2nd Annual
MEDICAL COMMUNICATIONS & THE DISSEMINATION OF SCIENTIFIC INFORMATION

Enhancing the Impact of Medical and Scientific Information & Communications through an Exhaustive Understanding of Physicians Payment Sunshine Act Compliance, Authorship Guidelines and Streamlined Publication Planning Strategies

PROGRAM OVERVIEW:

The healthcare industry, from manufacturers to HCPs, through to its customers are continually evolving and the role of medical communications has congruently grown more complex. Today, medical communication executives are charged with the complicated undertaking of elevating internal and external stakeholders’ medical product knowledge and awareness, while remaining compliant in a regulatory environment focused on complete transparency. Executives are also faced with the immense challenge of converting intricate clinical and scientific data into straightforward and understandable messages while determining the most appropriate avenue for dissemination.

Continuing to build on the success of our 1st Annual Medical Communications and Dissemination of Scientific Information conference in January 2012, this meeting will highlight industry leaders in medical communications and information operations along with legal experts and medical journal editors, who as presenters will share their experiences and knowledge which will be of great benefit to all attending delegates. Key industry opinion leaders will discuss and debate a multitude of issues from compliance considerations of the Physicians Payment Sunshine Act (PSSA) and corporate integrity agreements through to communicating messages with available new social and digital technologies to better reach HCPs and consumers. Expert panelists will also address the ever present challenge of “doing more with less” and maintaining relationships with HCPs/KOLs.

Designed for pharmaceutical and device companies alike, this two-day executive level meeting will provide participants with extensive, in-depth learning and knowledge share. Through case study driven presentations, as well as round table panel discussions complemented by multiple networking opportunities, the program will foster a sense of collaboration and promises to be a valuable program for medical communications and information executives.

DISTINGUISHED PRESENTERS INCLUDE:

Debra Mayo
VP, Global Scientific Communication
TEVA PHARMACEUTICALS

Linda Levitt, PhD
Sr. Director, Scientific Communications
Surgical Solutions Clinical Affairs
COVIDIEN

Annamarie Clegg, MD, CMPP
Vice President, Strategic Services
CHC GROUP

Elisabeth Fine
Associate Director, Global Medical Affairs
BIOGEN IDEC

Karen D. Mittelman, PhD
Director, PCS Global Publications
SANOFI-AVENTIS

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

Katharine Channing
Director, Medical Communications
BAYER HEALTHCARE

Neil Adams
Publishing Manager
NATURE PUBLISHING GROUP

Peter Gannon
Senior Vice President, Business Development & Partnerships
WITHNİ3

Karen Anderson
Director of Medical Communications
GENZYMÉ

Ricardo Martinez
Director, Medical Information and Publications
KCI MEDİCAL

Stephen Douthwaite
President
ALPHABIOTCOM, LLC

Linda Carlson
VP, Medical Operations, Information & Education
EMD SERONON

Jerald Korn
Deputy Compliance Officer
MILLENIUM PHARMACEUTICALS

Jennifer Elliott
Manager, Publications & Analytics
MILLENIUM PHARMACEUTICALS

Terry Materese
Executive Publisher
ELSEVIER

Pat Iannuzzelli
Publications Director
GLAXOSMITHKLINE

Dr. Richard I. Shader
Editor-in-Chief, Clinical Therapeutics
ELSEVIER

Carolyn McAuliffe
Strategic Communications, Publication Planning Manager
BAUSCH & LOMB

Dennis P. Healy, Ph.D.
Global Medical Affairs Oncology
BAYER HEALTHCARE PHARMACEUTICALS

Josephine Solano
Head, Global Medical Communications and Health Economics and Outcomes Research
PFIZER

Monica R. Chmielewski, Esq.
Counsel
FOLEY & LARDNER LLP

Alan Minsk
Partner
ARNALL GOLDEN GREGORY LLP

Mahnu V. Davar
Associate
ARNOLD & PORTER LLP

CONFERENCE SPONSORS:

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MEDIA PARTNERS:
Clinical Professor of Psychiatry & Behavioral Sciences

8:00 SUSTAINING QUALITY AND TRANSPARENT COMMUNICATION OPERATIONS WITH RESTRICTED BUDGETS

As budgets have been downsized throughout all departments in recent years, medical communication divisions have been encumbered with an increasing amount of obligations while facing declining personnel numbers and financial resources. In the era of the informed patient, where consumers are researching medical conditions, treatments, and procedures almost daily it is vital for scientific information to remain easily accessible and current despite tightening budgets. Communication executives are being commissioned to ascertain what new processes, methodologies, and technologies organizations can employ to increase scientific information availability without increasing departmental budgets.

- Prioritizing essential processes and streamlining internal functions
- Maintaining open collaboration networks with internal & external stakeholders
- Discovering resource opportunities without straining current budget

Katharine Channing, Director, Medical Communications

BAYER HEALTHCARE

8:50 REGULATORY & LEGAL COMPLIANCE CONSIDERATIONS SURROUNDING SCIENTIFIC INFORMATION DISSEMINATION

The life science industry remains one of the most regulated industries throughout the world and these regulations have grave implications for not only medical manufacturers but doctors and hospitals. The recent heightened legal concerns surrounding interactions between HCPs and manufacturing organizations has many medical communication executives extremely cautious when determining the material of scientific and clinical materials distributed to sales and marketing departments. Executives are striving to evade common compliance pitfalls through thorough examination of current communication regulations regarding: risk and benefit fair balance, scientific vs. promotional materials, and the ever-plaguing off-label compliance practices.

- Proper utilization of MSL relationships
- Installation of internal compliance benchmarks and review processes
- Review of regulatory & legal environment concerning HCP communications

Alan Minsk, Partner

ARNALL GOLDEN GREGORY LLP

9:40 COFFEE & NETWORKING BREAK

10:00 PANEL DISCUSSION: RECOGNIZING THE IMPORTANCE OF STRONG RELATIONSHIPS WITH INDUSTRY KEES

- Development of compliant KEE (Key External Expert) engagement methodologies
- Discuss the importance of maintaining heavily regulated KEE relationships and the effect of medical communications
- Data perspective that could arise from long-term KEE relationships

Karen Anderson, Director of Medical Communications

GENZYME

Ricardo Martinez, Director, Medical Information and Publications

KCI MEDICAL

Linda Levitt, Senior Director Scientific Communications

COVIDIEN

Stephen Douthwaite, President

ALPHABIOTIC, LLC

10:50 EVALUATION OF THE INTRICACIES RELATED TO THE PHYSICIAN’S PAYMENT SUNSHINE ACT

As of January 2013 medical device and pharmaceutical organizations are obligated to initiate collection and documentation of all financial transactions with official reporting requirements set for soon after. These measures of transparency are aimed at decreasing public perception of bias and fraud within the healthcare community. Compliance with Sunshine Act regulations has been a primary concern for executives throughout all departments but is a crucial concern for medical affairs departments based upon growing relationships with industry KEES and HCPs. Medical communication executives are evaluating the potential impact that this increased transparency will have on information dissemination and publication operations.

- Review of Sunshine Act implementation and reporting deadlines
- Sunshine Act’s influence on the use of external writing support
- Imbedding transparency measures into information distribution processes

Monica R. Chmielewski, Esq., Counsel

FOLEY & LARDNER LLP

Jerald Kom, Deputy Compliance Office

MILLENNIUM PHARMACEUTICALS

11:40 CASE STUDY PRESENTATION: A STAKEHOLDER’S PERSPECTIVE ON EFFECTIVE MEDICAL COMMUNICATION ACTIVITIES

- The balance between tailoring messages to satisfy the needs of multiple stakeholders while maintaining compliance with ICME & GPP2 guidelines
- Address changes in viewship caused by available digital technology and social media alternatives
- Publication process challenges faced by authors, publishers and reviewers

Leslie Citrome, MD, MPH, Clinical Professor of Psychiatry & Behavioral Sciences

NEW YORK MEDICAL COLLEGE

12:30 LUNCHEON FOR ALL ATTENDEES, SPEAKERS & SPONSORS

2:00 PFIZER CASE STUDY: TRAINING PROGRAMS TO ENHANCE MEDICAL SCIENTISTS COMMUNICATION STRATEGIES WHEN ADDRESSING A VARIETY OF STAKEHOLDERS

Josephine Sollano, Head, Global Medical Communications and Health Economics and Outcomes Research

PFIZER

2:50 WITHIN3 CASE STUDY PRESENTATION

Peter Gannon, Senior VP, Business Development and Partnerships

3:40 COFFEE & NETWORKING BREAK

3:50 GLAXOSMITHKLINE CASE STUDY: IMPROVING TRANSPARENCY AND DATA DISCLOSURE

It is crucial that studies evaluating medical interventions be disclosed and reported transparently, publicly, and accurately. To raise standards in scientific publishing and improve transparency, GlaxoSmithKline (GSK) has taken steps to incorporate best practice guidelines into our internal policies and processes. These policies around disclosure and publication of GSK-sponsored studies have been revised to take into account the terms of the Corporate Integrity Agreement (CIA) recently signed between GSK and the US government. The CIA provides GSK with an opportunity to build on practices we have already implemented to align with our company values. The terms of this agreement cover a range of activities related to scientific engagement within the US, including publications and disclosure of study results and interactions with US healthcare providers. This presentation will focus on:

- How the publications process at GSK has evolved to meet the challenges of increased focus on transparency & compliance obligations within the industry
- Means of improving data transparency, including granting external access to patient-level data to qualified investigators and researchers
- Changes in GSK publications processes & policies to accommodate the CIA
- Monitoring efficacy of data disclosure against internal & external standards

Pat Iannuzzelli, Publications Director

GLAXOSMITHKLINE

4:40 ROUNDTABLE DISCUSSION: JOURNAL EDITORS’ PERSPECTIVE ON THE CURRENT SCIENTIFIC INFORMATION ENVIRONMENT

- Evolution of how readers are accessing articles and its effect on publication strategies
- Hurdles confronted by authors & editors during publication submission & review processes
- The future of industry and medical journal partnerships and collaborations

Leslie Citrome, MD, MPH, Clinical Professor of Psychiatry & Behavioral Sciences

NEW YORK MEDICAL COLLEGE

Terry Materese, Executive Publisher

ELSEVIER

Dr. Richard I. Shader, Editor-in-Chief, Clinical Therapeutics

ELSEVIER

5:30 DAY ONE CONFERENCE CONCLUSION
8:50 OVERCOMING COPYRIGHT COMPLIANCE CHALLENGES OF SCIENTIFIC INFORMATION SHARING

It is widely known that any form of written communication is heavily regulated through comprehensive copyright laws and the increasing usage of open access communities to distribute scientific information has sparked a re-interest in the legalities of copyright compliance. As the available avenues of distribution expand, medical communication executives are re-evaluating current copyright restrictions and legal implications that affect not only an organization’s distribution tactics but how end-users are able to access this information. Scientific communication executives must possess a basic working knowledge of copyright restrictions in order to properly release and track all scientific messages. • Legal implications of copyright infringement on organizations • Review of the various type of content licensing • Copyright compliance on an international publishing scale

9:40 COFFEE & NETWORKING BREAK

10:00 ANALYZING RECENT CIA REQUIREMENTS TO ENSURE MEDICAL COMMUNICATIONS REGULATORY COMPLIANCE

The 2011-2012 FY has seen some of the highest court settlement fees paid by life science organizations in response to regulatory and compliance infringement charges. The rise in compliance investigations can be cited as a clear cause for the corresponding increase of implemented corporate integrity agreements throughout the life science industry. These often restrictive agreements have a typical lifespan of five years, in which organizations are obligated to function under close regulatory scrutiny and abide by a straightforward series of guidelines established by the OIG. It is vital for medical communications executives to have a comprehensive understanding of current enforcement trends in order to potentially stave off future compliance infractions that could result in the enforcement of a CIA. • Dissecting CIs on medical communication departments • Installation of transparency monitoring measures to record organization’s HCP contact • Ensuring compliant separation of sales interactions from education-based communications

Mahnu V. Davar, Associate ARNOLD & PORTER LLP

10:50 PANEL DISCUSSION: INDUSTRY PERSPECTIVE ON AUTHORSHIP GUIDELINES AND GHOSTWRITING

• Debating the fine line between acceptable use of medical writers & inappropriate use of ghostwriting • Evaluate the current environment of journal publication policies regarding ghostwriting and writing acknowledgement • Industry strategies to counteract the public’s perception of bias in scientific papers

Neil Adams, Publishing Manager NATURE PUBLISHING GROUP

Karen Anderson, Director of Medical Communications GENZYME

Carolyn McAuliffe, Strategic Communications, Publication Planning Mgr. BAUSCH & LOMB

Annemarie Clegg, MD, CMP, Vice President, Strategic Services CHC GROUP

11:40 SCIENTIFIC INFORMATION DISTRIBUTION ALTERNATIVES: OPEN ACCESS VS. PRINT JOURNALS

In the past, there has been a perception throughout the scientific community that open access publications are of lesser quality than those that have passed through the peer review quality checks of print journals. In 2001, the launch of professionally coordinated open access biomedical journals, which charge authors article or manuscript processing fees, began to challenge the traditional stigma surrounding open access publishing practices. Also, many publicly funded organizations, including the NIH, require that research conducted through agency grants must publish results in a freely available format. This expansion of publishing has many communication executives questioning the future of open access publication avenues and wondering if traditional print journals will remain the gold standard of scientific publications.

Dennis P. Healy, Ph.D., Global Medical Affairs Oncology BAYER HEALTHCARE PHARMACEUTICALS
SECOND ANNUAL MEDICAL COMMUNICATIONS AND THE DISSEMINATION OF SCIENTIFIC INFORMATION
FEBRUARY 21-22 / BOSTON, MA

WHO SHOULD ATTEND:
Executives that will find this program of greatest relevance are those currently working to enhance scientific and medical communications operations within pharmaceutical, biotechnology, medical device, and diagnostic corporations. Job titles of those executives that will find this program to be most applicable to their job functions include:

- Medical and Scientific Communications
- Medical and Scientific Affairs
- Medical Information
- Publications Planning
- Medical Writing

SPONSORSHIP OPPORTUNITIES:
At this time, there are a variety of sponsorship and exhibition opportunities available for companies wishing to increase their visibility and participation in the program, ranging from keynote speaking opportunities through to exhibitor and documentation sponsors. Organizations most suitable for this type of exposure provide services and solutions including:

- Medical Marketing Communications
- eDetailing
- Software & Services for Medical Communications
- Social Media Aggregation Services
- Digital Communications Provider
- Global Communications Consultants

PREVIOUS ATTENDEES INCLUDE:
Amgen – Director of Global Publications
Amgen – Director of Medical Communications
Ariad Pharmaceuticals – Head of Medical Writing
Bausch & Lomb – Manager of Global Medical Affairs
Bayer Healthcare – Global Medical Affairs
Biogen Idec – Associate Director of Global Medical Affairs
BioMarin – Associate Director, Medical Writing
BMJ Publishing Group – Clinical Epidemiology Editor
Bristol-Myers Squibb – Executive Director of Medical Information
BTG International – Head, Medical Communications
Carefusion – Vice President of Medical Affairs
Cephalon – Director of Medical Communications
Coviden – Manager of Post Market Research & Publications
Cubist Pharmaceuticals – Mng., Publications & External Research
Dyax – Associate Director of Medical Communications
Elsevier – Publishing Director, Global Medical Research
EMD Serono – Senior Director, Medical Affairs
EMD Serono – Program Manager, Medical Affairs
F. Hoffman-La Roche – Director, Global Publications
Forest Research Institute – Assistant Director, Medical Affairs
Genzyme – Director of Medical Communications
Genzyme – Associate Director, Scientific Communications
GlaxoSmithKline – Director of Publications Practices
GlaxoSmithKline – Regional Publication Manager
Grifols – Manager of Scientific Information
Grifols – Director of Publications Planning
Human Genome Sciences – Senior Director of Medical Affairs
Human Genome Sciences – Associate Director, Knowledge Mgmt.
Incyte Corporation – Exec. Director, Medical & Scientific Writing
Incyte Corporation – Publications Specialist
Ironwood Pharmaceuticals – Director of Medical Writing
Janssen Biotech – Senior Director Medical Writing
Janssen Services – Manager of Publications
Janssen Therapeutics – Senior Publications Specialist
Jazz Pharmaceuticals – Senior Manager, Medical Information
John Hopkins Medicine – Director of Electronic Media
Merck – Publications Manager
Merck – Director, Publication Services
Millennium Pharmaceuticals – Sr. Dir., Medical Communications
Millennium Pharmaceuticals – Mgr., Publications & Analytics
Millennium Pharmaceuticals – Senior Manager, Publications
Nature Publishing Group – Publishing Manager
Novartis – Executive Director, Scientific Communications
Novartis – Associate Director, Publications
Novartis – Medical Publication Lead, Global Medical Affairs
Novo Nordisk – Senior Director, Strategic Scientific Information
NPS Pharmaceuticals – Head of Medical Affairs
Optimer Pharmaceuticals – Exec. Dir., Scientific Communications
Optimer Pharmaceuticals – Manager, Scientific Publications
Organogenesis, Inc – Manager, Scientific Communications
Otsuka America – Director, Medical Information
Pfizer – Director, Publications Management Team
Pfizer – Head, Global Medical communications & HEOR
Roche – Senior Director, Scientific Relations & Publications
Sanofi-Aventis – Senior Director, Medical Communications
Shionogi – Director, Publications Planning & Management
Shire Pharmaceuticals – Director of Publications
Sui Generis Health – Director, Operations
Takeda – Director, Medical & Scientific Publications
Teva – Director, Scientific Communications, Medical Affairs
Upsher-Smith Laboratories – Medical Affairs
Vertex Pharmaceuticals – Director, Medical Affairs
ViroPharma Incorporated – Director, Medical Communications
ViroPharma Incorporated – VP, Global Medical Affairs

CONTACT Q1 PRODUCTIONS:

CHICAGO
500 N. Dearborn, Suite 500
Chicago, IL 60654
Phone: 312.822.8100
Fax: 312.602.3834

LONDON
London House
271-273 King Street
London, W6 9LZ
Phone: +44 (0) 208 233 2833
Fax: +44 (0) 207 504 3792

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