### 21<sup>ST</sup> Annual Workshop on Medical Communications

# Defining the Future of Medical Communications

Preworkshop Tutorials: March 14, 2010

Workshop: March 15-17, 2010

JW Marriott Camelback Inn Resort & Spa, Scottsdale, AZ, USA



#### STEERING COMMITTEE CHAIRS

Alicia Alexander Cadogan, PHARMD Director, Medical Information Pfizer Inc

**Lynn Bass, PharmD**Senior Regional Medical Liaison
Scientific Affairs, Amgen Inc.

See page 2 for a complete list of Program Committee members.

#### Who Should Attend

Professionals who work in the following areas:

- · Medical communications
- Medical liaisons
- Medical information
- · Medical call center environment
- · Industry, academia, and government

### **Preworkshop Highlights**

#### Sunday, March 14

• Core Curriculum - Full-day session 8:00 AM-4:30 PM

Separate registration is required. See page 11.

This program is specifically designed to meet the needs of individuals new to pharmaceutical industry-based medical communications. Those who have been in this function for less than 1 year would gain the most from attending.

• Afternoon Tutorials - 1:30-5:00 PM

Separate registration is required. See page 11.

- Medical Science Liaisons
- Literature Searching/Medical Writing
- Evidence-based Medicine
- Practical Applications of Biostatistics

### **Workshop Highlights**

#### Monday, March 15

- Opening Session Health Care Reform Update
- Appropriate data sources: Evidence-based medicine versus alternative sources
- Breakout sessions for field-based medical liaisons (interactions with academia and MSL 2009 survey results), contact center (handling of product recalls, and emerging technology), and headquarters-based medical communications (sharing information between companies, and promotional review)
- · Welcoming reception featuring speed networking

#### Tuesday, March 16

- The future of medical communications
- · Leadership and professional development
- Podium and poster pearls
- Breakout sessions on customer insights, compliance, and sales training
- Evening reception featuring professional poster presentations

#### Wednesday, March 17

- · Regulatory Review
- Medical communications experience with Risk Evaluation and Mitigation Strategy (REMS)



Drug Information Association, Inc. 800 Enterprise Road, Suite 200 Horsham PA 19044 LISA

**Regional Offices** 



#### **PROGRAM COMMITTEE**

Maureen Baldwin, RN, MSN Associate Director, US Contact Center, Pfizer Inc

Christopher Dadas, PharmD
Director, Medical Affairs, Allergan

Sara Doshi, PharmD Consultant, Global Medical Information, Eli Lilly and Company

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

Senior Manager, Medical Communications, Genentech, Inc.

Leena Jindia, MS, PharmD

Director, Medical Information, Tibotec
Therapeutics, Division of Centocor
Ortho Biotech Services, LLC

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

Timothy E. Poe, PharmD
Director, Product Information and
Patient Services, GSK Response Center,
GlaxoSmithKline

**Jennifer L. Riggins, PharmD**Director, Global Medical Customer
Solutions, Eli Lilly and Company

Rebecca A. Vermeulen, RPh Senior Director, Global Medical Customer Solutions, Eli Lilly and Company

Ramineh Zoka, PharmD, MS Senior Director, Clinical Science Liaison, Centocor Ortho Biotech Services, LLC

#### CONTINUING EDUCATION

#### **Physician Continuing Medical Education**



This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of Postgraduate Institute for Medicine (PIM) and the Drug Information Association. PIM is accredited by the ACCME to provide continuing medical education for physicians.

#### Credit Designation

Postgraduate Institute for Medicine designates this educational activity for a maximum of 7.25 AMA PRA Category 1 Credit(s) $^{\text{TM}}$ . Physicians should only claim credit commensurate with the extent of their participation in the activity. (Conference Tutorials)

Core Curriculum Tutorial: 7.25 AMA PRA Category 1 Credit(s)™, Tutorials #1, 2, 3, and 4: 3.25 AMA PRA Category 1 Credit(s)™ each

Postgraduate Institute for Medicine designates this educational activity for a maximum of 16.25 AMA PRA Category 1 Credit(s) $^{\text{m}}$ . Physicians should only claim credit commensurate with the extent of their participation in the activity. (Conference)

Conference: 16.25 AMA PRA Category 1 Credit(s)™

#### **Pharmacist Continuing Education**



The Drug Information Association is accredited by the Accreditation Council for Pharmacy Education as a Provider of continuing pharmacy education. Type of Activity: Knowledge

This **Program** is designated for 11.5 contact hours or 1.15 continuing education units (CEUs). 286-000-10-009-L04-P. **Tutorial #1** is designated for 3.25 contact hours or .325 continuing education units (CEUs). 286-000-10-007-L04-P. **Tutorial #4** is designated for 3.25 contact hours or .325 continuing education units (CEUs). 286-000-10-008-L04-P.

Continuing pharmacy education credits are not available for the following sessions: Plenary Session 1; Breakout Session 2-1; Breakout Session 2-3; Breakout Session 3-1; Speed Networking Reception; Plenary Session 5; Luncheon/Professional Poster Session; Breakout Session 6-2; Plenary Session 7; Resident Poster Session/Reception

#### **Nursing Continuing Education**



The Drug Information Association will offer nursing credits for this conference in collaboration with Corexcel.

Corexcel is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation. This conference is designated for a maximum of 15.5 nursing contact hours.

#### Credit Designation

Core Curriculum Tutorial: 6.75 nursing contact hours; Tutorials #1, 2, 3, and 4: 3.25 nursing contact hours each; Conference: 15.5 nursing contact hours

To receive a statement of credit, participants must attend the program and complete the online credit request process through My Transcript at www.diahome. org. Participants will be able to download a statement of credit upon successful submission of the credit request. Complete details and instructions for accessing My Transcript will be included in the final program.

**Disclosure Policy:** It is Drug Information Association policy that all faculty participating in continuing education activities must disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Faculty disclosure will be included in the course materials.

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

- Demonstrate core competencies in industry-based drug information practice for both field-based and headquarter-based; verbal and written responses; provision of on-label and off-label information; medical and scientific literature evaluation; regulatory and legal applications; and scientific balance versus fair balance
- · Discuss important and recent developments regarding health care reform and regulatory guidances related to medical communications
- Recognize medical communications involvement in job functions such as promotional review, REMS, training, compliance, and referencing
- · Assess the current landscape for field-based medical communications, and identify ways to enhance their ability to interact with academicians
- Discuss the do's and don'ts of dissemination of off-label information
- Identify obstacles and opportunities on the horizon for medical communications, and potential ways to benefit from both

### DAY 1 | SUNDAY, MARCH 14, 2010 CORE CURRICULUM

7:00-8:00 AM CORE CURRICULUM REGISTRATION AND CONTINENTAL BREAKFAST (Confirmed attendees only)

8:00-8:30 AM WELCOME AND INTRODUCTIONS

**CHAIRPERSON** 

Stacey Fung, PharmD

Senior Manager, Medical Communications, Genentech, Inc.

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.

#### **FACULTY**

**Tanya Knight-Klimas, PharmD,** Medical Information Manager, MedCommunications

**William Lai, PharmD, MBA,** Senior Manager, Medical Affairs, Baxter Healthcare Corporation

**Carol L. Mitchell, MD,** Associate Global Information Consultant, Global Medical Information, Eli Lilly and Company

Nima Patel, PharmD, Cardiovascular Medical Information Senior Manager, Bristol-Myers Squibb

**Julia Petses, PharmD,** Director, Oncology/Urology Medical Information Services, sanofi-aventis U.S.

Jim R. Wilkinson, PhD, Director, Scientific Affairs, Amgen Inc.

**Danielle Ziernicki, PharmD,** Director, Global Regulatory Affairs Strategic Policy and Support, Johnson & Johnson Pharmaceuticals Group

8:30-10:00 AM CORE CURRICULUM SESSION 1

8:30-9:30 AM Session 1A: Regulatory Environment and

Medical Communications Practices

**F**ACULTY

Danielle Ziernicki, PharmD

This session introduces the current regulatory environment that influences the activities of a 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.

#### **Learning Objectives**

Attendees will build on their existing knowledge and information presented in Session 1A regarding the regulatory environment that influences Medical Communications practice. Case presentations will be discussed by the faculty and attendees.

9:30-10:00 AM Session 1B: Regulatory Considerations to Medical

**Communications Practices** 

FACULTY

Danielle Ziernicki, PharmD Stacey Fung, PharmD

10:00-10:15 AM REFRESHMENT BREAK

10:15-11:00 AM CORE CURRICULUM SESSION 2

**Current Practices in Medical Communications** 

FACULTY

Jim R. Wilkinson, PhD William Lai, PharmD, MBA Julia Petses, PharmD

This session will review the growing roles and responsibilities that Medical Communications professionals have and how the group supports healthcare professionals and patients, as well as the commercial success of the business. Topics will include scientific meeting support, publication planning, medical education, promotional review as well as collaboration with internal partners.

11:00 AM-12:00 PM CORE CURRICULUM SESSION 3

Tricks of Advanced Literature Searching

**FACULTY** 

Carol L. Mitchell, MD

Literature searching is a vital skill for Medical Communications professionals. This session will review "slicks tricks of the trade" for searchers of medical literature. Each attendee will walk away with a new trick that can be applied as soon as the next question is asked.

12:00-1:00 PM NETWORKING LUNCHEON

(Confirmed Core Curriculum attendees only)

1:00-4:30 PM CORE CURRICULUM SESSION 4

#### **Common Responsibilities of Medical Communications Staff**

This session will discuss the common responsibilities of Medical Communications staff. Routine activities of receiving, researching, and formulating scientific responses to unsolicited questions will be reviewed. Topics will include contact centers, formulary dossiers, compendia, internal team support, promotional review, and scientific meeting support. 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; groups will be asked to discuss and share their ideal responses to the situations.

Attendees will be divided into two groups – Session A and Session B. Both groups will run concurrently with attendees rotating to the other session after the refreshment break.

#### Session A

FACILITY

Julia Petses, PharmD

Danielle Ziernicki, PharmD

William Lai, PharmD, MBA

Stacey Fung, PharmD (Core Curriculum Chair)

Session B

FACULTY

Tanya Knight-Klimas, PharmD Jim R. Wilkinson, PhD Nima Patel, PharmD

#### DAY 1 | SUNDAY, MARCH 14, 2010

#### 12:00-5:00 PM REGISTRATION FOR TUTORIALS AND WORKSHOP

1:30-5:00 PM TUTORIAL #1

#### **Evidence-Based Medicine: Trials and Tribulations**

CHAIRPERSON AND FACULTY

#### C. Daniel Mullins, PhD

Professor, Pharmaceutical Health Services Research Department University of Maryland School of Pharmacy

Evidence-based medicine (EBM) reflects the practice of medicine that is informed by the best available evidence at the point of medical care decision making. EBM requires the generation and evaluation of valid and reliable evidence for medical decision making. While clinical practice guidelines provide significant support for EBM, often there is new evidence that has emerged since the publication of practice guidelines. Thus, quality health care delivery and informed decision making hinges on appropriate study design and analysis of emerging evidence. A variety of evidence grading systems exist, many of which suggest that (meta analyses of) clinical trials provide the most reliable framework for assessing evidence of effectiveness; however, there are a variety of alternative sources of evidence that inform medical decision making and EBM.

The American Recovery and Reinvestment Act (ARRA) contained \$1.1 billion for comparative effectiveness research aimed at providing patients, clinicians, payers and others with evidence-based information to make informed decisions about health care. Increased focus on CER raises new questions concerning how evidence generation, analysis, and synthesis inter-relate and how the communication across various stakeholders interested in assessing the value of new health care technologies and those who participate in decision making regarding utilization can provide feedback to improve both processes. This workshop provides an overview of EBM, CER, and the ability to provide synergistic coordination despite their divergent objectives.

#### **Learning Objectives**

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

- Describe sources and hierarchies of evidence used to inform evidencebased medicine
- Compare and contrast study designs and interpretation of results across clinical trials and observation studies
- Demonstrate how comparative effectiveness research will alter how medical evidence is generated and evaluated
- Discuss the government's dynamic role in assessing the value of drugs and other health technologies

1:30-5:00 PM TUTORIAL #2

# Pithy Prose and Deft Discovery: Not Just Another Writing and Searching Course for the Medical Communications Professional

CHAIRPERSON AND FACULTY

#### Carol L. Mitchell, MD

Associate Global Information Consultant, Eli Lilly and Company

#### FACULTY

#### **Evelyn Hermes-Desantis, PharmD, BCPS**

Clinical Associate Professor, Department of Pharmacy Practice and Administration, Rutgers University

Get the goo out of your writing and put your finger on the information you're looking for! Two veteran educators, both passionate about the written word and the art of searching, will share their secrets for creating concise *yet* complete documents in conjunction with maintaining a command of the literature.

#### **Learning Objectives**

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

- Explain what an informationist is and strive to be one
- Recite the four basic design principles and be more aware of the "look" of documents
- Create appropriate medical letters, focusing on the "how" as well as the "what" when communicating data through techniques such as repetition/ parallelism, paragraphing, non-text options, and easy-to-scan headings
- Understand five ways in medical letters to "cut out fat" while covering more ground in less space
- Figure out how to develop a Subject Heading-based architecture for content domain monitoring
- Develop an agile and real-time content awareness model for staying abreast of the medical literature by adopting a discipline of frequent daily searching

#### **Target Audience**

Medical Communications, medical call center environment, medical liaisons, and medical information professionals.

1:30-5:00 PM TUTORIAL #3

#### **Medical Science Liaison Forum 2010**

CHAIRPERSON

#### J. Lynn Bass, PharmD

Senior Regional Medical Liaison, Amgen Scientific Affairs

FACULTY

#### Marc J. Scheineson, Esq.

Allston & Bird, LLP

#### Brvan Vaughn

Managing Partner, TriNet Pharma

#### Beth A. Price

Executive Vice President, The Medical Affairs Company

The activities of the Medical Science Liaison (MSL) continues to evolve beyond the original thought leader development role. MSLs in 2010 are engaging in a variety of collaborative activities with key opinion leaders, Investigators, academicians, and others while facing more restrictive regulatory guidances. MSLs are a crucial and direct conduit from these academic and clinical communities to the sponsor company.

In this tutorial, we will discuss challenges to the modern day MSL role and provide innovative solutions from leaders in this field, representing a variety of companies.

#### **Learning Objectives**

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

- Discuss the current and evolving status of the MSL professional and identify key topic areas influencing MSLs in the 2010
- Discuss key strategies for hiring and retaining the best MSL team
- Discuss key regulatory and compliance guidelines affecting the MSL role

1:30-5:00 PM TUTORIAL #4

#### A Review in Practical Applications of Biostatistics

CHAIRPERSON AND FACULTY

#### Timothy A. Candy, PharmD, MS, BCPS

Senior Manager, Regulatory Affairs, Advertising/Promotion, Baxter Healthcare Corporation

This course is intended to provide a broad overview of the most common terms, topics, and techniques used in biostatistics. There will not be a focus on the specific equations and formulas employed but rather the practical application of these statistical techniques. The course is intended for any professional who has to interpret medical literature or internal study protocols and reports to determine clinical relevance to a specific subject or area of research. Actual examples from the medical literature will be used to help illustrate these concepts. This course will be very beneficial to people who have had no formal education in the area of biostatistics. However, this session can also serve as an excellent refresher course for those individuals who have had some experience with biostatistics.

#### **Learning Objectives**

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

- Discuss common terms and concepts of biostatistics useful in the evaluation of scientific literature
- Describe various concepts within hypothesis testing, one of the most common statistical analysis techniques employed in clinical study designs
- Demonstrate the importance of determining the estimated power of a study design and its relevance to interpreting clinical study results
- Describe common areas of misinterpreting statistical results

### DAY 2 | MONDAY, MARCH 15, 2010

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

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

**PLENARY SESSION 1** 

Alicia Alexander Cadogan, PharmD Director, Medical Information, Pfizer Inc

Health Care Reform: An Update

CHAIRPERSON

8:30-10:00 AM

#### Lesley Fierro, PharmD, MS

Associate Vice President, Medical Information Services, sanofi-aventis

How will health care reform affect the pharmaceutical industry and in particular medical communications? This session will provide up-to-date information about the status of health care reform legislation and current issues. Our keynote

speaker, Michael McCaughan, will provide the latest information on topics of interest such as reimbursement, ePrescribing, electronic medical records, comparative effectiveness, REMS, and other issues related to medical communications.

#### **KEYNOTE PRESENTER**

#### Michael McCaughan

Editor-in-chief, FDC/Windhover Biopharma Group

#### Learning Objectives

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

- Understand the latest information related to health care reform legislation and its impact on the pharmaceutical industry
- Discuss the potential impact of health care reform on medical communications groups
- Identify opportunities for office- and field-based groups to expand communications with health care providers and payers

10:00-10:30 AM REFRESHMENT BREAK

10:30 AM-12:00 PM SPECIAL PRESENTATION

#### Fair Game: Resources for Medical Communications

CHAIRPERSON

#### Christopher Dadas, PharmD

Central Regional Director, Allergan Medical Affairs

This session will explore some of the appropriate sources of information and materials that can be shared with health care professionals from a pharmaceutical company. We will focus on what MSLs and Medical Information groups use as tools to help educate or respond to medical requests.

#### **Learning Objectives**

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

- Discuss current and evolving resources used by medical communications
- Discuss emerging methods of communication that may impact the pharmaceutical industry
- Review regulatory guidelines that allow for appropriate scientific communication

#### Speaker

#### Alan Minsk, JD

Partner and Chair, Food & Drug Practice Team Arnall Golden Gregory LLP

12:00-1:00 PM NETWORKING LUNCHEON/DINNER SIGN UPS

#### **BREAKOUT SESSION 2-1**

#### Is There Still Room for Strategy in the Fieldbased Liaison Role within the Current Regulatory Environment?

CHAIRPERSON

#### **Beth Lowenthal**

The role of the Medical Liaison has continued to evolve since its inception more than 40 years ago. Each year, new guidances from the FDA, learnings from OIG corporate integrity agreements (CIAs), and academic center guidelines have forced companies to re-evaluate how they deploy their fieldbased teams and what activities they can safely and compliantly engage in. This session will explore the changes that have occurred and how companies have responded to these changes to ensure scientific exchange and education is preserved between companies and academic centers. The role of strategy will also be explored as it relates to planning and the communication of the value of field based teams to others within the organization. Finally, the session will explore how these changes have and will continue to affect managed care field-based teams.

#### **Learning Objectives**

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

- Review the traditional roles of the medical liaison and explore how the activities have changed over time
- Discuss new changes with institutions and the federal government that have helped to shape how medical liaisons function in their role today
- Explore how these changes have impacted strategy planning at the management level and the challenges that face managers in communicating the value of their teams
- Discuss how these changes have empowered and shaped the role of the managed care liaison

#### Guy M. Chisolm, III, PhD

Vice Chair, Lerner Research Institute

#### Beth Lowenthal, PharmD, MBA

#### **Archie Stone, PhD**

Director, Medical Science Liaisons, Merz Pharmaceuticals

#### Peter Sheehan

Business Development, REPtrax offered by deView Electronics

#### **BREAKOUT SESSION 2-2**

# Preparing for a Tidal Wave of Calls – How Preparation Can Turn Turmoil into Triumph

#### **CHAIRPERSON**

#### **Pete Guillot**

President, CenterFirst Consulting, LLC

Medical Information contact centers provide a key interface among the company, the medical community, and customers. When events occur that cause a sudden spike in interest in the company or its products, calls to the contact center can spike. Preparation for the spike is critical. If the calls are handled poorly and customers wait endlessly for less than fulfilling responses, then the initial problem is exacerbated by the response. However, if the center handles the situation with calm and precision, confidence is restored to customers, employees, and the general public.

#### Learning Objectives:

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

- Learn how one company prepared for product launch by working closely with other functional areas
- Hear how working with your outsource partner is as critical as working with other internal partners when contingency planning

#### The Contact Center as Critical Product Launch Tool

#### Rupa Shah, PharmD

Associate Director, Medical Communications, Bristol-Myers Squibb

# Working with a Outsource Partner on Contingency Planning

#### Paul Biedenbach, PharmD

Director, Operations, PPD

#### Julia Petses, PharmD

Director, Medical Information Services, Oncology, sanofi-aventis

#### **BREAKOUT SESSION 2-3**

#### It Takes Two to Tango

**CHAIRPERSON** 

#### Sara Doshi, PharmD

Consultant, Medical Information Eli Lilly and Company

Medical Information departments continue to explore how to improve their global operations with technical solutions and human resources. This is increasingly challenging as Medical Information departments also find themselves in the midst of an ongoing sequence of corporate integrations and product acquisitions. These may include interdepartmental changes, large pharma plus large pharma mergers, large pharma plus small pharma mergers, as well as the in-licensing of compounds from various sized companies. This session will review how a Medical Information department adapts when they incorporate new stakeholders for several of these scenarios and for products of various market sizes and at varying points in their lifecycle. Speakers will discuss strategies for sharing data/information, collaborative approaches to problem solving, and aligning talent synergistically.

#### **Learning Objectives**

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

- Identify key learnings from a combined globalization-integration Medical Information technology project
- List factors to consider and potential approaches when working in in-license alliance partnerships of various corporate and market sizes.
- Gain insights into handling a product launch with an alliance partner (ie, building a joint Medical Information team from the ground up) and how the "division of labor" between partners may change or transition over time.

#### Elke Blaetz, RPh, MS

Global Medical Information Leader, Roche

#### Phil Naughten, PharmD

Director, Affiliate and Alliance Coordination, Takeda Pharmaceuticals North America, Inc.

#### Cynthia Larmore, RN, MSN

Associate Medical Information Consultant, Eli Lilly and Company

#### **BREAKOUT SESSION 3-1**

Medical Liaison Survey #5: Reassessment of Medical Liaison Program Demographics and Characteristics, Demonstration of Value and Assessment of Resource Utilization

CHAIRPERSON

#### Craig Klinger, RPh(not presented)

Senior Medical Liaison Consultant, Lilly USA, LLC

Medical liaison programs are well established throughout the pharmaceutical industry. They exist in companies of all sizes, and also include biotech and device companies. As the role of the medical liaison expands, the challenges of the role continue to be numerous and differ across companies.

In four previous medical liaison surveys, information was gathered on a wide variety of topics. These topics included team demographics, medical liaison position responsibilities, training programs for medical liaisons (both established and newly hired), establishing the value of medical liaisons within the organization, nontraditional staffing options, compliance issues, roles in the health outcomes environment, competitive intelligence, career strategies, virtual office tools, and clinical trial support

This 5<sup>th</sup> annual survey of medical liaison practices will gather data on topics from previous surveys in an attempt to evaluate trends over the past several years. Updated information on medical liaison program characteristics and demographics will be collected, along with information on how ML value is demonstrated to business partners. New data collection will be focused on resources used by medical liaisons to obtain and communicate scientific information.

This survey will be administered to both medical liaisons and medical liaison managers across the industry. Survey results will be presented.

#### **Learning Objectives**

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

- Discuss the trends seen over the last several years within the role of the medical liaison with regards to ML characteristics and demographics
- Explain how medical liaison programs are demonstrating value to business partners
- Identify how medical liaisons are obtaining and communicating scientific information to thought leaders

#### Craig Klinger, RPh (not presented)

J. Lynn Bass, PharmD

#### Chris Marrone, PharmD

Senior Outcomes Liaison, Lilly USA

### BREAKOUT SESSION 3-2

#### Managing Traditional Needs with Emerging Technology

CHAIRPERSON

#### Nicole Corder, RPh, MBA

Director, The Lilly Answers Center, Lilly USA, LLC

To advance to the next generation Contact Center, we must embrace innovative technology solutions that will allow us to meet the needs of our customers through a variety of ways. In this session, we will take a look at how to enhance the customer experience through the integration of traditional and emerging communication channels. To consider a variety of customer types, we must look for ways to conquer unique staffing models without sacrificing our regulatory requirements. We will take a look at the Remote Agent program, along with an indepth view of how to accomplish a quality environment. The purpose of this session will be to demonstrate how we can accomplish the interdependencies that relate to merging our customer needs with technology, but never sacrificing our quality. After the presentations, the audience will be encouraged to participate in an interactive question and answer session.

#### **Learning Objectives**

At the conclusion of this session, participants should be

- Describe emerging channels to meet our customer's needs
- Identify implementation challenges for today's technology advancements
- Learn how to successfully utilize "at home" agents to create flexibility to your staffing model
- Discuss the challenges to maintain a QC/QA environment without limiting the ability to be creative with today's technology and staffing models

## Emerging Customer Communication Channels

#### Linda Comp

Senior Vice President, Client Services, Telerx

### Remote Agent Program

#### Bronwyn Binaxas, RPh

Contact Center Lead Pharmacist, Rocky Mountain Poison and Drug Center

#### Maintaining QC/QA Environment Katherine Cahill Moore, RPh

Manager, The Lilly Answers Center, Lilly USA, LLC

#### BREAKOUT SESSION 3-3 Promotional Review: The Role of Medical Communications

**CHAIRPERSONS** 

#### Stacey Fung, PharmD

Senior Manager, Medical Communications, Genentech. Inc.

#### Lois Jessen, MS, PharmD

Director, US Pharmaceuticals Law and Promotion Compliance, Bristol-Myers Squibb

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. The promotional review process will be described along with findings from a benchmarking survey of Medical Communications roles in promotional review. Key considerations for conducting an effective review will be discussed. While Medical Communications focuses on scientific evidence, the importance of collaboration in developing effective and compliant material will be discussed. Lastly, an interactive discussion with participants' input on samples of promotional pieces will take place.

#### **Learning Objectives**

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

- Recognize the key areas of focus for Medical Communications review of promotional material
- Describe the various models for promotional review committees and how best to work with the team

#### Findings of a Benchmarking Survey on the Role of Medical Communications for Promotional Review

#### Ellen Yang, PharmD

Medical Communications Fellow Genentech, Inc.

#### Alyson Sous, PharmD

Postdoctoral Fellow Bayer HealthCare Pharmaceuticals/ Rutgers University

# Overview of Best Practices for Review of Promotional Materials

#### Lois Jessen, MS, PharmD

Director, US Pharmaceuticals Law and Promotion Compliance, Bristol-Myers Squibb

#### Interactive Discussion and Review of Sample Promotional Materials

#### Stacey Fung, PharmD

Senior Manager, Medical Communications, Genentech. Inc.

#### 5:00-6:30 PM WELCOME/SPEED NETWORKING RECEPTION

#### CHAIRPERSON

**Jennifer L. Riggins, PharmD,** Director, eCapabilities, Global Medical Customer Solutions, Eli Lilly and Company

Building Your Network through Speed Networking. Come one, come all, and be ready to talk. Put your business cards to good use. Join us for this exciting, energetic, and structured way of building your professional network. Speed networking, as defined by macmillandictionaries.com, is the "method of making a potential business contact by briefly talking to a series of people at an organized event and exchanging contact details".

During this session, you will have the opportunity to meet and greet 15 professional colleagues in five-minute increments. This session promises to be loads of fun, will help you be better connected for the rest of the Medical Communications meeting, and will give you an extended network to call on when you return to your "day job". Please bring 15-20 business cards for exchanging.

#### **Learning Objectives**

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

- Expand their professional network by meeting and interacting with colleagues in a structured setting
- Identify people to engage in further dialogue throughout the Medical Communications meeting

7:00 PM DINNER ON THE TOWN

### DAY 2 | TUESDAY, MARCH 16, 2010

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

8:00-10:00 AM PLENARY SESSION 4

#### Is a Medical Letter a Thing of the Past?

CHAIRPERSON

#### Rebecca Vermeulen, RPh

Senior Director, Global Medical Customer Solutions, Eli Lilly and Company

As communication channels continue to evolve, new generations enter the work-force, and the wave of new social media tools expand in usage into our daily work as a means of receiving information, it is realistic to wonder how traditional means of responding to customer questions will need to change to ensure we are providing information in the way people want to receive it. The focus of this session is to understand what channels are most valued by our customers, how to modify our business operating platforms to provide information in this content rich environment, and how medical information colleagues can participate in these innovative social media tools.

#### **Learning Objectives**

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

- Discuss the current state of stakeholder expectations, what is wanted vs. what is needed
- Demonstrate how to operationalize an effort to bring change within an organization
- Analyze learnings from a social media platform that were successfully implemented
- · Identify the different channels and how to manage risk

## What Modes of Communication Are Wanted and Needed by Our Customers Today?

#### **Duncan Arbour**

Senior Consultant Blue Latitude

#### How Can Your Organization Make Needed Changes?

#### Karla Anderson

Life Sciences Commercial Operations Price Waterhouse Coopers

### Real Experience Implementing a New Platform in Partnership with

#### Poonam Bordoloi, PharmD

Senior Manager, Internal Medicine Medical Information Services sanofi-aventis

#### 10:00-10:30 AM REFRESHMENT BREAK

#### 10:30-11:30 AM PLENARY SESSION 5

#### **Podium Pearls**

**CHAIRPERSON** 

#### Dominick Albano, PharmD, MBA

Assistant Vice President, Medical Information Pfizer Inc

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

#### 11:30 AM-1:00 PM LUNCHEON/PROFESSIONAL POSTER SESSION

Take some time to network with your peers while you view posters prepared by Medical Communications professionals. This is a great opportunity to discuss topics of interest with colleagues and view some of the interesting work being done in Medical Communications.



#### **BREAKOUT SESSION 6-1**

Customer Insights: Understanding and Creating Value for Our Customers

#### **CHAIRPERSON**

#### Leena Jindia, MS, PharmD

Director, Medical Information, Tibotec Therapeutics, Division of Centocor Ortho Biotech Services LLC

Consumers and healthcare professionals actively seek information from Medical Communications departments based on their unmet medical needs. We will discuss the results of a customer satisfaction market research study and outline how to implement customer feedback to improve the quality of service. Customer inquiries can be another significant source to gather customer insights. We will discuss the potential strategies for evaluating customer inquiries to generate a deeper understanding of their needs and subsequent application of that understanding to the development of solutions for both the customer and the organization. Next we will highlight the increasing number of Latino consumers and the specific customer service skills needed by contact center representatives to be successful in such interactions.

#### **Learning Objectives**

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

- Understand the evolving needs of our customers in today's technology era
- How can medical information continue to provide value to its customers
- Describe potential sources of customer insights and its application
- Understand how to analyze voice of customer data to identify insights
- What role does cultural difference play in customer expectations? A focus on the Latino customers and the soft skills needed for effective communication with those customers.

Evaluating the Quality of Services through a Medical Information Market Research Study Leena Jindia, MS, PharmD

Mining for Insights: Voice of Customer Analysis

#### Erica Heverin, PharmD

Associate Director, Medical Communications, Ortho-McNeil Janssen Scientific Affairs, LLC

Cultural Insights: The Latino Perspective Richard Shapiro

President, ENTREVISTA, a Division of The Center for Client Retention

#### **BREAKOUT SESSION 6-2**

Hot Topics in Medical Communications Quality and Compliance

#### CHAIRPERSON

#### Monica Kwarcinski, PharmD

Senior Director, Medical Services, Purdue Pharma L.P.

This session will review the results of a survey conducted to identify current quality and compliance practices within pharmaceutical industry Medical Communications departments. An overview of what to expect when an external audit is conducted will also be presented as well as useful information regarding how to mitigate risk in the Medical Communications arena. Lastly, a panel of seasoned colleagues will provide factors to consider when developing and maintaining quality and compliance practices within Medical Communications. After the presentations the audience will be encouraged to participate in an interactive question and answer session.

#### **Learning Objectives**

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

- Describe current quality and compliance practices within pharmaceutical industry Medical Communication departments
- Describe what to expect during an external audit
- Learn how to mitigate risk in Medical Communications
- Discuss factors to consider in developing and maintaining quality and compliance practices within Medical Communications departments

Medical Communications Quality and Compliance Survey Results Monica Kwarcinski, PharmD

# Risk Mitigation in Medical Communications Mark A. DeWyngaert, PhD, MBA

Managing Director, Huron Consulting Group

#### **P**ANELISTS

#### Joyce Martin, PharmD

Senior Manager, Quality Assurance, Compliance, and Training, Medical Communications, Genentech, Inc.

#### Joseph Tuazon, PharmD

Director/Team Leader Pfizer Medical Information

#### BREAKOUT SESSION 6-3 Engaging Medical Communications as a Strategic Partner with Sales Training: Three Models for Success

#### CHAIRPERSON

#### Mary Sendi, PharmD

Senior Director, Medical Information, Pfizer Inc

This session was developed for headquarter-based Medical Communications professionals and will address several success models where Medical Communications is partnering in excellence with sales training. This session is designed to describe the concept of medical information leadership beyond responding to medical inquiries and opportunities for headquarter-based Medical Communications professionals to partner with sales training in the learning continuum from development to delivery of field-based product information materials. The session will describe current initiatives within the pharmaceutical industry addressing this topic, address potential future programs and implementation concerns, and propose next steps to build a case for change.

#### **Learning Objectives**

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

- Identify the business outcomes and value of building a strategic partnership between sales training and Medical Communications to deliver field-based product information materials
- Describe how one Medical Communications department has partnered with sales training for the development and review process of learning systems and/or backgrounders
- Describe how one Medical Communications department has partnered with sales training to evaluate and implement innovative programs aimed at delivering high-quality and cost-effective training.

#### **Steve Wells**

Senior Director, Commercial Learning and Development, Pfizer Inc

#### Kiumars Q. Vadiei, PhD, RPh, FCP

Senior Director, Global Medical Communications, Clinical Development and Medical Affairs, Shire Pharmaceuticals, Inc.

#### Seema G. Patel, PharmD

Associate Director, Medical Communications, Ortho-McNeil Janssen Scientific Affairs, LLC 2:30-3:00 PM REFRESHMENT BREAK

3:00-4:30 PM PLENARY SESSION 7

# Leading with Passion; Leading through Values Chairperson

#### CHAIRPERSON

#### Alicia Alexander Cadogan, PharmD

A great leader once said, "People don't care how much you know until they know how much you care." How is it that some leaders are able to inspire and others cannot? How do leaders recognize dedication and commitment in their employees, and how does that affect working relationships, performance, development, and retention? Whether you are a leader or an individual contributor, your attitude and professional value system have a significant impact on how your team functions and how individuals achieve. In this session, we will learn more about the principles that guide the concept of leading by example, and why this is a critical success factor. We will then hear examples of how the principles of success have shaped or influenced the careers of both leaders and individual contributors in Medical Communications. Lastly, we will share simple steps that each person can perform to help them lead by example every day.

#### **Learning Objectives**

Upon completion of this session, participants will be able to do the following:

- Identify the opportunities that each person has to be a leader each day
- Find the passion in their work, and communicate that passion to those with whom they interact
- Focus on values in leadership (integrity, courage, and empathy)
- Relate to the examples shared and apply these examples to their own circumstances

#### Presenter

#### **Steve Stefano**

Author, *Passion and I.C.E.;* Former Vice President, GlaxoSmithKline; Member of Board of Directors, Valiant Pharmaceuticals

#### **Panelists**

#### Tiziana Fox, PharmD

Senior Director, Medical Communications Ortho-McNeill Janssen Scientific Affairs, LLC

#### Lvnn Bass. PharmD

Regional Medical Liaison II, Amgen, Inc.

#### Nicole Corder, RPh, MBA

Director, The Lilly Answers Center, Lilly USA, LLC

#### 4:30-6:30 PM RECEPTION/RESIDENT POSTER SESSION

#### **CHAIRPERSON**

#### Lesley Fierro, PharmD, MS

Take some time to network with your peers while you view posters prepared by Medical Communications residents and fellows. This is a great opportunity to discuss topics of interest with colleagues and view some of the interesting work being done by up-and-coming industry residents and fellows.

### DAY 4 | WEDNESDAY, MARCH 17, 2010

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

8:00-10:00 AM PLENARY SESSION 8

**Regulatory Review** 

CHAIRPERSON

#### Timothy E. Poe, PharmD

Director, Product Information and Patient Services, GSK Response Center

This session will provide the latest information on activities of office-based and field-based Medical Communications personnel that may have important regulatory implications.

Topics will include provision of medical product information in a variety of situations and audiences as well as updates on recent activities by DDMAC and the Office of Inspector General (OIG). Areas of interest around dissemination of scientific literature, medical education, and other recent activities of the FDA pertinent to Medical Communications will be discussed.

This will be an interactive session with opportunity for discussion and questions from the audience.

#### Learning Objectives

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

- Discuss recent regulatory actions and the impact on Medical Communications practices
- Discuss how actions of other government agencies affect the pharmaceutical industry and Medical Communications practices

#### Lucy Rose, MBA, PA-C

President, Lucy Rose and Associates, LLC

10:00-10:15 AM REFRESHMENT BREAK

#### 10:15-11:45 AM PLENARY SESSION 9

# Medical Communications Experience with Risk Evaluation and Mitigation Strategies (REMS)

CHAIRPERSON

#### Ramineh Zoka, PharmD, MS

Senior Director, Clinical Science Liaison, Medical Affairs, Centocor Ortho Biotech Services, LLC

Risk Evaluation and Mitigation Strategies (REMS) are becoming part of the fabric of pharmaceutical companies to ensure the safe use of their marketed medications. Medical Communications staff plays a critical role in shaping and implementation of this process. During this session, an overview of the key components of REMS will be provided, and examples of how Medical Communications staff have contributed to the successful planning and implementation of REMS programs will be discussed.

#### Peter E. Callegari, MD

Vice President, Medical Group, Immunology Medical Affairs Centocor Ortho Biotech Services, LLC

#### Annette Stemhagen, DrPH, FISPE

Senior Vice President, Safety, Epidemiology, Registries and Risk Management, United BioSource Corporation

#### Learning Objectives

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

- To provide an overview on REMS including all its potential components: the Medication Guide, the Communication Plan, and Elements to Assure Safe Use
- To describe how Medical Communications staff, including medical information, the call center and field medical liaisons may be impacted by REMS, and how they may be involved in pre-REMS approval and its implementation

#### 11:45 AM-12:00 PM CLOSING REMARKS

#### J. Lynn Bass, PharmD

Senior Regional Medical Liaison, Scientific Affairs, Amgen Inc.

12:00 PM WORKSHOP ADJOURNED

# **REGISTRATION FORM**Register online or fax this page to +1.215.442.6199

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#### **CANCELLATION POLICY: On or before MARCH 8, 2010**

Administrative fee that will be withheld from refund amount:

Member or Nonmember = \$200

After

FEB. 20, 2010

US \$1510 🗖

FEB. 20, 2010

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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.

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