

DIA Medical Writing Conference

Navigating Your Way Through the Complex World of Medical Writing

ID# 14660 | January 24, 2014
Scitech Center | Mumbai, India



PROGRAM COMMITTEE

Bindu Narang

Director
Scientific Writing and Regulatory Affairs
Sciformix

Rajesh Pandey

Offering Lead, Medical Writing
TCS

Sunita Nair

Head, Knowledge Services
Capita India

“Contrary to what some people seem to believe, simple writing is not the product of simple minds. A simple, unpretentious style has both grace and power. By not calling attention to itself, it allows the reader to focus on the message.”

- Richard Lederer and Richard Dowis

India Office

A-303, Wellington Business Park I
Andheri-Kurla Road, Marol, Andheri (East)
Mumbai 400 059 India
www.diahome.org

Worldwide Headquarters

800 Enterprise Road, Suite 200
Horsham, PA 19044, USA

PROGRAM CHAIR



Nimita Limaye
Vice President,
Medical Writing
Risk-based
Monitoring
and CDM
TCS

PROGRAM OVERVIEW

Medical Writing is a niche area, but is rapidly establishing its footprint in India. As we move up the value chain, it is increasingly critical to be aware of changing perspectives towards data transparency, ensuring ethical compliance, and the need to address regulatory requirements. This workshop will discuss the intricacies of authoring complex documents, health economics analyses, and the recognition of global trends of off shoring increasingly complex medical writing work to India. Attendees will also learn about vendor assessments and how to overcome challenges to establish effective partnerships.

PROGRAM HIGHLIGHTS

- Managing the regulatory angle – guidance on how to respond to health authority questions
- Driving ethics in document authoring, data transparency and trial disclosures, responding to HCP queries
- Key players and subtle interfaces – negotiating your way with multiple stakeholders to craft the final document
- Outsourcing trends, the MW RFP – what to expect, intricacies in establishing a narrative writing partnership, and managing the risk in outsourcing safety reports
- Ensuring the right SPIRIT on protocols and a comparative analyses of clinical overviews versus summaries

WHO SHOULD ATTEND

Professionals, researchers, and clinicians involved in drug discovery with development and regulatory affairs including:

- Regulatory writers
- Publication specialists
- Clinicians
- Ethics committee members
- Outsourcing professionals
- Regulatory and clinical research professionals
- Global players looking at setting up medical writing operations in India

*All attendees will receive a
DIA Certificate of Attendance.*





Conference Agenda

8:30-9:00 *Registration*

9:00-9:30 *Inauguration*

Session 1 | Medical Writing: Managing the Regulatory Angle

SESSION CHAIR

Bindu Narang

Director, Scientific Writing and Regulatory Affairs
Sciformix

9:30-10:00 *Responding to HAQ Questions, Response Documents:
The Role of the Medical Writer*

Rajashri Ojha

SME, Global Regulatory Operations Lead
Cognizant Technology Solutions

10:00-10:30 *The Data Transparency Initiative: Trial Disclosures
and FDA8001*

Mark Barnes

Partner, Ropes and Gray, LLP

10:30-11:00 *Generating Evidence in Health Economic Analyses*

Sunita Nair

Head, Knowledge Services
Capita India

11:00-11:30 *Tea Break and Networking*

Session 2 | Outsourcing in Medical Writing

SESSION CHAIR

Anuprita Sheth

Senior Manager, Global Regulatory Affairs and Safety
Amgen

11:30-12:00 *Challenges and Successes in Managing a Narrative
Writing Partnership: The Do's and Don'ts*

Swati Sharma

Customer Leader
TCS

Vanitha Prasad

Group Leader, Regulatory Medical Writing, IIS
Novartis Healthcare Pvt. Ltd.

12:00-12:30 *Outsourcing Safety Reports: Managing Risks*

Preeti Verma

Senior Manager
Kinapse

12:30-1:15 *Panel Discussion: Outsourcing Trends in
Medical Writing – What do we see in RFPs?*

PANEL CHAIR

Nimita Limaye

Vice President, Medical Writing, Risk-based Monitoring and CDM
TCS

PANELISTS

Anuprita Sheth

Senior Manager, Global Regulatory Affairs and Safety
Amgen

Debjani Dasgupta

Deputy General Manager, Operations
Cognizant Technology Solutions

Roopa Basrur

Director Medical Writing Services India & General Manager Business
Administration (GMBA)
Parexel

Gaurav Srivastava

Global Category Manager, DSS
Novartis

1:15-2:15 *Networking Lunch*

Session 3 | Medical Communications

SESSION CHAIR

Sandeep Kamat

Associate Vice President, Medical Affairs
Cactus Communications

2:15-2:45 *Ethical Aspects in Document Authoring*

Nandini Kumar

Former Deputy Director General
ICMR

2:45-3:15 *Nuances of Working with Authors in
Developing Manuscripts*

Sandeep Kamat

Associate Vice President, Medical Affairs
Cactus Communications

3:15-3:45 *Responding to HCP Questions: The Role of the
Medical Writer*

Bindu Narang

Director, Scientific Writing and Regulatory Affairs
Sciformix

3:45-4:15 *Tea Break and Networking*

Session 4 | Regulatory Writing

SESSION CHAIR

Sunita Nair

Head, Knowledge Services
Capita India

4:15-4:45 *Writing Robust Protocols – with the Right SPIRIT*

Payal Bharadwaj

SME and Senior Manager, Medical Writing
TCS

4:45-5:15 *Writing Clinical Overviews and Summaries:
A Comparative Analysis*

Suhasini Sharma

Director, Medical Affairs
Sciformix

5:15-6:00 *Panel Discussion: Interfaces in Medical Writing:
Clinicians, Biostatisticians, Regulatory Affairs, CDM
and Medical Writing*

PANEL CHAIR

Anish Desai

Director, Medical & Clinical Affairs
Johnson & Johnson

PANELISTS

Rajesh Pandey

Offering Lead, Medical Writing
TCS

Shubhangi Manjrekar

Manager Biostatistics & Programming
Cognizant Technology Solutions

Chirag Trivedi

Associate Director, Project Management & Strategic Initiatives
Sanofi-Aventis

Bobby George

Vice President, Regulatory Affairs
Reliance Lifesciences

Vote of Thanks



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Including DIA's Global Resources:

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STUDENT	500 INR
TWO-YEAR	3,509 INR
THREE-YEAR	4,972 INR
TEN-YEAR	13,650 INR

VENUE DETAILS Scitech Center Mumbai India 7, Prabhat Nagar, Jogeshwari West, Jogeshwari West, Mumbai. **Land Mark: Next To Unichem Limited CONTACT Kanchan Patel: Kanchan.Patel@diaindia.org; cell: + 91 98.2062.1844	MEETING MANAGER Manoj Trivedi Senior Manager, Marketing and Program Development DIA (India) Private Limited cell: +91 98.1977.7493 Manoj.Trivedi@diaindia.org
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▶ **CANCELLATION POLICY: On or before JANUARY 13, 2014**
 Cancellations must be in writing and received by January 13, 2014. Registrants who do not cancel in writing by that date and do not attend the event will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations.

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.

Upon cancellation, the administrative fee that	FULL MEETING CANCELLATION All refunds will be issued in the currency of original payment
will be withheld from refund amount is:	75% of the Delegate fee

PLEASE CONSIDER THIS FORM AS AN INVOICE
DIA Medical Writing Conference
 Meeting I.D. # 14660 | January 24, 2014 | Scitech Center | Mumbai, India

REGISTRATION FEES <i>Registration fee includes refreshment breaks, luncheons.</i> Join DIA now to qualify to save on future events and to receive all the benefits of membership. To see all the benefits of DIA membership, visit www.diahome.org and click on Membership. *A limited number of student registrations are available. A student is an undergraduate/graduate who can document enrollment in a Signature accredited, degree granting, academic program. Please send completed registration form, copy of student identification, and payment.	<table border="1"> <thead> <tr> <th colspan="4">DELEGATE REGISTRATION</th> </tr> <tr> <th></th> <th>BASIC RATE</th> <th>SERVICE TAX</th> <th>TOTAL</th> </tr> </thead> <tbody> <tr> <td>Industry</td> <td>5000</td> <td>618</td> <td>5618 INR</td> </tr> <tr> <td>Academia</td> <td>4000</td> <td>494</td> <td>4494 INR</td> </tr> <tr> <td>Student</td> <td>1000</td> <td>124</td> <td>1124 INR</td> </tr> </tbody> </table> <p align="right">TOTAL AMOUNT: _____</p> <p align="right">ORGANISATION PAN No.: _____</p>	DELEGATE REGISTRATION					BASIC RATE	SERVICE TAX	TOTAL	Industry	5000	618	5618 INR	Academia	4000	494	4494 INR	Student	1000	124	1124 INR
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REGISTRATION TERMS AND CONDITIONS: Registration form should be duly filled, signed by the authorized person. You are requested to email the duly filled and signed Registration Form first and then courier/mail it along with registration fees on or before 5 working days of the workshop.

Please check the applicable category: <input type="checkbox"/> Academia <input type="checkbox"/> Industry <input type="checkbox"/> Student PLEASE PRINT ALL INFORMATION CLEARLY Degrees: _____ <input type="checkbox"/> Dr. <input type="checkbox"/> Mr. <input type="checkbox"/> Ms. Last Name (Family Name) _____ First Name _____ Job Title _____ Affiliation (Company) _____ Address (Please write your address in the format required for delivery to your country.) _____ Postal Code _____ City _____ State _____ Country _____ Telephone Number _____ Fax Number _____ Mobile Number _____ email (Required for confirmation) _____	PAYMENT INFORMATION Completed form, along with draft/cheque made payable to DIA (India) Private Limited should be sent to: Bhavesh Vora Senior Executive Accounts Bhavesh.Vora@diaindia.org Drug Information Association A- 303, Wellington Business Park 1, Andheri Kurla Rd. Marol Naka, Andheri East, Mumbai 400059 INDIA +91 22.6523.0676 (tel) +91 98.2097.2630 (cell)
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