medical and Scientific Communications 2013 Forum from Your Mobile Device!

Mobile App is available for iPhones, iPads, and Android devices. The app is designed to enhance attendees experience and provide valuable information in one place! Download the app to access a wide range of information, as well as the ability to:

- Manage your Agenda
- Stay in the Know with Event Alerts and Announcements
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To download, search for "MSC 2013" in your device's app store.

What's More...

Complete a Evaluation for each Session on Your Mobile App and Be Entered to Win an iPad!

DIA
www.diahome.org

8:00 AM-4:45 PM CORE CURRICULUM

CHAIRPERSON

Jim Wilkinson, PhD
Executive Director, Medical Communications
Amgen, Inc.

FACULTY

Danielle Ziernicki, PharmD
Director, Global Regulatory Policy and Intelligence
Janssen Research & Development LLC

Jackie Morton
Research Information Specialist
Amgen Libraries

Michael Cuozzo, PharmD
Director, Crisis Management- Global Consumer Care
Johnson & Johnson Consumer Companies, Inc.

Jihwon Im, PharmD
Principal Scientist
Genentech, A Member of the Roche Group

Rebecca Falcone, PharmD
Senior Manager, US Medical Information Services
Sanofi U.S.

Kurt T. Kreiter, PhD
Director, Medical Information
Biogen Idec Global Medical Affairs

Jennifer Totten, PharmD
Scientific Communications
Forest Research Institute

This activity is specifically designed to meet the needs of individuals new to biopharmaceutical industry-based medical communications. Attendees will learn and discuss skill sets that provide value to both internal and external customers. Those who have been in their functional role for less than 1 year would gain the most from attending.

Core Curriculum Learning Objectives:
At the conclusion of this session, participants should be able to:

- Identify activities that Medical Communication professionals participate in that provide global value to both internal and external customers, as part of working in interdisciplinary teams
- Describe how the regulatory environment influences Medical Communications practices
- Identify regulatory resources available and how to apply them to your day-to-day work
- Identify critical steps that a Medical Communications professional should take when receiving an unsolicited inquiry, including evaluating the available data and sources of information
- Determine the important elements of planning for a scientific presence at a medical congress, including the provision of medical information and the optimal use of technology at this type of venue
- Recognize the importance of the payer environment by evaluating AMCP/EBM dossier requirements
- Describe the distinct scientific value that Medical Communications provides on promotional review committees and how to balance the provision of marketing support while avoiding common pitfalls in that role

8:00-9:45 AM CORE CURRICULUM-SESSION 1

8:00–8:30 AM WELCOME AND INTRODUCTIONS

Jim Wilkinson, PhD

Following opening remarks, the Core Curriculum faculty will introduce themselves to the attendees and provide descriptions of their career paths leading to their current roles in Medical Communications. The faculty will then describe their current responsibilities, allowing the audience to begin to see similarities and differences in the practice of Medical Communications across the industry. A short networking and business card exchange will close out the opening talk.

8:30–8:45 AM CURRENT PRACTICES IN MEDICAL COMMUNICATIONS

Jim Wilkinson, PhD

This short session will highlight the core and growing roles and responsibilities that Medical Communications professionals have taken to support health care professionals, patients and ultimately the commercial success of the business. Landscape changes within our industry, and how this may affect our job responsibilities, will also be briefly summarized.

8:45–9:45 AM REGULATORY ENVIRONMENT AND MEDICAL COMMUNICATIONS PRACTICES

Danielle Ziernicki, PharmD

This session introduces the current regulatory environment that influences the activities of a US-based Medical Communications professional. An overview of the pharmaceutical industry and DDMAC regulations will be reviewed, along with the rationale for many of the activities common in Medical Communications departments which will include a case study presentation.

9:45–10:00 AM BREAK

10:00-12:00 PM CORE CURRICULUM – SESSION 2

10:00–11:00 AM HELPFUL TRICKS OF THE TRADE 1: ADVANCED LITERATURE SEARCHING AND EVALUATION

Jackie Morton

Literature searching is a vital skill for all Medical Communications professionals. This session will review key medical literature database search strategies and each attendee will walk away with knowledge that can be applied immediately in their daily work. An interactive case presentation will be discussed by the faculty and attendees.

11:00 AM–12:00 PM HELPFUL TRICKS OF THE TRADE 2: REGULATORY RESOURCES IN THE PUBLIC DOMAIN

Danielle Ziernicki, PharmD

There are multiple regulatory resources available for Medical Communications professionals, many of them for free. This session will review resources available in the public domain and how they can help you successfully deliver results. An interactive case presentation will be discussed by the faculty and attendees.

12:00–1:00 PM LUNCH

1:00-4:45 PM CORE CURRICULUM – SESSION 3 AND 4

These two sessions will delve deeper into the challenging aspects of six different areas of our industry practices. This includes activities such as identifying the critical steps that a medical communications professional should take when receiving an inquiry, evaluating the sources of information/data available when preparing a response, the importance of fair balance and documenting responses. Topics will also include formulary dossier communications, promotional review, global activities, interactions with medical science liaisons (MSLs) and activities at scientific congresses. Role playing and mock examples will be used to re-enforce principles that emphasize the importance of our role to the industry and to the customers we serve. Attendees will be presented with real-life scenarios that represent challenges that are common to our roles and will be asked to discuss and share their responses to the situations.

1:00–2:45 PM SESSION 3

Best Practices for Handling Medical Inquiries

Mike Cuozzo, PharmD

Promotional Review Committee Overview

Jihwon Im, PharmD

Strategic Role of Medical Communications at Medical Congresses

Rebecca Falcone, PharmD

2:45–3:00 PM BREAK

3:00–4:45 PM SESSION 4

Global Considerations for Medical Communications

Kurt T. Kreiter, PhD

AMCP Dossier and the Managed Care Perspective

Jennifer Totten, PharmD

Effective Interactions with the Field-Based MSLs

Jim Wilkinson, PhD

1:30-5:00 PM **PRECONFERENCE TUTORIALS (**PLEASE NOTE: LUNCH IS NOT SERVED FOR TUTORIAL PARTICIPANTS.)**

TUTORIAL #1

Instilling Quality in Promotional Materials via Medical Communications Input in 2013

CHAIRPERSON

Stacey Fung, PharmD
Associate Director, Medical Communications
Genentech, A Member of the Roche Group

Promotional review is a critical component to successful marketing of products. Medical Communications can play a key role in ensuring scientific accuracy and clinical relevancy of the content. Topics relevant for Medical Communications Professionals performing promotional review will be covered. The discussion will be interactive and provide information relevant to the current regulatory environment, discuss real-world applications and include concerns of government agencies. An update on new policies will be provided. An overview of how medical communications can effectively instill quality medical content in promotional materials will be provided. From the start, medical communications professionals are able to collaborate with internal teams and vendor partners to ensure quality promotional materials. While Medical Communications focuses on scientific evidence, the importance of collaboration in developing effective and compliant material will be reviewed. A dialogue on working with cross functional review teams and vendor partners including how to be a savvy medical reviewer, impact of effective and clear SOPs and guidance documents, and training of team members will occur. Key considerations for conducting an effective medical review will be shared. Information on fair balance, required claim support, and comparative claims will be examined. Lastly, an interactive discussion with participants' input on samples of promotional pieces will take place. Samples of good and bad promotional materials along with recent enforcement activities will be reviewed.

Tutorial Learning Objectives:
At the conclusion of this tutorial, participants should be able to:

- Describe and apply promotional regulations for promotional materials
- Recognize key areas of focus for Medical Communications review of promotional material
- Explain how to complete an initial review of draft promotional materials
- Describe the various models for promotional review committees
- Discuss how best to work with the review team

FACULTY

Lois Jessen, MS, PharmD
Director, US Pharmaceuticals Law and Promotion Compliance
Otsuka Pharmaceutical Development and Communication Inc.

Kristin Goettner, PharmD
Associate Director, Medical Information
Janssen Scientific Affairs, LLC

TUTORIAL #2

Medical Communications: Compliance in 2013

CHAIRPERSON

Monica Kwarcinski, PharmD
Executive Director, Medical Services
Purdue Pharma LP

Pharmaceutical industry compliance obligations have increased dramatically over the last several years. In light of this, 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 tutorial 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 tutorial with opportunity for discussion and questions from the audience.

Tutorial Learning Objectives:
At the conclusion of this tutorial, participants should be able to:

- Discuss compliance hot topics in Medical Communications such as medical inquiry documentation, response development and documentation, staff training, and sales force facilitated inquiries
- Describe compliance aspects of recently surveyed medical communications practices
- List the factors to consider when developing, implementing, and maintaining QA, compliance, and training programs
- Discuss the 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)
- Recognize how to mitigate risk in Medical Communications

FACULTY

Mark A. DeWyngaert, PhD
Managing Director
Huron Life Sciences

Joyce Martin, PharmD
Associate Director, US Medical Affairs Compliance (gMAC)
Genentech, A Member of the Roche Group

TUTORIAL #3

Contact Center 101

CHAIRPERSON

David Bowers, PharmD
Director, Medical Communications
PPD

This tutorial will provide an in-depth understanding of the art and science of effectively managing a contact center. This will be an interactive session that will include hands-on activities and examples for managers and employees to learn how to make a difference in caller wait times and even staffing costs. Contact center fundamentals such as technology and terminology will be discussed before exploring more advanced topics such as validating resource requirements in the contact center.

Tutorial Learning Objectives:
At the conclusion of this tutorial, participants should be able to:

- Discuss how to measure performance of employees, teams, and managers to identify areas for improvement to providing medical information to medical information customers
- Identify the impact of a single employee's performance on wait times for medical information customers
- Recognize the key strategies of forecasting inquiries and scheduling staff in order to maximize staff availability to patients and health care professionals
- Discuss contact center technology systems to ensure that the contact center is effectively utilizing available technology
- Describe how to integrate video, chat and other media into the contact center

FACULTY

Michael Boudreau
Manager, Workforce & Information Management, The Lilly Answers Center
Eli Lilly and Company

Paul Biedenbach
Director, Medical Communications
PPD

TUTORIAL #4

Medical Writing: Clinical Overview

Chairperson

Patricia A. Matone, PhD
President
Scientific Information Services LLC

This course provides an in-depth analysis of the preparation of a Clinical Overview for pharmaceutical products (drugs and biologics) in accordance with ICH guidelines concerning development of Module 2.5 of a Common Technical Document (CTD).

- The objectives, structure, and format of the Clinical Overview is explored, with attention given to developing a document suitable for multi-region submissions.
- The inclusion and presentation of clinical and nonclinical data are discussed in detail, with emphasis on how to effectively use the other technical summaries within the CTD.
- Insight is provided on how to prepare a document that successfully communicates the benefits and risks of the investigational product.
- Specific examples are provided regarding how to frame the different sections of the Clinical Overview to best communicate the product's unique attributes.
- While the course emphasis is on developing the Clinical Overview for a new chemical entity, insight in to developing the Clinical Overview for other type of submissions will be provided.

Tutorial Learning Objectives:
At the conclusion of this tutorial, participants should be able to:

- Communicate the role of a Clinical Overview (Module 2.5) in a CTD
- Describe the structure and format of a Clinical Overview in accordance with ICH guidelines
- Develop strategies regarding the placement and presentation of information different sections of the Clinical Overview
- Explain how to effectively cross-reference to other components of the CTD
- Develop a submission-ready Clinical Overview that successfully communicates all available information concerning the benefits and risks of an investigational product
- Recognize how to modify the Clinical Overview for different submission types

Faculty

Patricia A. Matone, PhD
President
Scientific Information Services LLC

DAY 2 | **TUESDAY, MARCH 19, 2013**

7:00-8:00 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:00-8:30 AM WELCOME AND OPENING REMARKS

Program Co-Chairpersons

Natalie Gearhart, PharmD
Associate Director, Medical Information Center
Jannsen Scientific Affairs, LLC

David Clemow, PhD
Clinical Research Scientist
Lilly USA LLC

Ramineh Zoka, MS, PharmD
Senior Director, Clinical Science Liaison, Medical Affairs
Janssen Services, LLC

Opening Speakers

Susan Cantrell
Director, North America
DIA

Stephen P. Spielberg, MD, PhD
Editor-in-Chief, Therapeutic Innovation & Regulatory Science DIA

8:30–9:45 AM OPENING PLENARY – SESSION 1

Politics, Policy and the First Amendment: What to Expect from Capitol Hill, HHS, FDA and the Courts during the Second Term of the Obama Administration

Chairpersons

David Cram, PharmD
Director, Medical Affairs
Corcept Therapeutics

Natalie Gearhart, PharmD
Associate Director, Medical Information Center
Jannsen Scientific Affairs, LLC

Keynote Presenter

John F. Kamp
Executive Director
Coalition for Healthcare Communication

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

- Discuss recent and important developments surrounding the health care environment important to Medical Communication, Medical Science Liaison, and Medical Writing professionals
- Identify major developments on "scientific exchange" related to industry and PhRMA petitions before the FDA
- Recognize the importance of recent judicial opinions on FDA regulation of off-label communications, especially U.S. v. Caronia reversing criminal conviction of a pharma employee
- Summarize the HHS rules implementing the "Sunshine" provisions of the Affordable Care Act
- Discuss legislative developments related to HHS, FDA, the Affordable Care Act, and the deductibility of communication and marketing costs by industry

9:45 – 10:00 AM REFRESHMENT BREAK/EXHIBITS

Below is the key for all breakout sessions throughout the entire forum. Please note that you are free to attend breakout sessions in any track based upon your level of interest and the topics that are offered.

BREAKOUTS A AND B

Medical Communications Track

BREAKOUTS C AND D

Medical Writing Publication and Regulatory Tracks:

Breakout C - Medical Writing – Regulatory Topics

Breakout D - Medical Writing – Publications Topics

BREAKOUT E

Medical Science Liaisons Track

10:00–11:30 AM BREAKOUT SESSIONS 2

MEDICAL COMMUNICATIONS TRACK 2A-B

Globalization: Smooth Ride or Bumpy Road

CHAIRPERSON

Sharon Leighton, PhD
Sharon Leighton Consultancy, UK

As more pharmaceutical companies implement global medical information functions or create virtual networks, new challenges arise. What works for one company may not apply for another organisation. So what does the road map look like across the industry? How do we successfully implement change to ensure medical speaks with one voice?

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

- Identify the challenges faced by pharmaceutical companies as they globalize their medical information operations and describe some of the solutions implemented
- Evaluate different global information technology models to ensure consistency of response, customer experience, and optimal compliance

FACULTY

Janet Davies
Director, International Medical Information and Medical Affairs Project Management
Gilead Sciences, UK

Lesley Fierro, PharmD, MS
Associate Vice President,
Medical Information Services
sanofi-aventis

10:00–11:30 AM BREAKOUT SESSIONS 2

MEDICAL WRITING PUBLICATION AND REGULATORY TRACKS 2C

Protocol Writing Strategies

CHAIRPERSON

Linda Fossati Wood, MPH
President, MedWrite, Inc.

Individual elements of a clinical protocol will be described and the relationship between the elements and how they function together to drive a clinical trial will be discussed. Strategies for reducing discrepancies will be discussed, as will the role of a protocol in development of other clinical documents. Examples will be used to illustrate the difference between elements, and common errors will be explored.

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

- Identify protocol elements and how they function together
- Describe strategies to reduce discrepancies
- Describe how protocol text contributes to the constellation of clinical documents

FACULTY

Linda Fossati Wood, MPH
President, MedWrite, Inc.

MEDICAL WRITING PUBLICATION AND REGULATORY TRACKS 2D

Clinical Trial Registration and Results Disclosure: Impact on Medical Writing and Publications

CHAIRPERSON

Barbara Godlew, RN, BA
President
The FAIRE Company

Clinical trial disclosure provides wide publicly available access to clinical trial protocols and trial results. Recent industry developments to share data and evolving journal requirements for data disclosure with manuscript submission affect medical writing and clinical/scientific manuscripts. This session will explore best practices in coordinating clinical trial disclosure, medical writing, and publications.

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

- Recognize current requirements and trends in clinical trial disclosure requirements and their relationship to publication practices
- Describe a major pharmaceutical company's best practices that govern their disclosure processes and how these relate to medical writing
- Recognize how disclosure requirements impacts publication plans, manuscript content, and time lines

FACULTY

Barbara Godlew, RN, BA
President
The FAIRE Company

Marla Jo Brickman, PhD
Director/Team Leader- Clinical Trial Disclosure Group
Pfizer Inc.

Maureen F. Garrity, PharmD
Director of Publications
Astellas Scientific and Medical Affairs

MEDICAL SCIENCE LIAISONS TRACK 2E

10:00-10:10 AM

Opening Remarks – MSL Track

Ramineh Zoka, MS, PharmD
Senior Director, Clinical Science Liaison, Medical Affairs
Janssen Services, LLC

10:10-11:30 AM

Reflection on the Escalating Growth of the Medical Science Liaison Role

CHAIRPERSON

J. Lynn Bass, PharmD
Director, Medical Science Liaisons
Jazz Pharmaceuticals

The pharmaceutical industry is composed of diverse constituents who, as a whole, result in a unique, overall industry. Since the inaugural team of Medical Science Liaisons (MSL) was deployed, the role and function of the individual MSL has evolved and pivoted in numerous directions. In addition, structuring and building MSL teams has become a challenge and is dependent on the needs of the unique components. Diverse skill sets and qualifications from both the management and individual contributor roles are required. This session will review the MSL role in the traditional pharmaceutical and biotech industries, and contrast and examine the unique qualities of MSLs deployed in the Medical Device and Diagnostics sector of the industry today. Guest panelists representing traditional pharmaceuticals and Biotech and Medical Diagnostics industries will share unique and common characteristics of each of these sectors.

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

- Identify the origin and history of the Medical Science Liaison Role
- Discuss the development of the Medical Science Liaison role in different sectors of the pharmaceutical industry
- Discuss the unique differences between today's traditional /biotech pharma and medical diagnostics MSL teams

FACULTY

Drew Scheifele, PhD
Senior Director/ Head, Medical Science Liaisons, US Medical Affairs
Biogen Idec

Vickee Altman, RN, BSN, MEd
MSA National MSL Manager
Roche Diagnostics

11:30 AM–1:30 PM BUFFET LUNCH/
ROUNDTABLE DISCUSSIONS/EXHIBITS

Medical and Scientific Communications Forum Networking Lunch Discussions - *Back by Popular Demand*

CHAIRPERSONS

Beth A. Price
Executive Vice President
The Medical Affairs Company

Julia Petses, PharmD
Director, Oncology/Urology Medical Information Services
sanofi –aventis

Attendees will have the opportunity to either dine on their own or grab their lunch and participate in not one but two luncheon sessions of networking roundtable discussions. These networking sessions will be led by one or multiple facilitators having expertise within a core medical affairs functional area that is specific to that table topic discussion (See topics below).

These informal networking sessions are designed to enable all roundtable participants to discuss topics of relevance to them, specific to their job functions and activities, and encourage information sharing into these topic areas from the perspectives of large, midsize and small, specialty companies including practices from participants in the device and diagnostics industries. Facilitators will help to guide discussions but the true catalysts of conversation will be the attendees! Please join your colleagues and engage in what will sure to be a variety of insightful (and delicious) networking sessions.

Roundtable Discussion Topics:

1. Freedom of Speech and Scientific Exchange-Implications for Medical Affairs
2. Medical Communications - Globalization of Medical Information
3. Medical Communications - Call Center – Hot Topics
4. Medical Communications - Risk Management-REMS
5. Medical Communications - Compliance
6. Medical Writing - Medical writing outsourcing
7. Medical Writing - Writing CTD summaries, overviews, and other registration documents
8. Medical Writing - Publication writing
9. MSL - Initial Evaluation & Selection of MSL Personnel - What qualities, requisites and experience do you employ when identifying new MSL personnel? Does it change depending on therapeutic area, stakeholder mix, activities?
10. MSL - MSL Value to Internal Constituents – how do your MSL teams collaborate with other constituent groups within your company? Do they support medical writing activities? Do they do clinical consults assisting the commercial team? Do they provide clinical support to PIs at trial sites? What other contributions can they provide to their internal partners?
11. MSL - MSL Technology Resources – what innovative tools and resources are your MSL teams utilizing? Do they engage in virtual presentations? If yes, how do they document? What reporting databases are being used? Pros and Cons?

11:30 AM–1:30 PM

Resident Session (Residents, Fellows, and Preceptors)

Resident, Fellow, and Preceptor Development Session. This is a special session for Residents, Fellows, and Preceptors only. No fee required to attend. Will be held in separate room during lunch.

CHAIRPERSON

Alicia Alexander Cadogan, PharmD
Director, Team Lead, Oncology
Pfizer Medical Information
Pfizer Inc.

FACULTY

Evelyn Hermes-DeSantis, PharmD, BCPS
Clinical Professor
Ernest Mario School of Pharmacy
Rutgers, The State University of New Jersey

Gregory Susla, PharmD, FCCM
Associate Director, Medical Information Coordinator, Medical Information Residency Program
MedImmune

Pharmaceutical Industry-based Drug Information Residency and Fellowship programs are an important step towards ensuring that the future of Medical Communications in the pharmaceutical industry is in capable hands. There is no governing structure to standardize these programs, and as a result the experience and training received can vary greatly in content and expectations. Although the trainees must be engaged and committed to meet their goals, the preceptor is critical to the success of the programs, and critical to the preparedness of the trainee upon completion of their experience. For this DIA session, we invite Residents, Fellows, and their preceptors to join us as we explore the training experience from the perspective of both the trainee and the preceptor. We will discuss some optimal preceptor activities, share success stories and challenges, and explore the possibility of working together through DIA to provide more structure to this important career development path.

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

- Discuss how to assess a resident or fellow's competencies gained during the training program
- Identify the roles and responsibilities of program's preceptors
- Identify best practices for the preceptor – trainee relationship that optimize educational outcomes
- Recognize how the DIA can strengthen and cultivate preceptor – trainee relationships through partnership

1:30–3:00 PM BREAKOUT SESSIONS 3

MEDICAL COMMUNICATIONS TRACK 3A-B

Transformation Within Medical Information To Adapt to the Changing Health Care Environment

CHAIRPERSON

Leena Jindia, MS, PharmD
Director, Medical Information
Janssen Scientific Affairs

It is no surprise that the health care landscape is changing rapidly around us! The evolving health care industry continues to pose new challenges to and opportunities for advancing the quality and efficiency of care to an increasing number of well-informed health care consumers. The role of Medical Information in pharmaceutical companies has become more important than ever with the increasing complexity in patient management in diverse populations with increasingly more complex therapies. Technological advances are making our customers are more informed than ever, demanding real-time, point-of-care medical information. This session will explore the elements of transformation within Medical Information critical for success in today's evolving health care environment. During this session the speakers will bring to life examples of strategic transformation within their respective organizations.

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

- Describe the factors driving transformation within Medical Information
- Explain the change methodology approach utilized during transformation of Medical Information
- Analyze the factors leading to success during this strategic journey of transformation and discuss end results
- Discuss the impact of company strategic changes and globalization on the MI group

FACULTY

Tiziana Fox, PharmD
Senior Director, Medical Information
Janssen Scientific Affairs, LLC

David J. Jones, MBA
Medical Affairs Development Director
TKG Healthcare Consulting

Poonam Bordoloi, PharmD
Senior, Internal Medicine and BioSurgery
sanofi

Patrick Reilly, PharmD
Vice President, Global Medical Information
Bristol-Myers Squibb

3:00-3:30 PM REFRESHMENT BREAK/EXHIBITS

1:30–3:00 PM BREAKOUT SESSIONS 3

MEDICAL WRITING PUBLICATION AND REGULATORY TRACKS 3C

Patient Reported Outcomes

CHAIRPERSON

Darryl L'Heureux, PhD
Medical Writer
CSL Behring

The importance of incorporating the patient's voice into the evaluation of new medical products has been recognized by regulators. Patient-reported outcomes (PROs) are increasingly being assessed in clinical trials to quantify treatment benefit and support product labeling claims. According to the U.S. Food and Drug Administration (FDA), a PRO is "any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else." Hence, the valid and reliable measurement of PRO endpoints in clinical trials is critical.

This session will cover the design and selection of PRO assessments or measurements within the regulatory framework. The FDA's qualification process for clinical outcome assessment tools will be addressed along with a pre-competitive approach to collaboratively developing and/or qualifying PRO instruments for use in clinical trials. In addition, the increasing use and significance of electronic capture of PRO data in clinical trials will be discussed.

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

- Explain the design of PRO assessment tools and appropriate selection and use of such tools
- Discuss advantages and disadvantages of working collaboratively within a pre-competitive consortium to develop and qualify PRO instruments for use in clinical trials where PRO endpoints are used to support product labeling claims
- Describe why electronic capture of PRO endpoint data in clinical trials is receiving increasing attention

FACULTY

Darryl L'Heureux, PhD
Medical Writer
CSL Behring

Stephen Joel Coons, PhD
Executive Director, Patient-Reported Outcome (PRO) Consortium
Critical Path Institute

Jason Lundy, PhD
Assistant Director, Patient-Reported Outcome Consortium
Critical Path Institute

MEDICAL WRITING PUBLICATION AND REGULATORY TRACKS 3D

Medical Writing for Social Media

CHAIRPERSON

Jennifer L. Riggins, PharmD
Director, Global Information Disclosure
Eli Lilly and Company

Social media and the use of smartphones and tablets have revolutionized how we interact, communicate, and access information. Breaking news is no longer saved for the nightly news on your local television station; news is communicated real time through social media platforms and applications such as Twitter, YouTube, and Facebook. Likewise, our communication model for the release of scientific information must also evolve. During this session, we will discuss channels and changes for scientific communication disclosures as well as potential pitfalls and "watch-outs". Additionally, we will present strategies for planning and preparing your medical writing team to be successful in this evolving information disclosure model.

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

- Describe the channels and changes facing medical writers as the disclosure model evolves
- Recognize and address potential pitfalls and challenges of using alternative channels, interactive graphics, and novel ways of releasing information
- Apply strategies for planning, adapting, and preparing medical writers for success in the evolving disclosure model

FACULTY

Jennifer L. Riggins, PharmD
Director, Global Information Disclosure
Eli Lilly and Company

MEDICAL SCIENCE LIAISONS TRACK 3E

"A Paradigm-Shift": Navigating a New Path for the Future of MSLs

CHAIRPERSONS

Rebecca Vermeulen, RPh
Senior Director, MSL BioOncology
Genentech

Anselm D'Costa, PhD
Executive Director, Field Medical Affairs
Daiichi Sankyo, Inc.

As the pharmaceutical industry strives to keep pace with the rapid evolution of the health care environment, the role of the MSL may need an overhaul. MSLs will need to add value across the continuum from early development though to late phase commercialization, and be armed with new skill sets to meet the emerging needs of existing and new customer segments.

This session will focus on how the anticipated future trends will impact customer engagement models and identify potential new opportunities to reinvigorate your teams. At the completion of the session individuals will be able to evaluate external trends and identify opportunities to organize MSL teams and integrate as needed to ensure success.

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

- State how MSLs can add value across the continuum and redefine key customer segmentation models that will enable success
- Identify topics related to performance measurement, new payment models, and greater patient engagement as new paradigms that must become central to health outcomes and value-based decision making
- Design compliant MSL engagement strategies that are tailored to individual TLs and ensure that MSL interactions are considered of value and service beyond the clinical data for the company products

FACULTY

Rebecca Vermeulen, RPh
Senior Director, MSL BioOncology
Genentech, A Member of the Roche Group

Dennis Honda, PharmD
Principal Health Outcomes Liaisons
Daiichi Sankyo Inc

Anselm D'Costa, PhD
Executive Director, Field Medical Affairs
Daiichi Sankyo, Inc.

3:00-3:30 PM REFRESHMENT BREAK/EXHIBITS

3:30-5:00 PM BREAKOUT SESSIONS 4

MEDICAL COMMUNICATIONS TRACK 4A

Outsourcing, Beyond the Call Center

Chairperson

Sara Doshi, PharmD
Manager, Global Medical Information Strategy
Eli Lilly and Company

This session will provide an overview of three different outsourcing models for medical information, beyond outsourcing of the call center. Speakers will review "real life" experiences with outsourcing including more selective sourcing models, such as a pilot to offshore the medical writing aspects of medical information work, all the way to outsourcing complete medical information support of a compound. Speakers will present their experiences, impacts to their organizations, important lessons learned, and will also look to the audience to provide additional insights and questions.

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

- Describe considerations and methodology for setting up an outsourcing service
- Discuss practicalities of a pilot model
- Recognize how learnings from others experiences may affect the parent organization
- Explan how different outsourcing models may or may not bring value to the organization

Faculty

Jay Kissel, PhD
Consultant, Medical Information
Eli Lilly and Company

Loree Levine
Associate Director, Immunoscience/Neuroscience
Bristol-Myers Squibb

Alexander Danyluk, PharmD
Director Medical Information
Janssen Scientific Affairs

MEDICAL COMMUNICATIONS TRACK 4B

Workforce Management in the Contact Center: Putting the Customers First

Chairperson

Nicole Corder, RPH, MBA
Director, The Lilly Answers Center
Lilly USA, LLC

Workforce Management is a key component to any contact center, regardless of the overall size of the operation. This session will provide an opportunity to learn more about what Workforce Management is, along with how and why it should be utilized to enhance our customer's experiences. Participants will also be able to learn implementations strategies for incorporating this role successfully into your culture. Discussions will also include how best to plan for those events that may be expected or unexpected, but where both require ensuring customer service is not sacrificed. Lastly, participants will hear about available software tools to enhance the Workforce capability and benefits of utilizing new technology. Throughout the program, keys for successful change management will be discussed.

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

- Explain what Workforce Management is and how it can be utilized to enhance the customer experience
- Discuss strategies for building a positive culture of change and understanding of the Workforce Management role
- Identify key events that can impact staffing and hear strategies for how to plan for these expected and unexpected events
- Summarize insights into new technological advances in Workforce Management

Faculty

Nicole Corder, RPH, MBA
Director, The Lilly Answers Center
Lilly USA, LLC

Daphne Hayes
Manager Operations
Medical Information Center
Janssen Scientific Affairs

5:00-6:00 PM **NETWORKING RECEPTION**

3:30-5:00 PM BREAKOUT SESSIONS 4

MEDICAL WRITING PUBLICATION AND REGULATORY TRACKS 4C

Paediatric Investigation Plans and Waiver

Chairperson

Matthias Dormeyer, PhD
Managing Director
MDC RegAffairs GmbH

Paediatric Investigation Plans (PIP) are a mandatory regulatory step to allow for marketing authorization in the EU. In such PIP it is described in detail how a medicinal product will be developed in the entire paediatric population. There are clear and important distinctions in the paediatric procedure in the EU compared to the US.

In this session an overview of the regulatory background and details of the paediatric legislation in the EU will be given. In addition, the formal PIP procedure will be presented as well as detailed guidance how to draft a PIP including experience from an applicant point of view as well as Agency experience and expectations.

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

- Explain the Paediatric Regulation in the EU and the role of Paediatric Investigation Plans
- Describe the design of a Paediatric Investigation Plan that will be compliant with current regulatory guidance
- Discuss how to organize a Paediatric Investigation Plan procedure

Faculty

Matthias Dormeyer, PhD
Managing Director
MDC RegAffairs GmbH

Birka Lehmann, MD
Director and Professor, 'Head of Executive Department P2 EU & International Affairs' Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte) [BfArM]

MEDICAL WRITING PUBLICATION AND REGULATORY TRACKS 4D

Publication Standards: The Consolidated Standards of Reporting Trials (CONSORT)

Chairperson

Tolu Taiwo, PharmD, MBA
Director of Medical Information
Horizon Pharma

The CONSORT method of clinical trial reporting will be covered in detail, examples will be covered which will illustrate the differences between what is considered "acceptable" and "not acceptable" trial reporting and the clarity in language and writing will be explored.

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

- Evaluate and critically appraise the validity of a RCT in a journal report
- Identify an article or a report that utilizes the CONSORT guidelines
- Apply the CONSORT to a RCT report

Faculty

Tolu Taiwo, PharmD, MBA
Director of Medical Information
Horizon Pharma

Janet Gough, MA
Consultant
Systems, Documentation, and Training

MEDICAL SCIENCE LIAISONS TRACK 4E

The Evolving Role of Field-based Medical in the Current Regulatory Environment

Chairperson

Hilary D. Mandler, PharmD
Director, Global MSL Operations
Shire

The life science industry continues to face challenges as additional regulations, investigations, and Corporate Integrity Agreements (CIAs) are being executed by the government. Although many Pharmaceutical and Device companies have implemented robust data systems and compliance infrastructures, the government is increasingly focused on identifying and mitigating compliance risks within the industry. Medical Science Liaisons, by virtue of their field-based roles, have increasingly become under scrutiny in these CIAs as the government's distinction between scientific exchange and promotion remains unclear. This session will focus on how some of the recent CIAs have impacted the MSL role, specifically relating to scientific engagement, scientific exchange, and the selection of a customer management system to document activities while mitigating risk.

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

- Recognize the high compliance risk areas for MSLs based upon recent CIAs
- Discuss the impact of compliance and risk mitigation on the evolution of the MSL role and scientific engagement models
- Identify three key compliance driven attributes you should consider when evaluating and selecting a customer engagement system

Faculty

Krystene W. Woodard, PharmD
Associate Director, Behavioral Health MSL Team
SHIRE

Hilary D. Mandler, PharmD
Director, Global MSL Operations
SHIRE

Chris Paap, PharmD, FCCP, BCPS
Team Leader/Senior Director
Vaccines & Infectious Diseases Field Based Medical
Pfizer Inc. - Medicines Development Group

5:00-6:00 PM NETWORKING RECEPTION

7:00-8:00 AM REGISTRATION/EXHIBITS AND CONTINENTAL BREAKFAST

8:00–9:30 AM BREAKOUT SESSIONS 5

MEDICAL COMMUNICATIONS TRACK 5A-B

Medical Communications for Managed Care

Chairperson

Iris Tam, PharmD
Director, Managed Care Medical Communication
Genentech, A Member of the Roche Group

With the rising cost of health care, managed care organizations and payers are increasingly tightening their control on drug utilization. Payers utilize the Pharmacy and Therapeutics (P&T) Committee process to make decisions regarding drug coverage and maintain drug formularies. The Academy of Managed Care Pharmacy (AMCP) has developed the AMCP Format for Formulary Submissions to guide manufacturers on the development and provision of product dossiers upon unsolicited requests from payers. This session will provide participants with an overview of the managed care landscape, an update of the Format, and a discussion of the evidentiary needs from a payer's perspective.

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

- Describe the evidentiary requirements that payers need when making formulary decisions
- Discuss the elements of the new addenda to the Format for Formulary Submissions regarding specialty pharmaceuticals, companion diagnostic tests, and comparative effectiveness research
- Identify potential actionable steps for improving the provision of medical information especially product dossiers to the payer audience when responding to unsolicited requests

Faculty

Steven Avey, RPh, MS
Vice President, Specialty Pharmacy
MedImpact

Pete Penna, PharmD
President
Formulary Resources, LLC

9:30-10:00 AM REFRESHMENT BREAK/EXHIBITS

7:00-8:00 AM REGISTRATION/EXHIBITS AND CONTINENTAL BREAKFAST

8:00–9:30 AM BREAKOUT SESSIONS 5

MEDICAL WRITING PUBLICATION AND REGULATORY TRACKS 5C-D

Medical Writing in Medical Communications and Medical Writing Certification

Chairperson

David B. Clemow, PhD
Senior Clinical Research Scientist
Eli Lilly and Company

Individual functional groups within the medical communications drug development umbrella and their relationship between each other will be discussed, with a focus on how medical writing is encompassed across these functional areas that include: medical call center, editor, education, information, liaison, promotion, regulatory writing, publication writing, and scientific nonclinical writing. Additionally, the details behind the American Medical Writers Association's medical writer certification efforts and what this might mean for the medical writing profession will be presented, with time for audience discussion.

Learning Objectives:

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

- Discuss details behind AMWA's medical writer certification
- Describe the complexity of the medical communication functional umbrella and where medical writing fits

Faculty

David B. Clemow, PhD
Senior Clinical Research Scientist
Eli Lilly and Company

MEDICAL SCIENCE LIAISONS TRACK 5E

Creating and Communicating the MSL Value Proposition throughout a Product's Life Cycle

Chairpersons

Carrie C. Murray, MSN, NP
Director, Global MSL Excellence
Bayer HealthCare Pharmaceuticals

Christina Cognata Smith, PharmD, MBA
Executive Director, Medical Affairs
Medicis Pharmaceutical Corp

Communication of MSL value is often an ongoing challenge for MSLs and MSL managers, particularly in the face of dynamic product life cycles. This session is intended to share three unique perspectives of the MSL value: the in-house director, the field-based manager and the MSL. Invited experts will use case studies to stimulate discussion of effective communication strategies in sharing the MSL value proposition with key stakeholders. Tips and guidance for the use of CRM and other communication tools will be shared.

Learning Objectives:

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

- Discuss the different but complementary views and communication of the MSL value proposition from multiple perspectives: MSL, Regional Director and National Director
- Identify key stakeholders and learn strategies for tailoring communication with each group
- Discuss potential challenges and learn strategies for objection handling
- Explore options for leveraging CRM systems for optimal communication
- Discuss how the product life cycle affects communication strategies for the MSL, Regional Director and National Director

Faculty

Randy Miller PharmD, RPh
Director, Field Based Medicine Operations
Boehringer Ingelheim Pharmaceuticals, Inc.

Laurie Broman, PharmD
Associate Director – Medical Affairs
Gilead Sciences

Nancy Rayhorn, RN, BSN
MSL
Janssen Services, LLC

9:30-10:00 AM REFRESHMENT BREAK/EXHIBITS

10:00-11:30 AM BREAKOUT SESSIONS 6

MEDICAL COMMUNICATIONS TRACK 6A-B

Podium Pearls

CHAIRPERSON

Stacey Fung, PharmD
Associate Director, Medical Communications
Genentech, A Member of the Roche Group

In this session, Medical Communications Professionals were invited to present their successes, challenges, and "pearls of wisdom" on various topics through podium presentations. Six presentation topics were selected from submitted abstracts for this unique opportunity to share podium pearls.

Assessing New and Emerging Roles of Medical Communication Professionals in Bio-Pharmaceutical Industry Settings: Evolution from Supporting to a Leading Role

Dannis Chang, PharmD
US Medical Affairs - Bio-Oncology
Medical Communications Scientist - Genentech, A Member of the Roche Group

New Communication Channels and Tools: An Overview and Trends in Adoption and Implementation

Renard Dubois, PharmD, MS
Associate Scientist, Medical Communications
Genentech, A Member of the Roche Group

Globalization Pilot-Transforming Medical Information Services (MIS)

Joyce P. Fairclough, PharmD
Manager, Metabolism & Medical Information Services
Sanofi

Enhanced Medical Information Website Increases Site Utilization

Steven Hays, PharmD, MBA
Associate Director, Medical Information
Pfizer Inc.

In-house Conversion of Medical Information Services from an External Vendor: Implementation and Outcomes

Hadley Le, PharmD
Associate Manager, Medical Information
Gilead Sciences, Inc.

Responding to Medical Information Inquiries More Efficiently: What's involved when the Process has Regulatory Implications?

Krupa Paranjpe, PharmD
Associate Director Medical Information
Pfizer Inc.

10:00-11:30 AM BREAKOUT SESSIONS 6

MEDICAL WRITING PUBLICATION AND REGULATORY TRACKS 6C

Device, Diagnostic, and Biotech Submissions

Chairperson

Susan Vintilla-Friedman
Principal
Vintilla Communications LLC

Preparations by medical writers and regulatory departments for the submission process need to become more collaborative than ever before, now that the most recent legislation includes electronic mandates and increased and earlier communications with FDA. FDASIA 2012 is landmark legislation that became effective on October 1, 2012 that reauthorized PDUFA and MDUFA and contains breakthrough mandates for electronic submissions to streamline the FDA review process. It institutes a process for bringing generic biologics to market and offers numerous critical provisions to reform FDA programs. These reforms include fostering greater interaction between drug/device sponsors and the FDA, and more engagement with patients including those with rare diseases. The impact to medical and scientific communicators working on device, diagnostic, and biotech submissions will be discussed from both the commercial and academic sponsor perspective.

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

- Identify recent FDA requirements for electronic submissions that are relevant to your organization
- Define strategies for increased communication with FDA and other stakeholders during the submission process
- Discuss new tools and processes needed for successful electronic submissions

Faculty

Susan Vintilla-Friedman
Principal
Vintilla Communications LLC

Antoinette Azevedo
President
e-SubmissionsSolutions.com and Sage Submissions

E. Mitchell Seymour, PhD, RAC
Regulatory Project Manager
Michigan Institute for Clinical and Health Research, University of Michigan Health System

MEDICAL WRITING PUBLICATION AND REGULATORY TRACKS 6D

Guidance on Guidelines: Understanding MOOSE and STROBE

Chairperson

Lili Fox Vélez, PhD
Writing -- Strategy -- Training

This session will provide the background of, rational for, and current utility of the MOOSE and STROBE guidelines. Panelists will describe how these guidelines are being used and how they are meant to improve manuscript quality.

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

- Recognize the primary guidelines for reporting evidence-based medicine
- Describe criteria set by the MOOSE and STROBE guidelines
- Explain how the EQUATOR website can help identify the most appropriate guidelines for publishing research results

Faculty

Lili Fox Vélez, PhD
Writing -- Strategy -- Training

Tom Lang, MA
Tom Lang Communications

MEDICAL SCIENCE LIAISONS TRACK 6E

MSL Performance Appraisal Continuum for Both Management and Individual Contributors: Coaching Feedback, Communication

Chairpersons

Vickee Altman, RN, BSN, MEd
MSA National MSL Manager
Roche Diagnostics

Eric Jozefiak, PharmD
Director, Field Medical Science
CV/Metabolics
Bristol-Myers Squibb

Coaching and mentoring towards an effective field medical dialogue. Moving past a data dump and towards customer articulation. The session will include an expert presentation, multi-disciplinary MSL panel discussion, and audience electronic response guided Q&A.

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

- Identify and apply effective dialogue in a customer-value guided discussion
- Describe how to enhance customer value driven feedback and guidance by coaching and mentoring in daily MSL management
- Discuss the differences and similarities between the MSL models related to customer touch points and effective field medical dialogue

Faculty

Vickee Altman, RN, BSN, MEd
MSA National MSL Manager
Roche Diagnostics

Eric Jozefiak, PharmD
Director, Field Medical Science
CV/Metabolics
Bristol-Myers Squibb

Kevin Appareti BS, MBA
Global Director, MSL, Office of Medical and Health Affairs
Phillips Healthcare

Bhrett McCabe, PhD
Licensed Clinical Psychologist/Founder-
The MindSide, LLC

11:30 AM-1:30 PM **LUNCHEON/PROFESSIONAL POSTER SESSION 7 /ROUNDTABLE DISCUSSIONS**

Poster Pearls

CHAIRPERSON

Stacey Fung, PharmD
Associate Director, Medical Communications
Genentech, A Member of the Roche Group

This session will offer a unique opportunity for any Medical Communications practitioner (e.g., information specialist, medical liaison, manager) to share their successes, challenges, and "pearls of wisdom" on various Medical Communications topics through poster presentations.

2013 Medical and Scientific Communications Forum Networking Lunch Discussions

CHAIRPERSONS

Beth A. Price
Executive Vice President
The Medical Affairs Company

Julia Petses, PharmD
Director, Oncology/Urology Medical Information Services
sanofi –Aventis

Attendees will have the opportunity to either dine on their own or grab their lunch and participate in not one but two luncheon sessions of networking roundtable discussions. These networking sessions will be led by one or multiple facilitators having expertise within a core medical affairs functional area that is specific to that table topic discussion (See topics below).

Roundtable Discussion Topics:

1. Freedom of Speech and Scientific Exchange-Implications for Medical Affairs
2. Medical Communications - Globalization of Medical Information
3. Medical Communications - Call Center – Hot Topics
4. Medical Communications - Risk Management-REMS
5. Medical Communications - Compliance
6. Medical Writing - Medical writing outsourcing
7. Medical Writing - Writing CTD summaries, overviews, and other registration documents
8. Medical Writing - Publication writing
9. MSL - Initial Evaluation & Selection of MSL Personnel - What qualities, requisites and experience do you employ when identifying new MSL personnel? Does it change depending on therapeutic area, stakeholder mix, activities?
10. MSL - MSL Value to Internal Constituents – how do your MSL teams collaborate with other constituent groups within your company? Do they support medical writing activities? Do they do clinical consults assisting the commercial team? Do they provide clinical support to PIs at trial sites? What other contributions can they provide to their internal partners?
11. MSL - MSL Technology Resources – what innovative tools and resources are your MSL teams utilizing? Do they engage in virtual presentations? If yes, how do they document? What reporting databases are being used? Pros and Cons?

1:30-3:00 PM **BREAKOUT SESSIONS 8**

MEDICAL COMMUNICATIONS TRACK 8A-B

Using Customer Input as a Key Source of Quality Improvement

CHAIRPERSON

Pete Guillot
President
CenterFirst Consulting, LLC

This session will be conducted in a workshop format. Experts from the customer service industry and medical information will provide an overview of techniques used to gather customer input, insider tips on improving survey results, and key learnings on how to use customer input to improve the quality and performance of your medical information communications. After each brief presentation, small groups of audience members will share their own experiences and present best practices to the entire group.

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

- Compare different customer survey techniques and identify the best one for your organization
- Describe how to critically evaluate the customer information collected to improve service quality
- Recognize how to present customer information in a manner that can influence employee performance and business partner decisions

FACULTY

Prachi Parmar, RPh
Director, Customer Experience
Pfizer Medical Information

Richard R. Shapiro
President
The Center For Client Retention

1:30-3:00 PM BREAKOUT SESSIONS 8

MEDICAL WRITING PUBLICATION AND REGULATORY TRACKS 8C

The Outsourcing of Medical Writing – Enabling Success Factors

CHAIRPERSON

Nimita Limaye, PhD
Vice President, Biometrics and Medical Writing
Tata Consultancy Services

As business models are changing, medical writing is increasingly being outsourced and considerable expertise is required in choosing the best fit for your organization in terms of the right outsourcing strategy. The appropriate business model, the right vendor and choosing the best writers are key factors contributing to the success of such partnerships. In addition, as there is a growing trend towards the offshoring of medical writing, this session also evaluates key elements that need to be factored in towards establishing successful global partnerships from a sponsor and a CRO perspective.

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

- Identify medical writing outsourcing models and understand the pros and cons of levels of outsourcing integration
- Discuss considerations in selecting an outsourcing model and select the right medical writers
- Recognize key factors from a sponsor and a CRO perspective in establishing successful off-shored partnerships

FACULTY

Frances Pu, PhD
Manager of Medical Writing
Renaissance Writing Services, LLC

Robin Whitsell
President
Whitsell Innovations, Inc.

Nimita Limaye, PhD
Vice President, Biometrics and Medical Writing
Tata Consultancy Services

MEDICAL WRITING PUBLICATION AND REGULATORY TRACKS 8D

Graphical Presentation for Publications

CHAIRPERSON

Peter Riebling, MS, RAC
Manager, Medical Writing
Daiichi Sankyo, Inc.

Figures are an important component of clinical trial publications. If a picture is worth a thousand words, then authors and medical writers should ensure that figures effectively display clinical trial results. This session will provide an overview of common types of figures (flow diagrams, Kaplan-Meier plots, forest plots, repeated-measures plots, etc). Guidelines for style and content will be reviewed. The audience will be invited to critique "good" and "bad" examples. Ultimately, the goal of this session is to promote the use of well-designed, easily interpretable graphs in clinical trial publications.

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

- Identify when data should be presented in graphical (as opposed to textual or tabular) format
- Effectively convey information in a graphical format
- Improve the graphical reporting of clinical trial results

FACULTY

Peter Riebling, MS, RAC
Manager, Medical Writing
Daiichi Sankyo, Inc.

Ann Winter-Vann, PhD
Medical Writer and Consultant
Whitsell Innovations, Inc.

MEDICAL SCIENCE LIAISONS TRACK 8E

Hot Topics in Operational Leadership

CHAIRPERSONS

Rachel Couchenour, PharmD, MBA
Director, Medical Affairs
Chelsea Therapeutics

Muriel Siadak, PA-C
Director, Medical Science Liaisons
Seattle Genetics

Operational considerations for a MSL team are becoming more complex with our current regulatory environment and require significant planning and oversight to ensure the team is properly resourced, sized, aligned (internally and externally) and targeted. The session will provide an overview of the operational issues you need to consider when starting or restructuring a team. The session will include an overarching presentation to cover current operational trends in MSL teams which will be followed by interactive small group discussions. Four topic area discussions will be facilitated by experts at separate tables. Topics for small group discussions include:

1. MSL Team Resource Modeling
2. Compliance Impact on MSL Operations
3. Structure, Staffing & Team Sizing, and
4. Evolving MSL customer segments – How do you find them and how to align a team to them?

Participants will have the opportunity to rotate between two discussion tables in 30 minute blocks.

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

- Identify the points to evaluate when sizing and aligning a new or current field based MSL team
- Describe MSL team resource needs and new models for resourcing based on therapeutic area need and industry standards
- Discuss the impact of the evolving compliance environment on MSL team operational needs

FACULTY

Gary Tyson
Principle
Pharma Initiatives Consulting Group

Table 1 - MSL Team Resource Modeling

Muriel Siadak, PA-C
Director, Medical Science Liaisons
Seattle Genetics

Table 2 - Compliance Impact on MSL Operations

Hilary D. Mandler, PharmD
Director, Global MSL Operations
SHIRE

Table 3 - Structure, Staffing & Team Sizing

Gary Tyson
Principle
Pharma Initiatives Consulting Group

Table 4 - Evolving MSL Customer Segments – How do you find them & align your team to them?

Randy Miller PharmD, RPh
Director, Field Based Medicine Operations
Boehringer Ingelheim Pharmaceuticals, Inc.

3:00-3:30 PM REFRESHMENT BREAK/EXHIBITS

3:30-5:00 PM BREAKOUT SESSIONS 9

MEDICAL COMMUNICATIONS TRACK 9A-B

Digital and Social Media : What should you know....and be thinking about it?

Chairperson

Patrick Reilly
Vice President, Global Medical Information
Bristol-Myers Squibb

It's more evident than ever HCPs use digital tools and social media not only to access medical information but also to keep themselves and patients informed. How can pharma utilize the current digital landscape and adapt to providing information to their customers in an effective way? Despite the lack of guidance provided by the FDA, how are companies experimenting with social media and mobile Apps?

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

- Identify current social media space and how it is being utilized by companies
- Recognize the importance of social media presence and its impact on delivering patient centered care
- Evaluate available digital tools and technology and how they are impacting patient care
- Identify future opportunities to utilize social media and digital tools to improve quality of service
- Discuss current guidance on social media provided by the FDA

Faculty

Christopher Graham
Executive Director, Promotion Integrity
Bristol-Myers Squibb

Doug Elwood, MD
Director, GMI Strategy and Innovation
Bristol-Myers Squibb

Leena Jindia, MS, PharmD
Director, Medical Information
Janssen Scientific Affairs

Timothy O'Grady
VP Business Development
WorldOne Interactive

3:30-5:00 PM BREAKOUT SESSIONS 9

MEDICAL WRITING PUBLICATION AND REGULATORY TRACKS 9C

The Development Safety Update Report (DSUR): Practical Experience for Medical Writers

CHAIRPERSON

Julia Cooper, PhD
Senior Director, Worldwide Head of Medical Writing Services
PAREXEL International Ltd.

The Development Safety Update Report (DSUR) is the required format for pre-approval annual safety reports in Europe, and is accepted by FDA in place of the IND annual report. This session will review practical experience with the DSUR as it relates to medical writers. Presentations will include case studies illustrating lessons learned for DSUR preparation, from the pharma company and CRO perspectives.

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

- Apply the required content and timing of the DSUR
- Discuss the pitfalls of preparing a DSUR and describe the key role of the medical writer in overcoming them
- Summarize the status of DSUR implementation and discuss the benefits and challenges of this harmonization

FACULTY

Julia Cooper, PhD
Senior Director, Worldwide Head of Medical Writing Services
PAREXEL International Ltd.

Kathy Thomas-Urban, PhD
Medical & Scientific Writer
Medical & Scientific Writing & Publication Services

MEDICAL WRITING PUBLICATION AND REGULATORY TRACKS 9D

Clinical Pharmacology Publication

CHAIRPERSON

Klaus J. Hermann, PhD
President
ClinCoRep LLC

General overview of clinical pharmacology and publishing.

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

- Evaluate the design of clinically relevant pharmacological studies
- Describe the publication process from submission to revision to acceptance
- Discuss how to analyze and choose appropriate information for each component of a manuscript from introduction to discussion

FACULTY

Klaus J. Hermann, PhD
President
ClinCoRep LLC

Anita Hjelmeland, PhD
Assistant Professor
Cleveland Clinic, Lerner College of Medicine of Case Western Reserve

MEDICAL SCIENCE LIAISONS TRACK 9E

Emerging Technology for MSLs

CHAIRPERSON

Craig Klinger, RPh
Medical Liaison Operations Consultant – Trainer
Lilly USA, LLC

As field based medical, MSLs are in need of a quick and easy way to gain access to information in order to provide answers to unsolicited questions from KOLs. This session will review various hardware, software and Apps that can be utilized to fulfill the MSLs needs. We will review the process for designing, developing and piloting Apps for use by field based medical. Address how these Apps can help ensure version control of medical response documents by linking to a single repository of information which can be shared per unsolicited requests. We will also discuss how the ever evolving world of technology has to be integrated into business processes to ensure all company needs are met in a timely and cost effective manner.

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

- Identify the needs of your organization, evaluate, and choose appropriate Apps currently available
- Discuss the process used to develop new Apps for your organization and how to implement them appropriately, both internally and externally
- Describe how to develop appropriate use guidelines of Apps for field-based medical personnel

FACULTY

Lesley Burcham
IT Consultant
Lilly USA, LLC

Paul Minne, PharmD
Senior Medical Science Liaison
Biogen Idec

Craig Klinger, RPh
Medical Liaison Operations Consultant – Trainer
Lilly USA, LLC

5:00-6:00 PM **RESIDENT AND FELLOW POSTER RECEPTION**

CHAIRPERSON

Alicia Alexander Cadogan, PharmD
Director, Team Lead, Oncology
Pfizer Medical Information
Pfizer Inc.

The residents and fellows will display their projects and will be eager to discuss their work with you. Please take advantage of this opportunity to learn from their research, share your perspective on their work, and discuss the results and impact on our business with them. Projects will cover a wide range of topics and represent many pharmaceutical companies. One project will be selected as the winner for having the biggest potential impact on how we practice Medical Communications.

6:30 PN **DINNER ON THE TOWN**

Sign up for dinner with your colleagues at your choice of several restaurants (transportation cost provided by DIA, however dinner cost is on your own).

7:00-8:00 AM REGISTRATION/EXHIBITS AND CONTINENTAL BREAKFAST

8:00–9:30 AM BREAKOUT SESSIONS 10

MEDICAL COMMUNICATIONS TRACK 10A

Hot Topics in Medical Communications

Chairperson

Alicia Alexander Cadogan, PharmD
Director, Team Lead, Oncology
Pfizer Medical Information
Pfizer Inc.

Did you ever wonder what others in the business are thinking when it comes to hot topics that affect our daily work? Well during this session you can hear a panel of experienced Medical Communications professionals share their perspectives and opinions on relevant and current topics. The topics will be closely linked to the current regulatory, political, and legislative landscape as it relates to the industry practice of Medical Communications. You are invited to add your own perspective to the discussion as this will be an unscripted conversation about what matters most to us today and how it will impact our practice tomorrow.

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

- Describe how the regulatory, political, and legislative landscape may impact the current practice of medical communications
- Describe different approaches as to how the best manage potential regulatory, political, and legislative impacts on the practice of medical communications and how we can best serve our customers and the patient regardless of these impacts

Faculty

Dominick Albano, PharmD, MBA
Regional Director, North and South America, Pfizer Medical Information
Pfizer Inc.

Lesley Fierro, PharmD, MS
Associate Vice President, Medical Information Services
sanofi-aventis

MEDICAL COMMUNICATIONS TRACK 10B

Hot Topics for Contact Centers

Chairperson

Maureen L. Baldwin, MSN, RN
Associate Director
Pfizer Inc.

Do you wonder if you colleagues in medical communications contact centers across the industry are facing the challenges you are everyday? During this session we will begin by presenting two topics currently impacting contact centers. First, the importance of developing a Business Contingency Plan (BCP) and when and how to implement it. You'll also hear two colleagues perspectives on a global initiative; one from the U.S and the other from Australia. We would then like you to participate by discussing topics/issues you are currently facing or best practices you have implemented.

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

- Discuss the importance of BCP
- List some situations that should be covered by a BCP
- Outline first steps in developing a BCP and how to manage during a crisis
- Discuss the importance of interdisciplinary teams when implementing a global process
- Describe strategies for effectively working with global partners

Faculty

Timothy E. Poe, PharmD
President
TEP Consulting, LLC

Barbara M. Bonetti, PharmD
Director, Medical Customer Interface
Pfizer Inc.

Rebecca Mascarenhas
Medical Information Manager
Pfizer Australia Pty Ltd

8:00–9:30 AM BREAKOUT SESSIONS 10

MEDICAL WRITING PUBLICATION AND REGULATORY TRACKS 10C

Globalization: Conducting Document Work around the Globe

CHAIRPERSON

Wendi Lau, MS
Senior Director, Global Medical Writing
Astellas Pharma Global Development, Inc

The complexities (and potential advantages!) of globalization have been a long-standing challenge within the pharmaceutical industry, and are particularly relevant for the development of complex scientific documents. The goal of this session is to describe successful strategies to develop high-quality regulatory and publications documents across multiple regions. Topics will include effective communication practices for global projects, approaches that maintain document quality and timelines across multiple time zones, and partnering across companies (both co-development and vendor-sponsor scenarios).

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

- Recognize the contemporary challenges involved with document work in the global environment
- Discuss best practices for effective partnering across regions for global regulatory submissions and scientific publications
- Identify best practices for cooperative document work when multiple companies are involved

FACULTY

Wendi Lau, MS
Senior Director, Medical Writing
Astellas Pharma Global Development

Noah Gourlie, MS
Senior Medical Writing Program Manager
Astellas Pharma Global Development

Michael John Mihm, PhD
Associate Medical Writing Program Director
Astellas Pharma Global Development

MEDICAL WRITING PUBLICATION AND REGULATORY TRACKS 10D

Publication Safety Writing

CHAIRPERSON

Darryl L'Heureux, PhD
Medical Writer
CSL Behring

The Publication Safety Writing session will present an overview of the challenges in publishing safety data for different stakeholders and audiences. Special consideration will be given to recent legislation including the Federal Food and Drug Administration Amendment Act, Risk Evaluation and Minimization Strategies (FDAAA) and the Trial and Experimental Studies Transparency (TEST) Act. These legislative acts have reformed industry's obligation to publish safety data and biomedical journals have responded with more rigorous publishing requirements. The need for clear and concise safety writing will also be addressed from the perspective of a potentially overlooked audience. As the safety of drugs under real-life conditions will allow clinicians to make more informed decisions for patient use, the perspective of patients, families, and advocates will be discussed and their distinctive need to evaluate safety and risks as a consumer. As most safety manuscripts are based on observational and pharmacoepidemiology programs, a detailed writing approach to overcome inherent challenges will be presented, as well as the role of Safety Registries and pharmacovigilence activities mandated by health authorities. This presentation will compare and contrast the features, strengths, and limitations of drug safety information gleaned from both observational safety registries and clinical trials. Results of well-written post-approval safety manuscripts provide scientific evidence that aids in the understanding and interpretation of safety data beyond the scope of pre-approval clinical trials.

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

- Describe the regulatory framework and requirements of safety publication writing in relation to FDAAA and TEST acts
- Define the role that long-term safety studies and registries play in communicating safety information
- Discuss the impact that recent legislation has had on publications involving mandated post-approval studies
- Demonstrate approaches and identify associated challenges for publishing observational data

FACULTY

Robin Whitsell
President, Whitsell Innovations, Inc.

Carole Baas, PhD
Lead Patient Advocate for Physical Sciences and Oncology Program
National Cancer Institute

Mary Whitman, PhD
Senior Director, Medical Affairs
Janssen Biotech, Inc.

MEDICAL SCIENCE LIAISONS TRACK 10E

Considerations for the Development and Communication of MSL Metrics

CHAIRPERSONS

Edmund J. Cunningham, PharmD
Director, Specialty Care MSLs
Medical Affairs
Eisai Inc

Edith Eby, PharmD
Executive Director, Medical Relations & Governance
Pfizer Inc.

The role of the Medical Science Liaison (MSL) throughout the phases of a product's life cycle continues to evolve and diversify. While thought leader development is a core activity for MSL teams, additional roles are emerging in areas such as clinical development and managed care clinical support. Regardless of the number or diversity of MSL activities, the optimal metrics for capturing and communicating these activities remain an area of uncertainty. This session discusses concepts involved in measuring and communicating MSL activities, which demonstrate alignment with corporate and Medical objectives while providing value to management and other internal customers.

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

- Identify the MSL teams role from early development through the end of a product's life cycle
- Discuss ways in which MSL goals are aligned with organizational and Medical Affairs goals
- Describe barriers to the identification of appropriate MSL metrics, both quantitative and qualitative
- Discuss the considerations associated with communicating MSL activities cross-functionally within an organization
- Demonstrate the impact of an MSL organization and how metrics can serve as a basis for supporting MSL resourcing

FACULTY

Edmund J. Cunningham, PharmD
Director, Specialty Care MSLs
Medical Affairs
Eisai Inc

Edith Eby, PharmD
Executive Director, Medical Relations & Governance
Pfizer Inc.

9:30–10:00 AM REFRESHMENT BREAK/EXHIBITS

10:00–11:30 AM BREAKOUT SESSIONS 11

MEDICAL COMMUNICATIONS TRACK 11A-B

Current Legal and Regulatory Landscape Impacting Medical and Scientific Communications

CHAIRPERSONS

Mary Sendi, PharmD
Director, Medical Information
Pfizer Inc.

Monica Kwarcinski, PharmD
Executive Director, Medical Services
Purdue Pharma LP

In a regulated industry such as ours, regulatory guidance documents from the Food and Drug Administration (FDA), corporate integrity agreements (CIAs) and the Office of Inspector General (OIG), and legal decisions affecting the pharmaceutical industry may substantially impact how we work in medical and scientific communications.

How has the 2011 FDA draft guidance entitled "Guidance for Industry Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Device" impacted industry interactions with consumers and health care providers? Has the guidance restricted, enhanced, or built upon current practices across Medical Communications Departments? How have recent CIA and State AG settlements impacted medical and scientific communications? What is the importance of recent judicial opinions on FDA regulation of off-label communications, especially U.S. v. Caronia? What is the potential impact on medical and scientific communications?

Learning Objectives:

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

- Describe compliance aspects of recently surveyed medical communications practices
- Discuss the policies and procedures the Office of Inspector General (OIG) and State Attorney General is requiring of Medical Information, Medical Science Liaisons, and Publications to have in place based on recent Corporate Integrity Agreements (CIA) and State AG settlements
- Discuss recent judicial opinions on the FDA's regulations of off-label communications, especially U.S .v. Caronia.
- Describe the process the FDA follows when creating Guidance to Industry including input Agency seeks from industry when preparing Guidance and monitoring adherence
- Discuss the role FDA guidance documents play in shaping the regulatory environment for medical and scientific communications
- Discuss the scope and limitations of existing FDA draft guidance in the medical and scientific communications area

FACULTY

Monica Kwarcinski, PharmD
Executive Director, Medical Services
Purdue Pharma LP

Kristin Graham Koehler
Partner
Sidley Austin LLP

Geoffrey M. Levitt
Senior Vice President and Associate General Counsel
Regulatory and Policy Law
Pfizer Inc.

11:30 AM-12:00 PM CLOSING REMARKS

PROGRAM CHAIRPERSON

Sara Doshi, PharmD
Manager, Global Medical Information Strategy
Eli Lilly and Company

9:30–10:00 AM REFRESHMENT BREAK/EXHIBITS

10:00–11:30 AM BREAKOUT SESSIONS 11

MEDICAL WRITING PUBLICATION AND REGULATORY TRACKS 11C

Responding to Regulatory Questions and Feedback

Chairperson

Noah Gourlie, MS
Senior Medical Writing Program Manager
Astellas Pharma Global Development

The session will provide an overview of the general principles behind preparing for regulatory questions after the submission of an application for regulatory approval (e.g., NDA or MAA), especially identifying steps that can be taken in advance of receiving the questions. The specific case and requirements of revising a Pediatric Investigation Plan after EMA Pediatric Committee application review will be examined in detail. Finally, best practices for managing the process of developing the responses will be discussed.

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

- Create a plan to address regulatory questions to support a submission (e.g., NDA/MAA)
- Create a package for submission based on revisions to Pediatric Investigation Plan as a result of EMA Pediatric Committee application review
- Describe best practices for managing the authoring and review of responses to regulatory questions

Faculty

Tracy Lovejoy, PharmD
Manager, Medical Writing Projects
Allergan, Inc.

Renee Primus, PhD, MS
Director, Global Regulatory Documentation
Bristol-Myers Squibb, Company

MEDICAL WRITING PUBLICATION AND REGULATORY TRACKS 11D

Coordination of a Global Clinical Trial Publications Plan: Strategic Approaches and Best Practices for a Successful Product Launch

Chairperson

Michael John Mihm, PhD
Associate Medical Writing Program Director
Astellas Pharma Global Development

Within the arena of medical communications, peer-reviewed publications remain the gold standard for the dissemination of novel scientific information. The goal of this session is to provide practical information to successfully plan and implement a global publications strategy for a new pharmaceutical. Topics will include the development of a publication strategy team, the identification of important medical questions and appropriate scientific venues for new data, and how to effectively resource and implement a publication plan globally.

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

- Recognize the contemporary challenges involved with the publication planning process
- Discuss best practices for effective publication planning
- Explain the inter-relatedness between Publication Coordinators and other Medical Communication professionals, and appreciate the value of collaboration within this space

Faculty

Stephen Valerio, MS, CMPP
Senior Global Publications Leader
Genentech, A Member of the Roche Group

Maureen F. Garrity, PharmD
Director of Publications
Astellas Scientific and Medical Affairs

Tim Mason, MSc
Manager, Global Scientific Communications
Eli Lilly and Company

MEDICAL SCIENCE LIAISONS TRACK 11E

Building Your "Brand" for Professional Development

Chairpersons

Edward Bezarro, RPh
Regional Director, Medical Development
Amylin Pharmaceuticals, Inc.

Fielding a MSL team represents an enormous cost for pharmaceutical companies. Since MSLs are the regular, customer-facing extension of Medical Affairs into the medical community, focusing development costs to optimize this relationship is of paramount importance. Thorough training, continued competency development and knowledge acquisition, and career development are important issues to both the individual MSL contributor as well as the management team. In addition, training and competency programs offer an opportunity to create a "brand" for both the team and individual contributor that sets them apart from competitors. Many large pharmaceutical companies have the financial resources to either outsource training and competency development programs, or have an in-house function dedicated to career development. Small and mid-size companies, and even some larger companies, rely on their management teams to develop and implement these programs. However, MSL managers may feel that they lack the fundamental knowledge and tools needed to successfully develop effective training and competency programs. Furthermore, as it relates to overall career development, MSLs and managers alike may have a certain sense of frustration in developing a career pathway, particularly for those who want to remain field based.

This session will discuss and highlight these issues. The panel will offer some suggestions for developing a comprehensive training and competency based development program while building your brand. Where the MSL role is headed in the future and how this relates to career development will also be discussed. Also discussed will be the ongoing evolution of the MSL role and how this relates to career development.

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

- Discuss the differences between on-boarding and continuous learning and how to apply adult learning principles to MSL training programs
- Outline the key aspects of a career development program for MSLs and the steps toward implementation
- Discuss the potential functions and opportunities for MSL teams and leaders of the future

Faculty

Kathryn Gann, PhD
Senior Regional Scientific Manager
Astra-Zeneca, LP

David A. Jencen, PhD
Owner, Jencen Performance Consultants LLC
Formerly National Director, Managed Markets Medical Liaisons, Novo Nordisk

Edith Eby, PharmD
Executive Director, Medical Relations & Governance
Pfizer Inc.

11:30 AM-12:00 PM CLOSING REMARKS

Program Chairperson

David Clemow, PhD
Clinical Research Scientist
Lilly USA LLC

Program Chairperson

Tolu Taiwo, PharmD
Director, Medical Information
Horizon Pharma

Program Chairperson

Lynn Bass, PharmD
Director, Medical Science Liaisons
Jazz Pharmaceuticals

REGISTRATION FORM
Register online or fax this page to +1.215.442.6199

Medical and Scientific Communications 2013 Annual Forum

Core Curriculum: March 18

Preconference (PM) Tutorials: March 18 | Conference: March 19-21

Event ID 13006 | The Sheraton Wild Horse Pass Resort & Spa | Chandler, AZ

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TUTORIALS: MONDAY, MARCH 18 1:30-5:00 PM

#1 Instilling Quality in Promotional Materials via Medical Communications Input in 2013	US $405 ❑
#2 Medical Communications: Compliance in 2013	US $405 ❑
#3 Contact Center 101	US $405 ❑
#4 Medical Writing: Clinical Overview	US $405 ❑

Registration is limited to ONE Tutorial..

CORE CURRICULUM: MARCH 18

This registration section is limited to the Core Curriculum only. You must complete this section if you wish to attend the Core Curriculum which is limited to 100 attendees. Your acceptance will be confirmed in writing.

Individuals new to pharmaceutical industry-based medical communications (less than 1 year in this function) would gain the most from attending the Core Curriculum.

❑ I wish to attend the Core Curriculum for an additional fee of US $295 ❑

❑ I have not attended the Core Curriculum before.

My department is:

❑ Contact Center ❑ Medical Information/Medical Communications

❑ Medical Liaison ❑ Other

Payment options: Register online at **www.diahome.org** or check payment method.

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❑ **BANK TRANSFER** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the Bank Transfer. Payment should be made in US dollars. Your name and company, as well as the Event I.D. # must be included on the transfer document to ensure payment to your account.

Participants with Disabilities: Reasonable accommodations will be made available to persons with disabilities who attend an educational activity. Contact the DIA office in writing at least 15 days prior to event to indicate your needs.

TRAVEL AND HOTEL

The most convenient airport is Phoenix Sky Harbor Airport and attendees should make airline reservations as early as possible. The Sheraton Wild Horse Pass Resort & Spa is holding a block of rooms at the reduced rate below until **February 9**, for DIA attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single $199+ **Double $199+**

Attendees must make their own hotel reservations. Contact Dixie Fuller at the Sheraton Wild Horse Pass Resort & Spa by telephone at +1.502.796.8276 or by email Dixie.Fuller@Sheraton.com and mention the DIA event. The hotel is located at 5594 West Wild Horse Pass Boulevard, Chandler, AZ 85226, USA.

CANCELLATION POLICY: On or before MARCH 4, 2013

Administrative fee that will be withheld from refund amount:

Member or Nonmember = $200

Government or Academia or Nonprofit (Member or Nonmember) = $100

Tutorial (if applicable) = $50

Cancellations must be in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations. You may transfer your registration to a colleague at any time but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable.

DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.

GROUP DISCOUNTS* Register 3 individuals from the same company and receive complimentary registration for a 4th! **All 4 individuals must register and prepay at the same time – no exceptions.** DIA will apply the value of the lowest applicable fee to this complimentary registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred. **Group registration is not available online and does not apply to the already-discounted fees for government or charitable nonprofit/academia.** To take advantage of this offer, please make a copy of this registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA.

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FOR FURTHER INFORMATION, CONTACT

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Phone +1.215.442.6181, Fax +1.215.293.5987, Carrie.Dunn@diahome.org
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Phone +1.215.442.6175, Fax +1.215.293.5940, Joann.boileau@diahome.org

FOR TABLETOP EXHIBIT INFORMATION, CONTACT

Shannon Lewis, Exhibits Associate
Phone +1.215.442.6149, Fax +1.215.442.6199, Shannon.Lewis@diahome.or

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