

Marketing Pharmaceuticals 2013: Workshop for Regulatory, Legal, Communications Professionals and Promotional Review Teams

February 20-21, 2013

Tutorial: February 19



PROGRAM COMMITTEE

Thomas W. Abrams, MBA, RPh

Director, Office of Prescription Drug Promotion, CDER, FDA

Glenn N. Byrd, MBA, RAC

Senior Director, Regulatory Affairs, MedImmune LLC

Mark Gaydos, BA

Vice President, US Regulatory Affairs Marketed Products, Sanofi

Michele Hardy

Vice President, Regulatory Advertising and Promotion Policy
GlaxoSmithKline

John T. Murray

President, Grayscale Compliance LLC

Wayne L. Pines, BA

President, Regulatory Services and Healthcare, APCO Worldwide Inc.

Janet L. "Lucy" Rose, MBA

President, Lucy Rose and Associates, LLC

Kristina Spranger, MPH

Director, Regulatory Promotion, Amgen Inc.

THE ANNUAL MEETING YOU CANNOT AFFORD TO MISS

Complying with the various regulatory and legal requirements remains highly challenging for pharmaceuticals, biologics and OTC drug, and medical devices. Marketing and promoting these products has never been as important or as complex as it is now.

The Food and Drug Administration, the Office of Inspector General/Department of Justice, and the states continue to take enforcement actions against companies that fail to understand or comply with the rules. In addition, there are many voluntary codes and other standards that companies must adapt to their own products.

The impending implementation of the Affordable Care Act and PDUFA V/FDASIA make the environment for companies even more challenging. Change is coming, and how drug and device manufacturers market their products will continue to evolve.

The penalties for non-compliance go beyond an FDA warning letter. The substantial fines, criminal and civil legal actions and corporate integrity agreements affect how every company and vendor does business.

This conference, conducted annually since 1989, brings these issues into clear focus.

This is the one conference that should be attended by your entire promotional review team. In just 2 days, you will:

- Gain a better understanding of how the regulatory and legal environment has evolved and affects the marketing and promotion of pharmaceuticals, biologics, and medical devices.
- Receive practical, day-to-day guidance based from the latest FDA enforcement actions, and the changes taking place and being contemplated.
- Get a first-hand update from the senior regulators at FDA on the status of social media guidances.
- Learn about recent FDA guidance documents and new policies currently in development or being considered.
- Hear about the latest enforcement activities by the centers within FDA that regulate medical marketing: drugs (CDER), biological products (CBER), and medical devices (CDRH).
- Gain new insights into the level of evidence FDA requires on making promotional claims.
- Attend breakout sessions designed for each member of your promotional review team to help foster a common understanding of how marketing is conducted in a highly regulated environment.

LEARNING OBJECTIVES

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

- Identify the trends reflected in the latest enforcement actions and policies issued by the FDA
- Discuss how companies are complying with government marketing requirements
- Explain how to work collaboratively with those who review promotional materials
- Discuss the policies and actions being taken by OIG and DOJ under the False Claims Act
- Describe how to market products while complying with the FDA and other policies and regulations

WHO SHOULD ATTEND

Professionals in pharmaceutical, biologics, and OTC drugs and medical device companies involved in:

- Marketing
- Marketing Communications
- Legal, Regulatory Affairs
- Public Relations/Corporate Affairs
- Medical Information and Affairs
- Advertising Agencies
- Compliance
- Senior Management

DIA WORLDWIDE HEADQUARTERS

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CONTINUING EDUCATION CREDITS



The Drug Information Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This program is designated for up to 14.5 contact hours or 1.45 continuing education units (CEU's).

Type of Activity: Knowledge

ACPE Credit Request Update

DIA is required by the Accreditation Council for Pharmacy Education (ACPE) to report pharmacy-requested CEUs through the CPE Monitor system. All ACPE-certified activity credit requests need to be submitted through DIA's My Transcript **within 45-days post activity**. Pharmacists will need to provide their National Association of Boards of Pharmacy (NABP) e-Profile ID and date of birth (MMDD) to ensure the data is submitted to the ACPE and NABP properly. If you need to obtain your NABP e-Profile, please visit www.cpemonitor.net.



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

As an IACET Authorized Provider, Drug Information Association offers CEUs for its programs that qualify under the ANSI/IACET Standard. Drug Information Association is authorized by IACET to offer up to 1.4 CEUs for the program. Participants must attend the entire program <and tutorial(s), if applicable> in order to be able to receive an IACET statement of credit. No partial credit will be awarded.

DIA's Certificate Program

This program is part of DIA's Certificate Program and is awarded the following:

- Regulatory Affairs Certificate Program: 8 Elective Units

For more information go to www.diahome.org/certificateprograms

If you would like to receive a statement of credit, you must attend the program <and tutorial, if applicable>, scan your name badge at each session you attend for each day of the program, and complete the on-line credit request process through My Transcript. To access My Transcript, please go to www.diahome.org, select "Login to My DIA" and you will be prompted for your user ID and password. Select "My Transcript" (left side bar) and "Credit Request" to process your credit request. Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests on **Thursday, March 7, 2013**.

Disclosure Policy

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

CONTINUING EDUCATION CREDIT ALLOCATION

Tutorial, OPDP/APLB and Compliance 101: A Primer: IACET: .3 CEUs; Pharmacy: 3.25 contact hours or .325 CEUs, 0286-0000-13-006-L03-P

Program:

IACET: 1.1 CEUs

Pharmacy:

Sessions 1 and 2: 3 contact hours or .3 CEUs, 0286-0000-13-007-L03-P

Sessions 3, 4, and 5: 3 contact hours or .3 CEUs, 0286-0000-13-008-L04-P

Session 6:

Breakout Session 1: 1.5 contact hour or .15 CEU, 0286-0000-13-009-L04-P

Breakout Session 2: 1.5 contact hour or .15 CEU, 0286-0000-13-010-L04-P

Break out Session 3: 1.5 contact hour or .15 CEU, 0286-0000-13-011-L04-P

Session 7:

Breakout Session 1: 1.5 contact hour or .15 CEU, 0286-0000-13-012-L04-P

Breakout Session 2: 1.5 contact hour or .15 CEU, 0286-0000-13-013-L04-P

Break out Session 3: 1.5 contact hour or .15 CEU, 0286-0000-13-014-L04-P

Sessions 8, 9, and Closing Remarks: 2.25 contact hours or .225 CEUs, 0286-0000-13-015-L04-P

Unless otherwise disclosed, the statements made by speakers represent their own opinions and not necessarily those of the organization they represent, or that of the Drug Information Association.

Speakers, agenda, and CE information are subject to change without notice.

Recording of any DIA educational material in any type of media, is prohibited without prior written consent from DIA.

To view DIA's Grievance Policy, please visit the CE page on DIA's website at www.diahome.org.

TUTORIAL DAY | FEBRUARY 19, 2013

12:30 – 1:30 PM TUTORIAL REGISTRATION

1:30 – 5:00 PM

OPDP/APLB and Compliance 101: A Primer

INSTRUCTORS:

Lucy Rose, MBA

President
Lucy Rose and Associates, LLC

Paul J. Savidge, JD, MBA

Vice President & Associate General Counsel,
Regulatory/Commercial Law
Bristol-Myers Squibb Co.

Michele Sharp, PharmD

Senior Director, Global Regulatory Affairs - US
Eli Lilly and Company

If you are new, or relatively new, to OPDP and/or advertising/promotional compliance, this tutorial is for you!! The leaders will provide a strong introductory foundation for anyone working in our new regulatory environment. Whether you are a regulatory, legal, medical, or marketing professional, the information will be interesting, practical and vital!

LEARNING OBJECTIVES:

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

- Discuss the current regulatory/compliance environment pertaining to prescription drugs, biologics and medical devices, both from an FDA and OIG/DOJ perspective
- Describe the FDA advertising and promotional requirements, including such topics as: claim support requirements, fair balance expectations, internet challenges, product booths at medical conventions, disease state programs, and public relations challenges

TARGET AUDIENCE:

This program is designed for individuals involved in marketing, legal, regulatory, public affairs, and advertising in the pharmaceutical and biologics industries, plus their consultants and agencies. If you are relatively new to this area, please join our experienced experts to gain the important information you need to maximize your conference learning!

CONFERENCE DAY 1 | FEBRUARY 20, 2013

7:00 – 8:25 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:25 – 8:30 AM WELCOME AND OPENING REMARKS

Wayne L. Pines

President, Regulatory Services and Healthcare
APCO Worldwide, Inc.

8:30 – 10:00 AM SESSION 1

FDA Update: Recent Enforcement Actions

SESSION CHAIR

Wayne L. Pines

President, Regulatory Services and Healthcare
APCO Worldwide, Inc.

This session provides an overview of current issues, laws and guidances relevant to the promotion of prescription drugs, biologics and medical devices. Learn the latest on policy development, enforcement and FDA's future initiatives.

CDER Update

Thomas W. Abrams, MBA, RPh

Director, Office of Prescription Drug Promotion (OPDP)
CDER, FDA

CBER Update

Lisa L. Stockbridge, PhD

Branch Chief, Advertising and Promotional Labeling Branch
CBER, FDA

FDA CDRH

Representative Invited

10:00 – 10:30 AM REFRESHMENT BREAK

10:30 AM – 12:00 PM SESSION 2**Substantial Evidence and Other Standards of Evidence in Promotion**

SESSION CHAIR

Glenn N. Byrd, MBA, RACSenior Director, Regulatory Affairs
MedImmune, LLC

The panel will discuss the quality/type of data needed to support various claims in prescription drug promotion. The quality/type of data that are required depends upon the type of claims one is seeking, such as treatment benefit claims (e.g., clinical outcomes, patient-reported outcomes) and non-clinical claims (e.g., convenience, ease of use), to cite a few. This area is a source of frequent discussion between companies' regulatory/legal reviewers and marketing teams. It is also a topic frequently cited by FDA in its enforcement actions. This session will explore the meaning of terms such as: substantial evidence, substantial clinical experience, adequate evidence, etc.; and examine related enforcement actions.

PANELISTS

Elaine Hu Cunningham, PharmDSenior Regulatory Review Officer, Office of Prescription Drug Promotion
CDER, FDA**Mark Hirsch, MD**Medical Team Leader, Division of Reproductive and Urologic Drug Products
FDA**James Stansbury, PhD, MPH**Endpoints Reviewer, Study Endpoints and Labeling Development (SEALD)
FDA**Eugene Sullivan, MD**Principal
EJS Consulting, LLC**12:00 – 1:30 PM LUNCH****1:30 – 2:30 PM SESSION 3****FDA Guidance Update**

SESSION CHAIR

Michele HardyVice President, Regulatory Advertising and Promotion Policy
GlaxoSmithKline

The panel will discuss guidances that significantly impacts the promotion and advertising of medical products. The panel will describe the importance of the guidances to the promotional practices and materials for medical products. The panel will also provide an update on future planning for FDA guidance development.

PANELISTS

Bryant Godfrey, JD, MHASenior Lead Regulatory Counsel
U.S. Food and Drug Administration
Office of Prescription Drug Promotion**Marci C. Kiester, PharmD**Associate Director, Office of Prescription Drug Promotion
CDER, FDA**Cynthia Ng, JD**Regulatory Counsel
FDA**Panelists Invited****2:30 – 3:30 PM SESSION 4****Social Media: Digital Tools and Considerations in Compliant Development**

SESSION CHAIR

Dale CookeVice President/Group Director, Regulatory Review
Digitas Health

This session will provide an overview of where we are today in the ever-evolving digital media world and tools which may help the industry better navigate the environment. Additionally, this session will feature an interactive forum to discuss considerations that colleagues from the industry take into account when developing apps, mobile platforms and more. The interactive session will be open to audience questions and thoughts as well.

PRESENTERS

Dale CookeVice President/Group Director, Regulatory Review
Digitas Health**Edwin J Tucker BSc, MB ChB, DPM, MRCP, MBA**Vice President, Head of PV Operations, Global Medical Safety
Janssen Research & Development

PANELISTS

Edwin J Tucker BSc, MB ChB, DPM, MRCP, MBAVice President, Head of PV Operations, Global Medical Safety
Janssen Research & Development**Leah Palmer, PharmD**Executive Director, Regulatory Promotion
Amgen Inc.**Amy Smith**World Wide Director, Regulatory Affairs
LifeScan, Inc.**Zafar Toor, PharmD**Director, Commercial Regulatory Affairs
Regulatory Core Functional Unit
Eisai Product Creation Systems**3:30 – 4:00 PM REFRESHMENT BREAK**

4:00 – 5:00 PM SESSION 5

Recent Updates and Future Trends in Corporate Integrity Agreements and Compliance Programs

SESSION CHAIR

John T. Murray

President
Grayscale Compliance LLC

Leading legal and compliance professionals will discuss the most recent Corporate Integrity Agreements and future trends in compliance programs. The panel will also discuss the recent decision from the U.S. Court of Appeals in case of the U.S. v. Caronia which represents a landmark challenge to FDA in its approach to regulating off-label promotion. The panel will discuss what it may or may not mean for FDA-regulated companies and their compliance programs.

PRESENTERS

William A. Sarraille
Partner
Sidley Austin, LLP

Kris Curry
Vice President, Health Care Compliance, Pharmaceuticals Group
Johnson & Johnson

Kathleen Meriwether
Principal, Assurance Services | Fraud Investigation & Dispute
Services
Ernst & Young

Doug H. Hallward-Driemeier
Partner
Ropes and Gray, LLP

5:00 – 6:00 PM RECEPTION

CONFERENCE DAY 2 | FEBRUARY 21, 2013

7:30 – 8:30 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:30 – 12:00 PM BREAKOUT SESSIONS

Breakout sessions offer attendees day-to-day practicalities in an interactive/hands-on/role-playing environment using case studies and simulation with information that can be taken back to the office and shared with colleagues. These sessions will offer the opportunity for companies to send all members of their "Promotional Review Teams" to enable them to work more cohesively together and with FDA (and other agencies).

8:30 – 10:00 AM SESSION 6

BREAKOUT SESSION 1

Product Communications in the Pre-Approval Phase

SESSION CHAIRPERSON

Mark Gaydos, BA

Vice President, US Regulatory Affairs
Marketed Products
Sanofi

PRESENTERS

Leah Palmer, PharmD
Executive Director, Regulatory
Promotion
Amgen

Alan R. Bennett, JD
Managing Partner
ROPES & GRAY LLP

Dennis Nosco, PhD, RAC
Senior Director, Global Labeling
Regulatory Affairs
Mallinckrodt, the Pharmaceuticals
business of Covidien Pharmaceuticals

This session will focus on the types of information a company might consider communicating about its research efforts, pipeline products and corresponding development programs. Select topics include:

- What, how, and to whom can companies communicate about research efforts and pipeline products while avoiding allegations of pre-approval or off-label promotion?
- What and when can a company proactively communicate about planned and ongoing clinical trials?
- What are the parameters a company should observe when developing a pre-approval disease awareness campaign?
- What are the pros and cons of a coming soon campaign?

BREAKOUT SESSION 2

Fundamental Issues in the Regulatory Evaluation of Health Economic Information

SESSION CHAIRPERSON

Philomena McArthur

Senior Director Regulatory Advertising & Promotion, Pharmaceuticals Group HCC
Janssen Pharmaceutical Companies of
Johnson & Johnson

PANELISTS

Robert J. Matheis, PhD

Senior Director, CER Communications,
Evidence Based Medicine
Sanofi

Meredith Manning, JD, MS, BA

Partner and Co-Director,
Pharmaceutical and Biotechnology
Practice Group
Hogan Lovells

Harlan Weisman, MD

Chairman & Chief Executive Officer
Coronado Biosciences, Inc.

This session will focus on the underlying issues with health economic analyses, what the methods are, what their strengths and weaknesses are from a substantiation perspective, and why these issues profoundly affect FDA policy in this area. This session will define the fundamental elements of HCEI, CER, RCTs, etc., and all of their respective relationships to the FDA substantial evidence standards.

BREAKOUT SESSION 3

Disease State and Unbranded Materials – Regulatory Challenges

SESSION CHAIRPERSON

Thomas M. Casola

Vice President, Global Regulatory Affairs,
Advertising, Promotion, and Labeling
Shire Specialty Pharmaceuticals

PRESENTERS

Michael S. Labson, JD
Partner
Covington & Burling LLP

Glenn N. Byrd, MBA, RAC
Senior Director, Regulatory Affairs
MedImmune, LLC

Bryant Lim, JD
Associate General Counsel
ViroPharma Incorporated

Companies are increasingly using disease state and unbranded materials including the creation of websites. These materials pose nuanced regulatory issues such as when does a company's disease or unbranded website become promotional in nature and how can a company use such websites in conjunction with product promotion. What if disease state and unbranded materials go beyond approved labeling? This session will also address use of disease state materials during the pre-approval stage.

10:00 – 10:30 AM BREAK

10:30 – 12:00 PM SESSION 7

BREAKOUT SESSION 1**Product Communications in the Pre-Approval Phase**

SESSION CHAIRPERSON

Mark Gaydos, BA

Vice President, US Regulatory Affairs
Marketed Products
Sanofi

PRESENTERS

Leah Palmer, PharmD

Executive Director, Regulatory
Promotion
Amgen Inc.

Dennis Nosco, PhD, RAC

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Regulatory Affairs
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Alan R. Bennett, JD

Managing Partner
ROPES & GRAY LLP

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Janssen Pharmaceutical Companies of
Johnson & Johnson

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Evidence Based Medicine
Sanofi

Meredith Manning, JD, MS, BA

Partner and Co-Director,
Pharmaceutical and Biotechnology
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12:00 – 1:30 PM LUNCH

1:30 – 2:30 PM SESSION 8

The Next Generation: Promotional Review Boards (online reviews)

SESSION CHAIR

Michael Misocky

President
Misocky Consulting Group LLC

Promotional Review Boards are responsible for ensuring the compliance of materials issued by drug companies. Increasingly, review boards are relying on electronic programming to make their review more efficient and systematic. This session will address how companies are using new electronic methods and examine the key elements of an efficient and compliant review system.

PRESENTERS

Dan J. Halberstadt, RPh

Senior Director, US Medical Communications & Knowledge
Management
Global Medical Affairs
Shire SP

Michele Sharp, PharmD

Senior Director, Global Regulatory Affairs – US
Eli Lilly and Company

Kinsey S. Reagan, Esq.

Partner
Kleinfeld, Kaplan and Becker, LLP

2:30 – 3:00 PM REFRESHMENT BREAK

3:00 – 4:00 PM SESSION 9

Question and Answer Session with FDA

SESSION CHAIR

Lucy Rose, MBA

President

Lucy Rose and Associates, LLC

Use this unique opportunity to bring your pressing questions for FDA to address in person. This session will attempt to answer any remaining questions from earlier sessions and to allow the audience to ask new questions to our FDA speakers.

PANELISTS

Thomas W. Abrams, MBA, RPh

Director, Office of Prescription Drug Promotion (OPDP)
CDER, FDA

Lisa L. Stockbridge, PhD

Branch Chief, Advertising and Promotional Labeling Branch
CBER, FDA

Deborah Wolf, JD

Regulatory Counsel, Office of Compliance
CDRH, FDA

4:00 – 4:15 PM CLOSING REMARKS

Wayne L. Pines

President, Regulatory Services and Healthcare
APCO Worldwide, Inc.

4:15 PM WORKSHOP ADJOURNED

REGISTRATION FORM

Register online or fax this page to +1.215.442.6199

Marketing Pharmaceuticals 2013: Workshop for Regulatory/Legal/Communications Professionals and Promotional Review Teams Event #13007

February 20-21 | Tutorial: February 19

Registration Fees If DIA cannot verify your membership, 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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TUTORIAL: TUESDAY, February 19, 2013

Half-day Afternoon: 1:30-5:00 PM
OPDP/APLB and Compliance 101: A Primer US \$405

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

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CHECK drawn on a US bank payable to and mailed along with this form to: Drug Information Association Inc, P.O. Box 95000-1240, Philadelphia, PA 19195-1240, USA. Please include a copy of this registration form to facilitate identification of attendee.

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

TRAVEL AND HOTEL The most convenient airport is Ronald Reagan Airport and attendees should make airline reservations as early as possible to ensure availability. **Grand Hyatt Washington is holding a block of rooms at the reduced rate below until January 21, 2013 for the DIA event attendees.** Room availability at this rate is guaranteed only until this date or until the block is filled.

Single \$269 / Double \$294

Attendees must make their own hotel reservations. Contact the Grand Hyatt Washington by telephone at +1.202.582.1234 and mention the DIA event. The hotel is located at 1000 H Street NW, Washington, DC 20001, USA.

CANCELLATION POLICY: On or before JANUARY 21, 2013
Administrative fee that will be withheld from refund amount:

Member or Nonmember = \$200

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

Preconference Workshop (if applicable) = \$50

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

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

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

EXHIBIT INFORMATION

Attendees may visit the exhibits during the event and receptions.

Contact **Jeff Korn, Exhibits Associate**, Phone **+1.215.442.6184**

Fax **+1.215.442.6199**, Email **Jeff.Korn@diahome.org**

EVENT INFORMATION

For registration questions, please contact **Vicki Adkinson** by phone at

+1.215.442.6162 or by Email **Vicki.Adkinson@diahome.org**

AGENDA INFORMATION

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Benjamin Zaitz, Program Manager

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Please check the applicable category:

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First Name _____

M.I. _____

Degrees _____

Dr. Mr. Ms.

Job Title _____

Company _____

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Country _____

email **Required for confirmation**

Phone Number _____

Fax Number _____

Required for confirmation