MEDICAL COMMUNICATIONS & THE DISSEMINATION OF SCIENTIFIC INFORMATION

Strategies for Successful and Compliant Medical Communication and Publication Planning within the Pharmaceutical Industry through the Use of Social Media, Teamwork between Departments and Global Communication

DISTINGUISHED PRESENTERS INCLUDE:

Elizabeth Loder, MD, MPH
Clinical Epidemiology Editor
BMJ

Alan G. Minsk
Partner
ARNALL GOLDEN GREGORY LLP

Colin J. Zick
Partner
FOLEY HOAG LLP

Michael Kahn
Director of Publications
SHIRE PHARMACEUTICALS

Judith A. Waltz
Partner
FOLEY & LARDNER LLP

Paula Williams
Associate Director, Medical Education
TEVA (Formerly Cephalon, Inc)

Karen Roy, MSc, CCMEP
Independent Consultant,
Former Senior Director, Medical Education
TEVA (Formerly Cephalon, Inc)

Lisa DeTora, PhD
Medical Publication Lead,
Global Medical Affairs
NOVARTIS

Paul F. Cavanaugh, Jr., PhD
Director, Publication Planning
and Management
FORMERLY WITH SHIONOGI INC.

Elizabeth Tracey, MS
Director of Electronic Media
JOHNS HOPKINS MEDICINE

Jodie Sherman Gillon
Director, Publications Management Team
PFIZER

Josephine A. Sollano, DR.PH
Head, Global Medical Communications & HEOR
PFIZER

Fran Young, MSN
Publications Director
SHIRE

Todd Parker, PhD, CMPP
Scientific Director
MEDTHINK SCIOM

Leighton Chipperfield
Publishing Director
ELSEVIER

Annemarie Clegg, MD
Vice President, Strategic Services
COMPLETE HEALTHCARE
COMMUNICATIONS, INC.

Barry Lubarsky, PhD
Director of Medical Affairs
VERTEX PHARMACEUTICALS

Suzana Giffin, PharmD
Executive Director,
Medical Information Head
AMGEN

Leslie Citrome, MD, MPH
Clinical Professor of Psychiatry & Behavioral Sciences
NEW YORK MEDICAL COLLEGE,
VALHALLA, NY

Nancy Griffith, PhD
Director, Medical Communications,
Global Medical Affairs
BIOGEN IDEC

Lance Hill
CEO
WITHIN3

Gary Evoniuk, PhD
Director of Publication Practices,
Medical Communications Quality & Practices, Office of the Chief Medical Officer
GLAXOSMITHKLINE
RESEARCH & DEVELOPMENT

Jelena Veljkovic, PhD
Senior Manager, Publications & Analytics
MILLENIUM: THE TAKEDA ONCOLOGY COMPANY

Faith DiBiasi, M(ASCP), CMPP, MBA
Associate Director, Knowledge Management, Medical Affairs
HUMAN GENOME SCIENCES, INC.

Renu Juneja, PhD
Senior Director of Strategic Scientific Communications
NOVO NORDISK

Conference Sponsors:

CHC GROUP

MedThink SciCom

KANTAR MEDIA

Within3

Alpha BioCom

Precision Integrity Passion

Media Partners:
DAY ONE / MONDAY, JANUARY 30 / MED COMMUNICATIONS & DISSEMINATION OF SCIENTIFIC INFORMATION

7:30 CONFERENCE REGISTRATION & CONTINENTAL BREAKFAST
8:20 OPENING REMARKS & CONFERENCE WELCOME

8:30 UNDERSTANDING THE SUNSHINE ACT AND KEY LEGISLATION AS IT IMPACTS MEDICAL COMMUNICATIONS
Compliance is a key concern for executives within every department of a pharmaceutical company, particularly as new legislation is passed and healthcare becomes an increasingly global industry. Medical affairs and communications departments are no exception to this rule as pharmaceutical companies pursue transparency and compliance in an era of increased regulatory scrutiny, healthcare reform, and the Sunshine Act. As legislation is passed that affects publications and information dissemination, medical communications departments must adapt to new and changing guidelines, as well as develop procedures for monitoring compliance.

- Examination of recent and pending legislation
- Strategies for ensuring ethical compliance
- Understanding Implications of the Physician Payment Sunshine Act

Colin J. Zick, Partner
FOLEY HOAG LLP

9:20 EVALUATING THE VITAL ROLE OF MEDICAL COMMUNICATIONS WITHIN RISK EVALUATION AND MITIGATION STRATEGIES
Risk Evaluation and Mitigation Strategies (REMS) have moved to the forefront of pharmaceutical priorities as they gain increasing importance in product commercialization. For this reason, medical affairs departments have become a key component of the process, and have begun working with commercial, safety, and regulatory teams to support REMS programs. Medical communications must maintain an active role in both the development and implementation of REMS programs while effectively communicating strategies for all stakeholders.

- Overview of key components of REMS and recent updates
- Role of Medical Communications within the development of REMS
- Case History in support of REMS implementation
- REMS impact on the effective communication of risks & benefits to all stakeholders

Karen Roy, MSc, CCMEP, Independent Consultant, Former Senior Director, Medical Education
TEVA (Formerly Cephalon, Inc)
Paula Williams, Associate Director, Medical Education
TEVA (Formerly Cephalon, Inc)

10:10 COFFEE & NETWORKING BREAK

10:30 LEGAL ISSUES TO CONSIDER WHEN DISSEMINATING MEDICAL COMMUNICATIONS
Particularly in the current regulatory environment, hospitals and physicians are wary of interacting with pharmaceutical companies and their representatives. Legality concerns abound throughout the dissemination and publication of medical communications within the pharmaceutical industry. However, by examining common pitfalls and concerns, such as publication of off-label data, balance between presentation of risks and benefits and scientific validation, promotion issues, pharmaceutical companies may reduce their legal risk while maximizing communication effectiveness.

- Compliant use of MSLs
- Recognizing & overcoming common legal hurdles surrounding dissemination
- Legal considerations surrounding the utilization of MSLs in information dissemination
- Strategies and tips for reducing legal risk

Alan G. Minsk, Partner
ARNALL GOLDEN GREGORY LLP

11:20 PANEL DISCUSSION: THE MEDICAL WRITER DEBATE: ACCEPTABLE USE VS. GHOST WRITING
The utilization of medical writers in the authorship of clinical evidence and studies has recently become a hot button issue throughout the pharmaceutical industry due to the stigma and mistrust that often surrounds the title and job function. While many companies and associations praise and legitimize the use of professional medical writers, others believe they are simply “ghost writers” who contribute to pharmaceutical agendas but are not listed or mentioned on reports. Through open and frank dialogue, this distinguished panel of experts will delve into and explore both sides of the argument as well as discuss best practices for working with medical writers while remaining compliant.

Todd Parker, MEDTHINK SCICOM
Lisa DeTora, PhD, NOVARTIS
Gary Evinuk, GLAXOSMITHKLINE
Leighton Rippenfield, ELSEVIER
Michael Kahn, SHIRE PHARMACEUTICALS

12:10 LUNCHEON FOR SPEAKERS, SPONSORS & ATTENDEES

1:30 KEY INVOLVEMENT OF MEDICAL COMMUNICATIONS WITHIN CIAs
Daunted by heightened examination and surveillance by the Office of Inspector General (OIG), pharmaceutical companies have seen a rise in the implementation of Corporate Integrity Agreements (CIAs). These restrictive agreements, which typically last for five years, are imposed after investigations regarding fraudulent behavior or misconduct, and are designed to ensure that these improprieties are not repeated. Medical affairs and communications departments frequently assume an active role as pharmaceutical companies aim to avoid and/or comply with CIAs.

- Overview of CIAs and recent trends
- Compliance with common OIG requirements
- The relationship of medical communications within CIA compliance

Judith A. Waitz, Partner
FOLEY & LARDNER LLP

2:20 CASE STUDY: DEVELOPING A COHESIVE MEDICAL COMMUNICATIONS & PUBLICATION PLANNING ENVIRONMENT
The relationship between medical communications, publications planning, and research departments is undoubtedly an important one, and teamwork between the two is paramount. As pharmaceutical companies continually strive towards transparency and compliance, they must constantly consider the publication of clinical evidence in a practical, appropriate and compelling manner. In order to effectively convey scientific information, medical communications, publication planning executives, and other key stakeholders must work together in the development and implementation of action plans.

- The importance of teamwork between departments
- Targeting appropriate vehicles for publication
- Engaging effective stakeholders

Jelena Veljkovic, Ph.D., Senior Manager, Publications and Analytics
MILLENIUM: THE TAKEDA ONCOLOGY COMPANY

3:10 COFFEE & NETWORKING BREAK

3:40 NEW STRATEGIES FOR COMMUNICATION AND COLLABORATION IN A CHANGING WORLD
At the essence of any medical communications plan is the ability to communicate seamlessly, quickly, and collaboratively between all constituents. The challenges of sharing current and accurate information with multiple stakeholders spread across the globe can be daunting. Embracing the opportunities new technology platforms offer the pharmaceutical industry, this discussion focuses on how to effectively implement an online community program to:

- Improve access to vital information, 24/7
- Foster dialogue about key issues between diverse audiences
- Increase transparency in a regulatory-compliant environment

Lance Hill, CEO
WITHIN3

4:20 A MEDICAL JOURNAL PERSPECTIVE ON TRANSPARENCY AND PUBLICATION OF SCIENTIFIC INFORMATION
The issue of transparency has unquestionably gained recent attention throughout the pharmaceutical industry as regulatory changes and scrutiny abound. In the interest of pursuing transience, the publication of clinical data and evidence within medical journals is consequential, yet it is not without hurdles. Such difficulties as publishing in at-capacity journals, authorship concerns and following varying guidelines are just a few issues that may arise and cause confusion. By exploring the medical journal perspective, pharmaceutical companies may better understand how to overcome these challenges while developing lasting relationships, remaining transparent and striving towards medical communication goals.

Elizabeth Loder, MD, MPH, Clinical Epidemiology Editor
BMJ

5:10 DAY ONE CONFERENCE CONCLUSION
8:00 CONFERENCE REGISTRATION & CONTINENTAL BREAKFAST

8:20 CHAIRPERSON’S OPENING REMARKS

8:30 METHODS FOR EFFECTIVELY STREAMLINING INTERNAL COMMUNICATION AND SCIENTIFIC DATA

The ability to access current and accurate medical information is important for executives across functions and departments within a pharmaceutical company. This is particularly important for MSL's and executives in the field who often must remotely obtain immediate data in order to answer physician questions and appropriately represent medical information and products. By taking steps to streamline internal medical communications, pharmaceutical companies may share data and information quickly and effectively both globally and remotely.

- Keeping data and information up to date and unbiased
- Methods for streamlining internal communication
- Useful technology for internal access of medical information

Josephine A. Sollano, DR.PH, Head, Global Medical Communications & Health Economics and Outcomes Research

PFIZER

9:20 PUBLISHING OF SCIENTIFIC INFORMATION AND PROVISION OF MEDICAL INFORMATION IN THE EMERGING MARKETS: OPPORTUNITIES AND CHALLENGES

Creating an international presence is undoubtedly an important consideration for pharmaceutical companies of every size, and in doing so, companies have begun looking beyond the typical markets to discover new opportunities. Emerging markets, such as the BRIC countries, have been a focal point for pharma companies in recent years as they present an important opportunity to launch products that meet unmet medical needs for patients around the world. As pharma companies continue to explore those up-and-coming markets, communicating and publishing medical information within them is an important concern on the path to successful market access.

- Overview of BRIC countries and other key markets
- Identifying key differences between audiences within emerging markets
- Varying regulations across borders
- Best practices for publishing scientific information within emerging markets

Suzana Giffin PharmD, Executive Director Medical Information Head

AMGEN

Fran Young, MSN, Publications Director

SHIRE

10:10 COFFEE & NETWORKING BREAK

10:30 MANAGING NEEDS & EXPECTATIONS: PERSPECTIVE FROM THE VIEWPOINTS OF THE EDITOR, AUTHOR, REVIEWER & READER

A successful publication strategy involves efforts to satisfy the needs and expectations of several different players involved while remaining consistent with ICME and GPP2 guidelines. Certain aspects of the publication process have not changed, such as finding the “right” journal and the appropriate steps when revising and responding to reviewers. Editors continue to seek papers that are likely to generate citations. Reviewers continue to be difficult to find. The biggest paradigm shift has been the ease of dissemination of published papers in electronic format and the advent of open-access journals. Push technology has allowed the “paper to come to the reader,” supplementing information the reader has chosen to search for on their own.

- Overview of Publisher/Editor requirements
- Challenges faced by authors, editors & reviewers in the publication process
- Medical Publishing Insights & Practices Initiative’s Author’s Submission Toolkit
- Changes in how readers access information & how it affects publication planning

Leslie Citrome, MD, MPH, Clinical Prof. of Psychiatry & Behavioral Sciences

NEW YORK MEDICAL COLLEGE, VALHALLA, NY

11:20 OVERCOMING ETHICAL AND COMPLIANCE CONCERNS SURROUNDING PUBLICATION AND AUTHORSHIP

There is no doubt that publication planning is a paramount aspect in the dissemination of medical information, however it also comes with its own set of hurdles, particularly in the current environment of increased scrutiny. Placing a greater emphasis on ethics and compliance has become the standard across industry due to recent legislation and increased attention surrounding these topics. Publication practices have followed this lead and placed a heightened priority on transparency. Understanding and complying with publishing guidelines and practices on a national and global basis is a key concern for pharma executives within companies of all sizes.

- Overview GPP2 and ICME guidelines & key global compliance concerns
- Compliance issues surrounding working with key opinion leaders & authors
- Ethical concerns surrounding publication planning and authorship

Jodie Sherman Gillon, PhD

PFIZER

Barry Lubarsky, PhD

VERTEX PHARMACEUTICALS

Jelena Veljikovic, MILLENNIUM: THE TAKEDA ONCOLOGY COMPANY

Nancy Griffith, PhD

BIOGEN IDEC

Leighton Chipperfield, ELSEVIER

Annemarie Clegg, MD

COMPLETE HEALTHCARE COMMUNICATIONS, INC.

12:10 LUNCHEON FOR SPEAKERS, SPONSORS & ATTENDEES

1:10 EMPOWERED PATIENTS & COMMUNICATING SCIENTIFIC INFORMATION THROUGH THE USE OF TECHNOLOGY & SOCIAL MEDIA

Communicating medical information to consumers has become an increasingly important concern for pharmaceutical companies, particularly as consumers evolve and become more empowered. As a consequence, companies have placed a heightened emphasis on communication, which becomes a particularly important concern across continents. As medical information is shared on a worldwide basis, pharmaceutical companies must quickly learn and adapt in order to maintain a competitive edge, remain compliant and develop effective procedures. For this reason, individuals and companies often have established various strategies and procedures surrounding medical communications, and have differing ideas of what works well, and what does not. By exploring varying perspectives, pharmaceutical companies will gain a further understanding of these differences and obtain key takeaways to implement into their own medical communications plans.

- How do communication strategies vary between companies?
- What are the key components of successful medical communication?
- What are some best practices and lessons learned?

Gary Evoniuk, PhD

Faith DiBlasi, M(ASCP)

GLAXOSMITHKLINE

HUMAN GENOME SCIENCES, INC.

Suzana Giffin, PharmD

AMGEN

2:50 COFFEE & NETWORKING BREAK

3:10 ACADEMIA AND THE PHARMACEUTICAL INDUSTRY: BUILDING EXTERNAL RELATIONSHIPS TO SUPPORT MEDICAL COMMUNICATION STRATEGIES

The important yet complex relationship between industry and academia is unquestionably beneficial to pharmaceutical companies in their pursuit of information dissemination; however it may also be tumultuous, particularly given recent increased scrutiny and regulation such as the Sunshine Act. As pharmaceutical companies strive to remain transparent while dispersing evidence and data effectively, these relationships move to the forefront of strategies and action plans. By collaborating with thought leaders within academia, pharmaceutical companies may gain invaluable insight and feedback into products and clinical studies.

- Working with academia throughout medical communications
- Engaging external stakeholders involved in medical communications
- Ethical & compliant relationships that may enhance medical information sharing

Renu Juneja, PhD, Sr. Director of Strategic Scientific Communications

NOVO NORDISK

4:00 SUCCESSFULLY NAVIGATING INTERNATIONAL MEDICAL COMMUNICATIONS IN KEY MARKETS

Within the increasingly globalized pharmaceutical industry, companies must place a heightened emphasis on communication, which becomes a particularly important concern across continents. As medical information is shared on a worldwide basis, pharmaceutical companies must consider differing audiences, procedures, languages and regulations. Within such important regions as Europe, Canada and the US, pharmaceutical companies must be diligent in order to remain compliant while successfully publishing and sharing information internationally.

- Exploration of important differences between key markets
- Examining publication procedures within key markets
- Strategies for sharing scientific information within key markets
- Working with global and local teams to achieve successful communication

Paul F. Cavanaugh, Jr., PhD, Dir., Publication Planning and Management FORMERLY WITH SHIONOGI INC.

4:50 CLOSING REMARKS & CONFERENCE CONCLUSION
UPCOMING Q1 PRODUCTIONS’ EVENT CALENDAR:

Life Science Chief Executive Forum
February 2-4, 2012
JACKSONVILLE, FL

eDiscovery for Financial Services
February 6-7, 2012
NEW YORK, NY

2nd Annual Diagnostic Performance Evaluations
February 27-28, 2012
PHILADELPHIA, PA

6th Annual Medical Device Clinical Research Conference
March 5-6, 2012
BALTIMORE, MD

Third Annual Device & Diagnostic Sales Training Conference
March 8-9, 2012
PHOENIX, AZ

3rd Annual Medical Device Clinical Training Conference
March 8-9, 2012
PHOENIX, AZ

Pharmaceutical Sales Training & Development
March 19-20, 2012
ATLANTA, GA

Life Science CIO Forum
March 22-24, 2012
PHOENIX, AZ

Maximizing Clinical Operations in Phase I-III Studies
March 29-30, 2012
CHICAGO, IL

Pharmaceutical Supply Chain Conference
April 19-20, 2012
PHILADELPHIA, PA

2nd Annual Pharmaceutical Manufacturing Forum
May 6-8, 2012
JACKSONVILLE, FL

Life Sciences Sales Training & Development in Latin America
May 7-8, 2012
MIAMI, FL

Pharmaceutical Regulatory Writing & Submissions Conference
May 14-15, 2012
BALTIMORE, MD

3rd Annual EU Device & Diagnostic Sales Training Conference
May 14-15, 2012
BERLIN

Medical Device PR & Corporate Communications Conference
May 14-15, 2012
CHICAGO, IL

Pharmaceutical Global Transparency Initiatives
May 21-22, 2012
BOSTON, MA

3rd Annual Life Science Financial Forum
June 10-12, 2011
SAN ANTONIO, TX

Life Science Tax Forum
June 10-12, 2012
SAN ANTONIO, TX

Pharmaceutical State Government Affairs
June 11-12, 2012
CHICAGO, IL

PREVIOUS PHARMACEUTICAL COMPANIES TO HAVE ATTENDED Q1 CONFERENCES INCLUDE:

Abbott Laboratories
Abbott Laboratories
Allergan
Amgen
Astellas
AstraZeneca
Auxilium Pharma
Bausch & Lomb
Baxter
Bayer
BioCryst Pharmaceuticals
Biogen Idec
Boehringer Ingelheim
Bristol Myers Squibb

Celgene
Centocor Ortho Biotech
Cephalon
Cooper Surgical
Crucell
Cubist Pharmaceuticals
Daichi Sankyo
Dyax
Eisai
Eli Lilly
Endo Pharmaceuticals
Fenwal, Inc.
Forest Labs

GE Healthcare
Genentech
Genzyme
Gilead
GlaxoSmithKline
Hospira
Inspire Pharmaceuticals
Janssen Pharmaceutical
Johnson & Johnson
Lundbeck
Merck
Mylan Pharmaceuticals
Novartis

Nyxomed
Onyx Pharmaceuticals
Pfizer
Presidio Pharmaceuticals
Sandoz
Sanofi-Aventis
Seattle Genetics
Roche
Shire
Takeda
Teva
Vertex Pharmaceuticals
Xceleron, Inc.

Q1 Productions designs and develops webinars, training courses, conference programs and forums aimed at specifically targeted audiences in order to provide strategic and timely information. Through a rigid production process focused on end-user research and design, our team is able to understand the immediate business concerns of today’s leading executives. Whether focusing on new or pending legislative issues, enhanced business processes or technologies that will drive efficiency and customer service, our programs provide solutions to the urgent needs of our attendees.

500 N. DEARBORN, SUITE 500   CHICAGO, IL 60654   (P) 312.822.8100   (F) 312.602.3834   www.q1productions.com