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18th Annual Conference on Medical Communications

Medical Information, Medical Liaisons, Contact Centers



March 4–7, 2007

Paradise Point Resort & Spa, San Diego, CA, USA

PROGRAM CHAIRS

MONICA KWARCINSKI, PHARM D

Senior Director, Medical Services, Purdue Pharma LP

REBECCA A. VERMEULEN, RPH

Director, Medical Information and Communication Services, US Medical Division, Eli Lilly and Company

PROGRAM COMMITTEE

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CAROLYN SEYSS, PHARM D

Director, Medical Information, Bristol-Myers Squibb

RAMINEH ZOKA, PHARM D, MS

Senior Director, Clinical Scientists, Medical Affairs Department, Centocor, Inc.

Expanded this year!

16 exciting, interactive breakout sessions – on topics essential to medical information, medical liaisons, and contact centers

CONFERENCE HIGHLIGHTS

- ▶ Sunday, March 4
 - Core Curriculum – in-depth discussions, case studies, roundtable discussions
 - Welcome Reception – casual atmosphere for meeting and networking with conference attendees
- ▶ Monday, March 5
 - Our changing healthcare landscape and implications for Medical Communications
 - Establishing the value proposition of pharmaceuticals
 - Breakout sessions on topics pertinent to field- and headquarters-based medical information practice
 - Evening reception featuring Resident Poster Presentations
- ▶ Tuesday, March 6
 - Application of Knowledge Management in Medical Communications
 - Podium and Poster Pearls
 - Recurring breakout sessions regarding medical writing, corporate coordination of external communications, medical information support of investigational and legacy products, customer service skills, and more
 - Sessions relevant for field-based medical personnel on identifying thought leaders and scientific hot topics
- ▶ Wednesday, March 7
 - Two important sessions related to regulatory and legal hot topics in Medical Communications
- ▶ *All speaker presentations will be available on CD-ROM for meeting attendees.*

GENERAL GOALS

- 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 changing healthcare landscape and implications for Medical Communications
- Describe establishing the value proposition of pharmaceutical products beyond safety and efficacy
- Review the importance of Knowledge Management in optimizing the practice of Medical Communications
- Communicate best practices through podium and poster pearls
- Identify and discuss legal and regulatory issues that influence medical communications groups

WHO SHOULD ATTEND Medical liaisons, as well as professionals working in:

- | | | |
|--------------------------|-----------------------------------|--------------------------------------|
| ▶ Medical communications | ▶ Medical call center environment | ▶ Industry, academia, and government |
| ▶ Medical information | | |

THIS PROGRAM WAS DEVELOPED BY THE MEDICAL COMMUNICATIONS SPECIAL INTEREST AREA COMMUNITY



Tabletop Exhibit Opportunity

Contact Erin Gilliland, Exhibits Associate
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VISIT WWW.DIAHOME.ORG FOR A COMPLETE SCHEDULE OF EVENTS!

DIA, 800 Enterprise Road, Suite 200, Horsham, PA 19044, USA tel: +1-215-442-6100 fax: +1-215-442-6199 email: dia@diahome.org



The Drug Information Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants may earn up to 21.5 contact hours or 2.15 continuing education units (CEU's) for completing the program and the Core Curriculum tutorial.

Nursing

The Drug Information Association will offer nursing credits for this program in collaboration with Corexcel. Corexcel is accredited as a provider of continuing education in nursing by the American Nurses Credentialing Center's Commission on Accreditation. Participants may earn up to 21 nursing contact hours for participating in the program and the Core Curriculum tutorial.



The Drug Information Association (DIA) has been reviewed and approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 1620 I Street, NW, Suite 615, Washington, DC 20006. The DIA has awarded up to 2.1 continuing education units (CEUs) to participants who successfully complete the program and the Core Curriculum tutorial.

Continuing Education Credit Allocation

Core Curriculum Tutorial: 286-000-07-006-L04; 6.25 contact hours (.625 CEUs); 6 nursing contact hours; .6 IACET CEUs

Conference: 286-000-07-005-L04; 15.25 contact hours (1.525 CEUs); 15 nursing contact hours; 1.5 IACET CEUs

To receive a statement of credit, please visit www.diahome.org. Detailed instructions on how to complete your credit request and download your certificate will be provided onsite.

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.

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

► Core Curriculum Tutorial

- Demonstrate core competencies in industry-based drug information in both headquarters-based and field-based practice environments
- Identify partnering opportunities for headquarter-based and field-based medical communications professionals
- Refine and enhance skills for searching the medical literature
- Describe the regulatory environment that influences the practice of medical communications

► Session 1

- Explain the impact of external trends on medical communications
- Discuss how the use of healthcare information technology can positively influence the image of our industry

► Session 2

- Discuss the new evidence requirements of government and commercial payors in assessing the value of medications
- Create a list of strategic imperatives that will allow the pharmaceutical industry to generate evidence that will support the access requirements of payors and demonstrate appropriate use in the postmarketing phase

► Session 3 – Breakout Sessions

Learning objectives are included in the agenda.

► Session 4 – Breakout Sessions

Learning objectives are included in the agenda.

► Session 5

- Define the elements of knowledge management
- Identify challenges to successful knowledge management initiatives

► Session 6 – Podium Pearls

► Session 7A – Breakout Sessions: Part 1

Learning objectives are included in the agenda.

► Session 7B – Breakout Sessions: Part 2

Learning objectives are included in the agenda.

► Session 8

- Discuss recent developments in the regulatory and legal arena
- Describe recent changes in legislation that affect the practice of medical communications
- Explain recent enforcement actions and how that affects the medical communications department
- Formulate recommendations to minimize risk

Statements made by speakers are their own opinion and not necessarily that of the organization they represent, or that of the Drug Information Association.

Speakers and agenda are subject to change without notice.

Recording of information, in any type of media, is prohibited at all DIA events without prior written consent from DIA.

DRUG INFORMATION ASSOCIATION <http://www.diahome.org>

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SUNDAY • MARCH 4

7:00-8:00 AM

CORE CURRICULUM REGISTRATION AND CONTINENTAL BREAKFAST FOR CONFIRMED CORE CURRICULUM ATTENDEES

8:00-8:30

WELCOME AND INTRODUCTIONS

FACULTY

Alicia Alexander Cadogan, PharmD (*Core Curriculum Chair*)
Director, Medical Communications, Wyeth Pharmaceuticals

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

Chris Dadas, PharmD
Director, Medical Affairs, Allergan

Stacey Fung, PharmD
Senior Scientist, Medical Communications, Genentech, Inc.

Kristen Mack, PharmD
Senior Medical Science Liaison, Clinical Affairs, Ortho Biotech, L.L.C.

Leena Jindia, MS, PharmD
Associate Director, Medical Information,
Ortho Biotech Clinical Affairs, LLS

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 for the audience to begin seeing similarities and differences in the practice of medical communications across the industry.

8:30-9:15 AM

CORE CURRICULUM SESSION 1

AN INTRODUCTION TO THE REGULATORY ENVIRONMENT

FACULTY

Danielle Iobbi Ziernicki, PharmD
Associate Director, Global Regulatory Policy and Intelligence,
Johnson & Johnson Pharmaceutical Research and Development

Attendees will build on their existing knowledge regarding the regulatory environment that influences medical communications practice. An overview of the pharmaceutical industry and DDMAC regulations will be presented along with the rationale for many of the routines common in our practice environment.

9:15-10:00 AM

CORE CURRICULUM SESSION 2

CURRENT PRACTICES IN MEDICAL COMMUNICATIONS

FACULTY

Alicia Alexander Cadogan, PharmD
Director, Medical Communications, Wyeth Pharmaceuticals

Kristen Mack, PharmD
Senior Medical Science Liaison, Clinical Affairs, Ortho Biotech, L.L.C.

In this interactive session, we will discuss the similarities and differences in the roles and responsibilities of medical communications professionals based at headquarters and those that are field-based. We will explore some of the routine activities of both groups, and understand the partnering opportunities that may exist between the two groups.

10:00-10:30 AM

REFRESHMENT BREAK

10:30-11:15 AM

CORE CURRICULUM SESSION 3

MEDICAL COMMUNICATIONS FROM THE PERSPECTIVE OF OUR CUSTOMERS AND PARTNERS

FACULTY

All Core Curriculum Faculty Members

Medical communications is a service-oriented role in which we typically serve two distinct audiences: external customers (health-care providers) and internal partners (commercial, regulatory, safety, sales, etc). Through case scenarios, and with audience participation, we will identify the types of services that are requested of us, and how our services benefit our external customers and internal partners.

11:15 AM-12:00 PM

CORE CURRICULUM SESSION 4

TRICKS OF ADVANCED LITERATURE SEARCHING

FACULTY

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

Literature searching is a vital skill for everyone in medical communications. But how do we know we are using technology to the fullest capacity? This interactive session will demonstrate "slick tricks of the trade" for field-based and headquarters-based searchers of the medical literature. Each participant will walk away with new, tangible skills that they can apply immediately upon return to their daily responsibilities.

12:00-1:00 PM

NETWORKING LUNCHEON FOR CONFIRMED CORE CURRICULUM ATTENDEES

1:00-4:30 PM

CORE CURRICULUM CONCURRENT AFTERNOON SESSIONS

In the afternoon, there will be two concurrent Core Curriculum sessions. Session A will focus on issues specific to headquarters-based medical communications, and Session B will focus on issues specific to field-based medical communications. Participants will select one session for the afternoon, based on their personal interest. (Note that session selection is not predetermined by the participant's current role).

CORE CURRICULUM CONCURRENT SESSION A: HEADQUARTERS-BASED MEDICAL COMMUNICATIONS

FACULTY

Alicia Alexander Cadogan, PharmD
Director, Medical Communications, Wyeth Pharmaceuticals

Stacey Fung, PharmD
Senior Scientist, Medical Communications, Genentech, Inc.

Leena Jindia, MS, PharmD
Associate Director, Medical Information,
Ortho Biotech Clinical Affairs, LLS

This session will discuss the common responsibilities of headquarters-based medical communications staff. Topics will include contact centers, phone skills, formulating clinical replies, and formulary dossiers. Role playing and mock examples will be used to reinforce principles that emphasize the importance of our role to the industry and to the customers we serve. After a break, participants will be divided into smaller working groups. The faculty will present several real-life scenarios that represent challenges that are common to our roles. Time will be allotted for the participants of the working groups to discuss the scenarios. The groups will then craft their ideal responses to the situations, and share their responses with the larger group.

2:30-3:00 PM

REFRESHMENT BREAK

CORE CURRICULUM CONCURRENT SESSION B: FIELD-BASED MEDICAL COMMUNICATIONS

FACULTY

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

Chris Dadas, PharmD
Director, Medical Affairs, Allergan

Kristen Mack, PharmD
Senior Medical Science Liaison, Clinical Affairs, Ortho Biotech, L.L.C.

This session will be an interactive review of current practices for field-based medical communications groups (FBMG). Case studies of common scenarios affecting FBMG will be used to emphasize important topics. For each scenario, the topic will be introduced with a few slides, after which the audience will be engaged in a group discussion.

4:30 PM

CORE CURRICULUM ADJOURNED

5:00-6:30 PM

WELCOME WINE AND CHEESE RECEPTION SPONSORED BY THE MEDICAL COMMUNICATIONS SPECIAL INTEREST AREA COMMUNITY (ALL CONFERENCE REGISTRANTS ARE INVITED TO ATTEND)

MONDAY • MARCH 5

7:00-8:00 AM

REGISTRATION AND CONTINENTAL BREAKFAST

8:00-8:15 AM

WELCOME AND OPENING REMARKS

Monica Kwarcinski, PharmD

Senior Director, Medical Services,
Purdue Pharma LP

8:15-9:45 AM

SESSION 1

OUR CHANGING HEALTHCARE LANDSCAPE

CHAIRPERSON

Rebecca A. Vermeulen, RPh

Director, Medical Information and Communication Services,
US Medical Division, Eli Lilly and Company

Our healthcare landscape is changing drastically, in particular as it relates to evolving customer and patient needs. The intent of this discussion is to gain a better understanding of external trends that will impact medical communications and the future of our companies. Topics that will be discussed encompass the changing information needs of external customers including the growing influence of payers and patients, and the rapid growth and utilization of health information technology – importantly, how we can positively impact the image of our industry.

Christian Clymer

Senior Director, Affordability and Access, PhRMA

David Medvedeff, PharmD, MBA

President, Informed Decisions

John O'Brien, PharmD, MPH

President, Responsible Health

9:45-10:15 AM

REFRESHMENT BREAK

10:15-11:45 AM

SESSION 2

MAXIMIZING THE VALUE OF MEDICATIONS BEYOND DRUG COST: FROM GENERATION OF EVIDENCE FOR ACCESS DECIS- IONS TO APPROPRIATE USE IN THE POSTMARKETING PHASE

CHAIRPERSON

Ramineh Zoka, PharmD, MS

Senior Director, Clinical Scientists, Medical Affairs Department,
Centocor, Inc.

This session will review recent trends and activities directed at increasing the value of medications in the eyes of payors. Health plans, employers, and government payors will increasingly require medications to show value beyond evidence generated in randomized controlled clinical trials designed for regulatory purposes. The value proposition for payors will be discussed as well as imperatives to generate clinical and outcomes evidence that demonstrate the value of medications in health systems.

David Domann, MS, RPh

Senior Director, Healthcare Quality Management, Ortho-McNeil
Janssen Scientific Affairs, LLC

Sean Sullivan, PhD

Professor of Pharmacy, Public Health and Medicine, Director,
Pharmaceutical Outcomes Research and Policy Programs, University
of Washington

11:45 AM-1:15 PM

NETWORKING LUNCHEON

1:15-2:45 PM

SESSION 3 – BREAKOUTS

1:15-2:45 PM

BREAKOUT SESSION 3-1

CAREER DEVELOPMENT: ARE YOU DOING EVERYTHING YOU CAN?

CHAIRPERSONS

Natalie C. Gearhart, PharmD

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

Hetal V. Patel, PharmD

Clinical Scientist - MSL, Medical Affairs, Centocor, Inc.

Learning Objectives: *At the conclusion of this breakout session, participants should be able to describe current and future career trends and the healthcare landscape, and to identify important dynamics of the career management process. Participants will develop a "positioning" statement, identify existing skills, and create a plan to attain new skills aligned with their career aspirations.*

Career development. You hear about it everywhere – from human resources, from your manager, even from colleagues. But why do some individuals seem to do it so well – almost effortlessly – while many of us feel like we're not making headway? We'll take this opportunity to talk about current career trends and the healthcare landscape: what's new and how will it change in the future. We will discuss the "do's" and "don'ts" of career management, and why some people are just so good at it! Most importantly, we will challenge you to assess your existing skills, define your current and desired "positioning" statement, identify your next career move, and create an action plan to ensure you achieve that goal.

IMPLICATIONS OF CURRENT CAREER TRENDS

Natalie C. Gearhart, PharmD

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

WHOSE JOB IS IT ANYWAY?

Hetal V. Patel, PharmD

Clinical Scientist - MSL, Medical Affairs, Centocor, Inc.

1:15-2:45 PM

BREAKOUT SESSION 3-2

CONTROVERSIES IN STATISTICS: A CLOSER LOOK

CHAIRPERSON

Joseph P. Casey, RPh, MBA

Assistant Director, Medical Affairs Knowledge Resource Center,
TAP Pharmaceutical Products Inc.

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

- Explain why these techniques are considered "controversial"
- List the advantages and disadvantages of various debated statistical techniques
- State examples of clinical trials that have utilized these techniques

Statistics is more of an art form rather than a pure science. This becomes problematic when evaluating medical literature and making healthcare decisions that are based on results from certain debatable statistical techniques. The intent of this session is to delve into the details of some “controversial” areas of statistics used in medical research, such as meta-analysis, intent-to-treat analysis, and frequentist versus Bayesian statistical techniques.

CONTROVERSIES IN STATISTICS: A CLOSER LOOK

Timothy A. Candy, PharmD, MS

Clinical Affairs Manager, Baxter Healthcare Corporation

1:15-2:45 PM

BREAKOUT SESSION 3-3

CRISIS MANAGEMENT

CHAIRPERSONS

Timothy E. Poe, PharmD

Acting Head, GSK Response Center, GlaxoSmithKline

Nancy Hildebrand, RPh

Strategy Team Leader, The Lilly Answers Center, Eli Lilly and Company

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

- Explain what constitutes a crisis
- Describe crisis preparation before it happens
- Select effective crisis management team members. Who are the right players across any scenario?
- Describe testing of the crisis plan
- Discuss how to evaluate successes and developmental opportunities post-crisis

Handling a crisis in the contact center involves understanding potential crisis situations, pre-crisis planning, dealing with the actual events, and “post-mortem” evaluations. Crises may include drug-related issues, power outages, and other security issues. Pre-crisis planning may include a number of steps to evaluate capacity, technology, vendors, etc.

Prior to, and during a crisis, it is important to have a designated team formed that can evaluate and make decisions on how to handle the crisis. This team may need to work cross-functionally depending upon how broad the crisis is in its effect throughout the company. Afterwards the team will need to assess how the situation was handled and what could be done to improve preparedness and execution of the plan.

CRISIS MANAGEMENT: THE SECURITY PERSPECTIVE

Oliver O. Wainwright

Director of Security, Roche (Nutley, NJ)

CRISIS MANAGEMENT: CONTACT CENTER PERSPECTIVE

Nicole F. Corder, RPh, MBA

Operations Manager, The Lilly Answers Center, Eli Lilly and Company

CRISIS MANAGEMENT: OUTSOURCE CONTACT CENTER

PERSPECTIVE

Brian Hedrick

Director of Operations, Professional Contact Center, PPDI

1:15-2:45 PM

BREAKOUT SESSION 3-4

SUPERVISORS' ROUNDTABLE: CONTEMPORARY ISSUES IN MEDICAL COMMUNICATIONS MANAGEMENT

CHAIRPERSON

Jennifer L. Riggins, PharmD

Manager, Global Medical Communications, Capabilities Development, Eli Lilly and Company

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

- Identify tactics for recruiting and retaining top talent within our organizations
- Discuss benefits and constraints of implementing flexible work arrangements
- Propose creative ways to reward, recognize, and motivate medical communications personnel

The purpose of Supervisors' Roundtable is to exchange ideas and to gain insight and perspective on issues facing medical communications supervisors. Topics for the session include employee recruiting and retention, flexible work arrangements, and reward and recognition. This session was developed for supervisors of medical communications personnel. Please come prepared to share your experiences, ideas, and solutions with your industry peers. Attendance at this session will be limited to accommodate the roundtable discussion format.

2:45-3:15 PM

REFRESHMENT BREAK

3:15-4:45 PM

SESSION 4 – BREAKOUTS

3:15-4:45 PM

BREAKOUT SESSION 4-1

CAREERS AND THE IMPETUS OF A FELLOWSHIP/RESIDENCY

CHAIRPERSON

Heather Schiappacasse, PharmD, MBA

Senior Manager, Medical Information Services, sanofi-aventis

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

- Recognize the benefits of hosting a post-doctoral training program
- Identify the benefits of a post-doctoral training experience for program participants

Post-doctoral training programs in the pharmaceutical industry have substantially grown in number over the past several years. This may be due in part to the increased utilization of post-doctoral professionals within the industry as the recognition of their value-add within an organization is greater than ever before. Hence, there are a myriad of benefits for a post-doctoral fellow/resident throughout, and upon completion of, a training program. During this session, we will briefly touch upon the importance of post-doctoral training programs to the host company/institution and then focus on the benefit of such an experience to the program participant. Through a roundtable discussion, past fellows/residents will share their previous experiences and detail aspects of their programs that enabled them to gain positions of strategic importance within the pharmaceutical industry.

NAVIGATING INTO THE MEDICAL SCIENCE LIAISON ROLE

Nana Wiafe, PharmD

Medical Science Liaison, Abbott Renal Care

UNDERSTANDING THE *PHARMACO* BEFORE THE *ECONOMICS*

Kellie Meyer, PharmD, MPH

Associate Director, Xcenda

POSTDOCTORAL INDUSTRY TRAINING: A VIEW FROM BOTH SIDES

Robert Kowalski, PharmD

Vice President, Global Regulatory Affairs, Schering-Plough

3:15-4:45 PM

BREAKOUT SESSION 4-2

PROMOTIONAL REVIEW: THE ROLE OF MEDICAL COMMUNICATIONS AND REGULATORY AFFAIRS

CHAIRPERSON

Kevin P. Tynan, PharmD, MBA

Senior Director, Medical Information, Centocor, Inc.

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

- Explain the critical and different roles that medical communications and regulatory affairs play in the promotional review process
- Identify approaches for the review of promotional material
- Describe how participation in promotional review can provide significant opportunity to expand responsibilities

Promotional review is a critical component to successful marketing of pharmaceuticals. Medical communications/information can play a major role in ensuring scientific accuracy of the content using appropriate evidence. The promotional review process will be described along with key considerations for conducting an effective review. In addition, there will be discussion on new opportunities that can arise from the interactions occurring through promotional review. While medical communications focuses on scientific evidence, regulatory affairs places emphasis on compliance with laws and regulations imposed by regulatory authorities. Examples of promotional pieces with potential compliance implications will be discussed.

PROMOTIONAL REVIEW: AN EVIDENCE-BASED APPROACH

Michael Cuozzo, PharmD

Senior Manager, Medical Information, Centocor, Inc.

THE MEDICAL ROLE IN PROMOTIONAL REVIEW: BEYOND CHECKING THE FACTS

Kristin R. Dragotta, PharmD

Manager, Medical Communications, Psychiatry, Ortho-McNeil Janssen Scientific Affairs, LLC

PHARMACEUTICAL ADVERTISING AND PROMOTION: REGULATORY CONSIDERATIONS

Sandra A. Kerr, RPh

Director, Regulatory Advertising and Promotion, Johnson & Johnson Pharmaceutical Research and Development, LLC

3:15-4:45 PM

BREAKOUT SESSION 4-3

GLOBALIZATION OF MEDICAL COMMUNICATIONS

CHAIRPERSONS

Thomas Gesell, PharmD

Global Head, Medical Information and Communication, Novartis Pharmaceuticals Corporation

Debra Skarda, MS, RN

Director, Global Medical Information, Abbott Laboratories

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

- Explain the impact of the differing priorities among various corporate partners
- Anticipate obstacles and identify solutions to overcome communication challenges within their organizations
- Apply networking strategies to become more successful in product communications

The purpose of this breakout session is to gain insight, develop perspective, and formulate solutions to the challenges of managing medical communications globally. Topics for this breakout include:

1. Dealing with differing priorities and product focus between affiliates and global
2. Challenges and solutions to optimize medical communications worldwide
3. Networking to optimize staffing and resources by encouraging dialog and leveraging centers of excellence

This breakout session will utilize a workshop format where teams share experiences and develop ideas to improve the quality of global medical communications.

3:15-4:45 PM

BREAKOUT SESSION 4-4

GATHERING AND EFFECTIVELY COMMUNICATING COMPETITIVE INTELLIGENCE

CHAIRPERSON

Christopher M. Marrone, PharmD

Medical Liaison Consultant, Eli Lilly and Company

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

- Recognize the importance of competitive intelligence
- Identify various competitive intelligence collection methods

Competitive intelligence can be defined as the collection, analysis, interpretation, and dissemination of publicly available information that has strategic importance.¹ The objective of competitive intelligence is to ethically and legally gather a wide range of information in a systematic way. Examples of competitive intelligence include: information that can provide a deeper understanding of a given therapeutic area, information on competitor products, and information on clinical plans. This session will provide an overview of competitive intelligence, with a focus on collection of intelligence from electronic and print resources, as well as primary intelligence collection.

¹ Combs RE, Moorhead JD. *The Competitive Intelligence Handbook*. Lanham, MD: Scarecrow Press; 1993.

OVERVIEW OF COMPETITIVE INTELLIGENCE

Patrick Bryant, PharmD, FSCIP

Director, UMKC Drug Information Center,
Clinical Associate Professor, UMKC School of Pharmacy

PRINT/ELECTRONIC COMPETITIVE INTELLIGENCE

Bonnie Hohhof

Director of Competitive Intelligence Research and Information,
Society of Competitive Intelligence Professionals

CONFERENCE COMPETITIVE INTELLIGENCE

Paul Dishman, PhD

Associate Professor, Competitive Intelligence and Marketing
Business Management, Brigham Young University

4:45-6:15 PM

RESIDENT POSTERS AND NETWORKING RECEPTION

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.



TUESDAY • MARCH 6

7:00-8:00 AM

REGISTRATION AND CONTINENTAL BREAKFAST

8:00-9:30 AM

SESSION 5

KNOWLEDGE MANAGEMENT: OPTIMIZING THE PRACTICE OF MEDICAL COMMUNICATIONS

CHAIRPERSONS

Dominick Albano, PharmD, MBA

Assistant Vice President, Global Medical Communications,
Wyeth Pharmaceuticals

Carolyn Seyss, PharmD

Director, Medical Information, Bristol-Myers Squibb

This session is designed to describe the concept of knowledge management (KM) in the pharmaceutical industry, how it specifically applies to medical communications, and opportunities for medical communications professionals. The session will include an overview and history of KM and describe current initiatives within the industry around KM. Specific examples from the medical communications field including those involving MSL processes and headquarters-based processes will be provided.

KNOWLEDGE MANAGEMENT: THE PAST, PRESENT, AND FUTURE

Andrew Kusiak, PhD

Professor, University of Iowa

KM CASE STUDY: MEDICAL COMMUNICATIONS DATABASE

Kathleen C. Solotkin, MSN, RN

Associate Medical Information Consultant, US Medical Information and
Communication Services, Eli Lilly and Company

KNOWLEDGE: FROM MANAGING DEVELOPMENT TO BUILDING PARTNERSHIPS

Kiumars Vadieli, PhD, RPh, FCP

Senior Director, Professional Services and Medical Information,
Medical Affairs Department, Cephalon Inc.

KNOWLEDGE MANAGEMENT: WHAT'S IT GOOD FOR?

Jeffrey B. Spears, PharmD

Director, Scientific Affairs, Talecris Biotherapeutics

9:30-10:00 AM

REFRESHMENT BREAK

10:00-11:30 AM

SESSION 6

PODIUM PEARLS

CHAIRPERSONS

Lesley Fierro, PharmD, MS

Senior Director, Medical Information Services, sanofi-aventis

Stacey Fung, PharmD

Senior Scientist, Medical Communications, Genentech, Inc.

This session will offer a unique opportunity for selected medical communications practitioners (e.g., information specialists, medical liaisons, managers) to share their successes, challenges, and "pearls of wisdom" on various medical communication topics through podium presentations.

11:30 AM-12:30 PM

LUNCHEON AND POSTER PEARLS

12:30-2:00 PM

SESSION 7A – BREAKOUTS: Part 1

Breakout Sessions 7-1 through 7-4 will be
repeated from 2:30-4:00 pm.

12:30-2:00 PM

BREAKOUT SESSION 7-1A

MEDICAL WRITING

CHAIRPERSON

Lesley Fierro, PharmD, MS

Senior Director, Medical Information Services, sanofi-aventis

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

- Identify and correct grammatical errors within medical responses
- Refine sentence structure to improve the clarity of medical responses
- Identify plagiarism in literature summaries
- Explain basic statistical terms and interpretation of statistics within study design.

This session will discuss topics of interest in the medical writing arena. Basic elements of writing style as applied to medical responses will be reviewed. The interpretation of basic statistical principles and their application in medical writing will be discussed. This session will mix didactic learning as well as interactive participation to achieve the objectives. This session is intended for those new to the field of medical information writing and those that want to review basic writing and statistical principles.

REVIEW OF BASIC ELEMENTS OF WRITING STYLE FOR MEDICAL RESPONSES

Eleni Allen, PharmD

Team Leader, Writing and Editorial Services, PPD, Inc.

BASIC STATISTICAL INTERPRETATION OF THE MEDICAL LITERATURE

Lois Jessen, MS, PharmD

Director, Medical Information, Bristol-Myers Squibb

12:30-2:00 PM

BREAKOUT SESSION 7-2A

MEDICAL INFORMATION SUPPORT ON INVESTIGATIONAL AND LEGACY PRODUCTS

CHAIRPERSON

Stacey Fung, PharmD

Senior Scientist, Medical Communications, Genentech, Inc.

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

- Describe different options for providing medical information for investigational and legacy products
- Identify limitations of providing medical information for investigational and legacy products
- Explain potential regulatory and legal considerations in dissemination of information

Provision of medical information during a product's life cycle, especially post-approval, is the core role of medical communications departments. Inquiries for products pre-approval (investigational products) or at the end of a product's life cycle (legacy products) may be included. Responding to inquiries for investigational and legacy products requires a balancing of departmental resources and evaluation of available data. Legacy products are typically beyond patent expiry, no longer actively promoted by the commercial organization, may be of low priority, or become available as generic equivalents. Legacy products may have also been discontinued or supply chain issues may have occurred. However, clinicians and patients continue to value the product and data continue to be published. Information on investigational products may have an impact on the treatment of a disease. However, the benefit risk profile is not established. Additionally, there may be competitive, confidentiality, legal, and regulatory reasons for the data to be unavailable for disclosure. Since organizations receive requests for information on legacy and investigational products, the scope or extent of services may vary. This session will provide a general overview and examples of providing medical information, including medical meeting support, for investigational and legacy products.

KEY CONSIDERATIONS IN MEDICAL INFORMATION SUPPORT OF INVESTIGATIONAL PRODUCTS

Cheryl Finch, PharmD

Director, Medical Information, Amgen Inc.

WHAT CAN WE SAY ABOUT INVESTIGATIONAL PRODUCTS, FROM INSIDE AND OUTSIDE (FIELD)?

Susan Malecha, PharmD, MBA

Senior Director, Field-based Liaisons, InterMune

MEDICAL INFORMATION FOR LEGACY PRODUCTS

Julia Petses, PharmD

Manager, Medical Information Services, sanofi-aventis

12:30-2:00 PM

BREAKOUT SESSION 7-3A

CORPORATE COORDINATION OF EXTERNAL COMMUNICATION

CHAIRPERSONS

Mark Eggleston, PharmD, MBA

Director, Medical Communications, Medical Affairs-ID/Vaccines, MedImmune, Inc.

Susan McGaurn

Director, Medical Science Liaisons, Cephalon, Inc.

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

- Identify mechanisms by which medical information and intelligence groups coordinate messaging of external communications
- Identify key stakeholders involved in the preparation and coordination of external messaging
- Illustrate best practices utilized in the dissemination of corporate communications
- Discuss opportunities for field-based coordinated external communications
- Discuss obstacles relevant to field-based dissemination of corporate communications

The purpose of this breakout session is to gain insight and perspective regarding the preparation, coordination, and dissemination of external corporate communications. Issues to address on this topic include mechanisms for coordinating external messaging, identifying key stakeholders involved in external corporate communication, and discussing obstacles relevant to external communication. This session was developed for headquarters-based and field-based medical affairs/information personnel, who may benefit from participating by sharing common challenges, experiences, and best practices. Career-track managers may also benefit from the discussion of successes and lessons learned.

Robert Fuentes, PharmD

Senior Director, Medical Information, MedImmune

Kevin Gilliland

Associate Director, MSL, Scientific Communications, Cephalon

12:30-2:00 PM

BREAKOUT SESSION 7-3A

SUPERVISOR FORUM FOR FIELD-BASED MEDICAL PERSONNEL

CHAIRPERSON

S. Mabelle Manuel, PhD

Director, Field Medical Affairs, Daiichi Sankyo, Inc.

Learning Objectives: At the conclusion of this breakout session, participants should be able to describe best practices among field-based medical leaders on communicating the value of field-based medical groups within the organization, accountability for delivering results, and legal/regulatory considerations and best practices.

This interactive workshop is intended for director-level associates who are ultimately responsible for oversight of and providing strategic direction for their organization's field-based medical groups. This workshop will break into three groups to discuss key topics and share best practices. The three topics of discussion will be:

- (1) Communicating the value of field-based medical groups within the organization

- (2) Accountability for delivering results
- (3) Legal/regulatory considerations and best practices

Facilitators for each discussion topic are listed below. The facilitators will rotate between groups to lead the discussions and will then report the collective results back to the group.

FACILITATORS

John Ohman, PharmD

Director, Medical Services, Solvay Pharmaceuticals, Inc.

Kyle Kennedy

Executive Vice President, Scientific Oriented Solutions

12:30-2:00 PM

BREAKOUT SESSION 7-5A

CONTACT CENTER CHALLENGES

CHAIRPERSON

John Di Brango, RN, MEd

Oncology Brand Leader, The Information Center, AstraZeneca LP

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

- Identify key qualities in employees that transcend to a customer receiving quality service
- Identify specific marketing techniques/approaches that work in organizations
- Explain the added value they bring to the organization and key metrics that explain the contact center's mission within the organization

As customers demand better customer service, the pharmaceutical contact center continually tries to reinvent itself to meet these demands. As consumers of health care, we also want world-class customer service from our physicians, pharmacists, and health care facilities and others expect the same quality when they call a pharmaceutical company. The qualities that make up a professional contact center employee begin the process of delivering on the promise of world class customer service – we will explore what qualities to look for during the hiring process. The next step is marketing the contact center to the larger organization and we will provide some specific strategies on this approach. Contact centers have traditionally been thought of as “call centers” but with evolving technology we will look beyond the phone and explore the “value-add” that contact centers bring to the organization.

ADDING VALUE BEYOND THE PHONE

Grant Andes

Senior Director, Information Center and CRM Capabilities, AstraZeneca LP

CONTACT CENTER SOFT SKILLS: FROM HIRING TO RETENTION

Pam Cates, RPh

Director of Operations, Professional Contact Center, PPD, Inc.

MARKETING YOUR CONTACT CENTER WITHIN YOUR ORGANIZATION

Maureen L. Baldwin, RN, MSN

Manager, US Contact Center, Global Medical Communications, Wyeth Pharmaceuticals

12:30-2:00 PM

BREAKOUT SESSION 7-6A

BUILDING RELATIONSHIPS FOR THE FUTURE

CHAIRPERSON

Lynn Bass, PharmD

Senior Regional Medical Liaison, Amgen Inc.

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

- Describe tactics to identify and partner with opinion leaders within a therapeutic field
- Describe key characteristics of opinion leaders
- Discuss training techniques an RML uses to establish successful relationships with opinion leaders

Medical liaisons are field-based scientists who engage in daily interactions with opinion leaders from various therapeutic areas. They undergo a rigorous training period in which they delve deep into the science of the therapeutic area of interest. However, another critical portion of their role is the identification and development of opinion leaders. Opinion leaders are classified as the leaders (academic, research, and clinical) in their field. Our session will discuss how these opinion leaders are identified within the medical liaison organization. Furthermore, we will also explore the different techniques and strategies employed to provide the medical liaison with the skills necessary for building successful relationships with these clients. The session will specifically discuss relationship-building training a medical liaison might receive, which may include soft skill training and other training programs. Finally, we will discuss how to maintain relationships long-term.

BUILDING RELATIONSHIPS WITH KEY OPINION LEADERS: AN EXPERIENTIAL TRAINING APPROACH

Dixie Bibb, RPh, MBA

Medical Liaison Trainer, Eli Lilly and Company

TACTICS FOR IDENTIFYING AND PARTNERING WITH OPINION LEADERS: THE PERSPECTIVE OF A MEDICAL SCIENCE LIAISON

Jonathan Raap, PharmD

Senior Regional Medical Liaison, Amgen Inc.

200-2:30 PM

REFRESHMENT BREAK

2:30-4:00 PM

SESSION 7B – BREAKOUTS: Part 2

Breakout Sessions 7-1 through 7-4
(12:30-2:00 pm) will be repeated from
2:30-4:00 pm.

2:30-4:00 PM

BREAKOUT SESSIONS 7-1B THROUGH 7-4B

Descriptions of Breakout Sessions 7-1A through 7-4A, begin on page 7.

2:30-4:00 PM

BREAKOUT SESSION 7-5B

VALUE BEYOND RESPONDING TO MEDICAL INQUIRIES

CHAIRPERSON

Mary Sendi, PharmD

Senior Director, Global Medical Communications, Wyeth Pharmaceuticals

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

- Identify current and future roles/activities within medical information groups beyond responding to medical inquiries that may be of value to medical communication professionals, as well as to the pharmaceutical industry
- Identify challenges [systems issues] to successful implementation of such medical information initiatives

This session is designed to describe the concept of medical information leadership beyond responding to medical inquiries in the pharmaceutical industry, how it specifically applies to medical communications, and opportunities for headquarter-based medical communications professionals. The session will describe current initiatives within the industry addressing this topic, address potential future programs and implementation concerns, and propose next steps to build a case for change.

MANAGED MARKETS MEDICAL LEADERSHIP: MEDICAL COMMUNICATIONS ROLE IN ISSUES MANAGEMENT EFFORTS

Mary Sendi, PharmD

Senior Director, Global Medical Communications, Wyeth Pharmaceuticals

BRAND MEDICAL LEADERSHIP: MEDICAL COMMUNICATIONS ROLE IN BRAND STRATEGY AND TACTICS

Kiumars Q. Vadieli, PhD, RPh, FCP

Senior Director, Professional Services and Medical Information, Medical Affairs Department, Cephalon, Inc.

GLOBAL MEDICAL LEADERSHIP: MEDICAL COMMUNICATIONS ROLE IN ELEVATING AWARENESS OF SCIENTIFIC TOPICS IN THE ORGANIZATION

Leena Jindia, MS, PharmD

Associate Director, Medical Information, Critical Care, Ortho Biotech Clinical Affairs, LLC

2:30-4:00 PM

BREAKOUT SESSION 7-6B

IDENTIFYING SCIENTIFIC HOT TOPICS FOR FIELD-BASED MEDICAL PERSONNEL

CHAIRPERSON

Craig Klinger, RPh

Senior Medical Liaison Consultant, Eli Lilly and Company

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

- Describe and adapt methods for identifying and distributing key scientific "hot topic" information with field-based medical personnel
- Recognize how "hot topic" information is analyzed and reviewed by field-based medical personnel
- Explain how appropriately implementing these methods will help further scientific exchange with thought leaders
- Identify ways in which this information is maintained for future reference as enduring materials

Identifying appropriate abstracts and articles for field-based medical personnel is paramount to staying current in their assigned therapeutic area. This session will discuss ways in which information is identified, shared and reviewed among field-based medical and broader business partners. This session will also address how these methods of sharing information among a field-based team can help facilitate interactions with clients. Finally, this session will address ways in which this information can be maintained in a central repository for future reference.

A FIELD-BASED NEEDS ASSESSMENT: WHY YOU NEED TO ENGAGE YOUR MEDICAL COMMUNICATIONS PERSONNEL

Beth A. Price

Executive Vice President, Science Oriented Solutions

YING OR YANG: TWO APPROACHES FOR MONITORING THE SCIENTIFIC LITERATURE

Dixie Bibb, RPh, MBA

Medical Liaison Trainer, Eli Lilly and Company

KNOWLEDGE MANAGEMENT: HOW IT'S GOOD FOR FIELD-BASED MEDICAL: A CASE STUDY

Jeffrey B. Spears, PharmD

Director, Scientific Affairs, Talecris Biotherapeutics



WEDNESDAY • MARCH 7

7:00-8:00 AM

REGISTRATION AND CONTINENTAL BREAKFAST

8:00-9:30 AM

SESSION 8

LEGAL AND REGULATORY OVERVIEW

CHAIRPERSON

Timothy E. Poe, PharmD

Acting Head, GSK Response Center, GlaxoSmithKline

"Just when you thought it was safe..." As background for this session, a summary of OIG guidances, pharmaceutical code, state regulations, privacy and FDA issues will be discussed. New developments will be highlighted and specific examples and scenarios of how these regulations and enforcements affect us will be provided. This will be an interactive session with opportunity for discussion and questions from the audience.

DISCUSSANTS

Alan Minsk

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

Lucy Rose, MBA, PA-C

President, Lucy Rose and Associates

9:30-10:00 AM

REFRESHMENT BREAK

10:00-11:30 AM

SESSION 8 continued

LEGAL AND REGULATORY OVERVIEW

11:30-11:45 AM

CLOSING REMARKS

Rebecca A. Vermeulen, RPh

Director, Medical Information and Communication Services, US Medical Division, Eli Lilly and Company

11:45 AM

CONFERENCE ADJOURNED

DIA MEDICAL COMMUNICATIONS CERTIFICATE PROGRAM

Developed exclusively for DIA members by DIA members, each a recognized expert in a given subject, the *DIA Medical Communications Certificate Program* incorporates industry best practices into a systematic, comprehensive curriculum of nine modules addressing the key aspects of medical communications. DIA offers continuing medical and/or pharmacy education credits to participants who review each module and receive a passing score of 80% or better on each module exam. In addition, the *DIA Medical Communications Certificate* will be issued to all participants who successfully complete all nine eLearning modules.

Module One

LITERATURE EVALUATION

Being able to critically evaluate the published medical and scientific literature on a product is a core component of providing the best information possible.

KEY TOPICS

- Abstract, introduction, subjects and setting
- Study design, controls, and deviation
- Measuring results
- Managing and describing data
- Interpreting and presenting results
- Causality and generalizability

Module Two

LITERATURE SEARCHING

Discover how to search the medical literature and select the best resources to satisfy the questions posed by consumers or health care professionals.

KEY TOPICS

- Formulating the inquiry
- Basic search approaches
- Online databases and the Internet
- Sources of published references
- Concluding the inquiry
- Copyright considerations

Module Three

MEDICAL WRITING

When responding to specific drug questions, write relevant, reliable, and appropriate responses that comply with regulatory guidances.

KEY TOPICS

- Regulatory guidelines
- Writing tips and recommendations
- Anatomy of a complete written response
- Quality assurance – the editing/review process
- Case study – writing and editing an abstract

Module Four

DATABASE MANAGEMENT

Understanding the basics of design, development, management, and application of data management systems and databases is fundamental to doing the best job possible.

KEY TOPICS

- Using a database for information management
- Design of the database system
- Responding to a request for medical information
- Types of responses
- Additional functions of the database

Module Five

CRISIS MANAGEMENT

Armed with the basic principles of crisis management, identify the type of crisis you are facing and select approaches to effectively handle it.

KEY TOPICS

- Types of crisis situations
- Crisis impacts
- Recalls and withdrawals
- Actions in managing a crisis
- Contingency planning
- Telephone technology – “the basics”

Module Six

MEDICAL INQUIRIES

Learn how to field questions, retrieve information, and verbally communicate the right answers for patients and their care providers.

KEY TOPICS

- Receiving an inquiry
- Understanding the information needs
- Identifying and evaluating information
- Developing, reviewing, and delivering the response
- Handling specific issues
- Documenting and assessing responses

Module Seven

REGULATORY ISSUES

Understand what aspects of Medical Communications FDA regulates and how to avoid common compliance pitfalls.

KEY TOPICS

- FDA jurisdiction and regulatory requirements
- Advertising and promotional labeling
- Special types of advertising and promotional events
- Promotion versus scientific exchange; solicited versus unsolicited requests
- The on-label and off-label controversy
- Direct-to-consumer promotion

Module Eight

PRODUCT LABELING

Learn the structure and components of the prescription drug label and the medication guide along with the legal and regulatory requirements for compliance.

KEY TOPICS

- Historical perspective and background
- The Federal Register and Code of Federal Regulations
- Anatomy of the package insert
- The medication guide

Module Nine

STATISTICS

Apply statistical concepts when evaluating literature, identify strengths and weaknesses in study design, and detect potential bias in the presentation of statistics.

KEY TOPICS

- Statistical concepts
- Basic statistics
- Hypothesis testing
- Study designs

For more information and online registration, go to www.diahome.org and click on Educational Opportunities/Training Courses/eLearning.

TRAVEL AND HOTEL The most convenient airport is San Diego International Airport and attendees should make airline reservations as early as possible to ensure availability. The Paradise Point Resort & Spa is holding a block of rooms at the reduced rate below until February 12, 2007, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single \$165 Double \$165

Please contact the Paradise Point Resort & Spa by telephone at +1-800-344-2626 and mention the DIA event. The hotel is located at 1404 Vacation Road, San Diego, CA 92109, USA.

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This special offer applies to travel on domestic segments of all United Airlines, United Express, PED, and United code share flights (UA*, operated by US Airways, US Airways Express and Air Canada).

Participants with Disabilities: *DIA event facilities and overnight accommodations are accessible to persons with disabilities. Services will be made available to sensory-impaired persons attending the event if requested at least 15 days prior to event. Contact the DIA office to indicate your needs.*

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18th Annual Conference for MEDICAL COMMUNICATIONS

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Paradise Point Resort & Spa, San Diego, USA | MARCH 4-7, 2007 | Meeting ID #07006

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Registration Fees If DIA cannot verify your membership upon receipt of registration form, you will be charged the nonmember fee. Registration fee includes refreshment breaks, luncheons, and reception (if applicable), and will be accepted by mail, fax, or online.

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