



**India Affiliate**

Ahmedabad Chapter

*Presents*

*Young Pharma Professionals Education Programme (YPPEP)*

*“The ART and SCIENCE of Medical Writing !”*

*On*

*Friday, 15th & Saturday, 16th November, 2013*

*At*

*AHMEDABAD MANAGEMENT ASSOCIATION,  
Near Atira, Polytechnic -IIM Road, Ahmedabad*

## Program Overview

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Medical Writing is a fast growing specialty in India with an increasing demand of qualified and experienced writers. Medical writing offers opportunities, both, as a professional associated with an organization as well as a freelancer. Being a medical writer however demands understanding the requirement of various scientific and regulatory documentation, and surely there has been a dearth of focused training programmes in this area.

We bring to you a unique training opportunity for both aspiring writers as well as seasoned professionals with these two 1-day workshops organized by ISPE on 15th and 16th of November, 2013.

The Basic workshop on day-1 entitled 'Essentials of Medical Writing' is designed to provide the participants with a broad introduction to the field of medical writing, discussing the essentials of writing skills and other general aspects related to scientific documentation. The Advanced workshop on day-2 entitled 'Prototypes of Medical Writing' will allow the participants to learn specifics of developing scientific publications as well as critical regulatory documentation.

Experienced faculty from different spheres of the profession will share their learning in focused intensive sessions dedicated to various aspects of medical writing.

## About ISPE

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ISPE, the International Society for Pharmaceutical Engineering, is the Society of choice for 25,000 pharmaceutical science and manufacturing professionals in 90 countries. ISPE aims to be the catalyst for "Connecting a World of Pharmaceutical Knowledge" by providing members with opportunities to develop technical knowledge, exchange practical experience and collaborate with global regulatory agencies and industry leaders. Founded in 1980, ISPE has worldwide headquarters in Tampa, Florida, USA; its European office in Brussels, Belgium; its Asia Pacific office in Singapore. Visit [www.ISPE.org](http://www.ISPE.org) for additional Society news and information.

## Learning Objectives

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- **At the end of the Day 1- Basic workshop, participants should be able to:**
  - Understand about medical writing as a profession and career
  - Understand what medical writing encompasses
  - Know about skill sets required as a medical writer
  - Learn about literature search the key aspect of any medical writing assignment
  - Apprehend a reviewer's role and responsibilities
  - Recognize the extent of statistics required for medical writers
  - Know about applying project management principles to medical writing
  
  - **At the end of the Day 2 - Advanced workshop, participants should be able to:**
  - Learn in details about publication writing, and regulatory writing; concurrence and difference
  - Receive training with hands-on exercises on writing scientific manuscript
  - Learn to develop a clinical study report as per ICH guidelines
  - Learn about application of lean principles to CSR writing
  - Receive overview of CTD and regulatory applications
  - Receive practical training on developing non-clinical and clinical overviews
- Module 2.4 & 2.5

## Distinguished Workshop Leaders/Facilitators

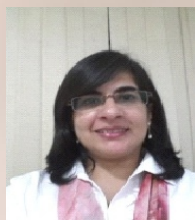
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**Dr Viraj Suvarna MBBS, MD, Msc**

***Medical Director, Boehringer Ingelheim India.***

With more than 15 years of experience in the Indian pharmaceutical industry, Dr Suvarna has spearheaded Medical Affairs as well as Clinical Research & Development in his various positions. Dr Suvarna is a Peer reviewer for Indian Journal of Pharmacology, Executive Committee member of ISCR responsible for Investigator Council; and Section Editor of Perspectives in Clinical Research (the official journal of ISCR). He is the member of Medical, Regulatory and Biotechnology, Ethics and Compliance, IPR and Innovation Committees of OPPI.



**Dr Sonica Sachdeva Batra MBBS, MD, DNB**

***Director, Medical and Scientific Affairs India & Global Head Medical Writing Jubilant Clinsys Ltd.***

Dr Batra has over 10 years of experience across various spheres of academics and Industry including clinical development/operations, medical monitoring/safety management of clinical trials and medical writing expertise across various therapeutic areas for all phases of clinical studies.



**Dr Charu Gautam MD**

***Associate VP, Global Clinical Operations, Clianza Research Ltd.***

Dr C. Gautam is a pharmaceutical physician with about 15 years of experience in academia and industry encompassing Bioequivalence studies, Phase I studies and Phase II/III studies in Oncology, Dermatology, Gastroenterology, Psychiatry amongst others. She has faced several regulatory audits and has been a speaker at various National and International Conferences for Clinical Trials and GCP trainings.



**Dr Hetal Shah PhD**

***Chief-Medical Writing, Arkus Clinical Trial Support Solutions.***

Dr Shah is a Pharmacologist with almost 10 years of first-hand experience in Medical writing as well as Clinical Project Management. She has been extensively involved in developing scientific publications as well as regulatory documentation for various international and national Pharms & CROs.

### Who should attend?

- Professionals, Researchers and Clinicians involved in Medical Writing and Medical Affairs
- Clinical Research professionals interested in Medical Writing
- Regulatory and Publication Writers
- Clinicians keen on publishing their own research
- Academic Scientists / Medical Students / Pharmacy undergraduates & postgraduates / Research associates
- Clinical Pharmacology Scientists
- Pharmacologists
- Outsourcing and Marketing Managers

# REGISTRATION FORM

## Young Pharma Professionals Education Programme (YPEP)

### “The ART and SCIENCE of Medical Writing !”

- Fees:**
- Non - Member - INR 3,500/- either day
  - Non Member - INR 6,500/- both day
  - Member - INR 3,000/- either day
  - Member - INR 5,500/- both day
  - Sponsor / group Discount: For any company deputing more than 5 participants a group discount of INR 200/- Per participant
  - Students: INR 1000/- 1 year ISPE membership [As per ISPE Standard] + Free attendance to Day 1
- For Students - Additional day (Day 2) Charge shall be same as per member charges elaborated here above.

**Name:** \_\_\_\_\_

**Designation:** \_\_\_\_\_

**Organization:** \_\_\_\_\_

**Address for Correspondence:** \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**City:** \_\_\_\_\_ **Pin:** \_\_\_\_\_ **State:** \_\_\_\_\_

**Mob Phone:** \_\_\_\_\_ **Direct Line:** \_\_\_\_\_ **Board Line:** \_\_\_\_\_

**E Mail (at Work):** \_\_\_\_\_ **E Mail (personal):** \_\_\_\_\_

**Payment Details: Cheque / DD No & date:** \_\_\_\_\_

**Issuing Bank , Address & Amount :** \_\_\_\_\_

**Cheques / DD must be made payable in Mumbai to “ISPE India Affiliate”**

**Completed registration form with payment must be sent to:**



**ISPE India Affiliate, 1001 Dalamal House,  
10th floor, Nariman Point, Mumbai 400021  
Tel: +91 22 3008 9475 / 76  
Fax: +91 22 2287 2560**

**Terms & Conditions :** After payment no refund will be given on cancellation, delegate name may be substituted with another, ISPE will not be responsible for any loss or damage, alteration or cancellation by your organization.