LUCKNOW

22 - 23 FEB 2018

Indian Society for Clinical Research
ISCR
Enhancing patient outcomes through clinical research

Indian Society for Clinical Research

Presents

A 2-Day Symposium on Medical Writing

Medical Writing for Non-Medical Writers

CSIR - Central Drug Research Institute, Lucknow, Uttar Pradesh 226031

22-23 February 2018

Indian Society for Clinical Research

Presents

A 2-Day Symposium on Medical Writing

Medical Writing for Non-Medical Writers

CSIR-Central Drug Research Institute, Lucknow, Uttar Pradesh 226031

22-23 February 2018

Introduction – Medical Writing for Pharmaceutical Companies has seen robust growth in India in the last decade. Furthermore, India has a large pool of trained and educated graduates and postgraduates in clinical research, medicine, pharmaceutical and life sciences. However, not many researchers from the nation's best clinical and medical research institutes take up medical writing as a career choice in the industry. This could in part be due to dearth of familiarity about medical writing as a career option as an alternate to the clinical, institutional, laboratory or medical research. To address this and to spread more awareness about medical writing, Indian Society for Clinical Research (ISCR) presents "A 2-day Symposium on Medical Writing" in Lucknow, the city of Nawabs, on 22-23 February 2018. In this two-day symposium, experts in the field of medical writing from Pharmaceutical Companies and Contract Research Organizations (CROs) will provide a high-level introduction to medical writing, which includes regulatory and manuscript writing. The symposium intends to introduce and orient the audience to diverse documents in scope, the competencies required to be a medical writer, and provide insight into career opportunities within medical writing.

Background and Objective – Regulatory medical writing and Pharma publication writing is a complex techno-scientific domain within the pharmaceutical industry. Medical writing in the pharmaceutical industry is different from the regular academic scientific writing, in the sense it involves not only the use of advanced technology (Document Management Systems, Publication Strategy Tools, Structured Authoring using Artificial Intelligence etc), but also project and people management skills. Additionally, the document types to be authored are varied, ranging from protocol study designs, patient narratives, clinical study reports to publications (just to name a few). Most of the regulatory medical writing in India is related to the development and authoring of documents for new chemical entities submitted to the Regulatory Authorities in the US and EU for approval.

Through this workshop, we want to bring awareness about alternate careers, in industries dealing with life science and drug development solutions, for research professionals and medical students. Majority of medical writing jobs in India are provided by IT companies like Tata Consultancy Services, Cognizant and Accenture etc, multinational pharma companies like Novartis, Eli Lilly, NovoNordisk and GSK etc and clinical research organizations like Parexel, IQVIA and SIRO Clinpharm etc.

Scope – To provide an overview on 1) medical writing and medical communications, 2) various documents in regulatory and non-regulatory pharmaceutical domain, 3) regulations governing the writing and submission of medical writing documents, and 4) career opportunities in medical writing in pharmaceutical companies, CROs and other medical writing business organizations

Intended Audience – Life Science, Medical & Pharmacy Graduates, Postgraduates, Research Scholars, Postdoctoral Fellows, Basic & Clinical Research Scientists, & other Clinical Research & Healthcare Professionals

Scientific Committee – Dr. Rajesh Kher (Janssen) – Chairperson, Dr. Roopa Basrur (Parexel), Dr. Jitendra Sharma (IQVIA), Shalini Dwivedi (Kinapse), Dr. Rajesh Pandey (TCS), Shivanand Jigajinni (IQVIA), Dr. Payal Bhardwaj (TCS), Vani Rana (Novo Nordisk), Anushila Vaishali (Novartis), Eti Mehrotra Srivastava (Kinapse)

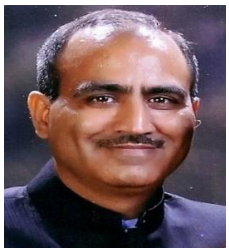
Agenda:

Time	Topic	Speaker
Day 1: 22 February 2018		
08:30 to 09:00	Registration and Breakfast	
09:00 to 09:15	Welcome	Rajesh Kher
09:15 to 10:00	Introduction to Medical Writing	Jitendra Sharma
10:00 to 10:45	Ethics in Medical Writing (copyright/plagiarism/paraphrasing)	Roopa Basrur
10:45 to 11:15	Tea Break & Networking	
11:15 to 12:00	Competencies Required in MW	Rajesh Pandey
12:00 to 13:00	Introduction to Different Types of Regulatory MW Documents	Rajesh Kher
13:00 to 14:00	Lunch Break	
14:00 to 14:30	Regulations in Regulatory Medical Writing (E3/E6)	Shivanand Jigajinni
14:30 to 15:15	Clinical Study Protocol	Vani Rana
15:15 to 15:45	Tea Break & Networking	
15:45 to 16:30	Clinical Study Reports	Anushila Vaishali
16:30 to 17:15	Patient Narratives	Shivanand Jigajinni
17:15 to 17:30	Day Wrap-up	
Day 2: 23 February 2018		
08:30 to 09:00	**Breakfast & Networking**	
09:00 to 10:00	Introduction to Publication Writing	Payal Bhardwaj
10:00 to 11:00	Regulations in Publication Writing	Shalini Dwivedi
11:00 to 11:30	**Tea Break & Networking**	
11:30 to 12:30	Panel Discussion: **Chairperson: Roopa Basrur** **Career Options in Medical Writing**	Jitendra Sharma, Rajesh Kher Shalini Dwivedi, Rajesh Pandey
12:30 to 13:00	**Symposium Close-out**	
13:00 to 14:00	**Lunch Break & Networking**	

Registration Fees:
Students - Rs 2500/-
Non-Students – Rs 5000/-

All registered delegates will get a "Certificate of Participation" from ISCR

For online registration (mandatory for all) - http://www.iscr.org/events-registration/
For online and offline payment - **http://www.iscr.org/payment-events-workshops/**
For more information, please feel free to write to info@iscr.org **or go to** http://www.iscr.org/indian-clinical-research-upcoming-events/



Rajesh Kher, PhD from SGPGIMS, Lucknow is presently working as Director, Global Business Operations of Janssen Regulatory Medical Writing. Prior to this, Rajesh was Associate Director & Head of Medical Writing & Pharmacovigilance at GVK Biosciences, Delhi (2008-10); Sr. Medical Writer at Eli Lilly, USA (2006-08); Assistant Research Professor at IUPUI, Indianapolis & Postdoctoral Fellow/Research Associate at University of Chicago.

Dr Roopa Basrur is Senior Director, Medical Writing Services at PAREXEL and leads a growing team of regulatory medical writers in India. She has over 15 years' experience in Medical Communications, Regulatory and Safety writing and has led and developed teams of writers in both a Pharma and CRO set up.

Roopa has previously held an administrative lead position for the PAREXEL Bengaluru offices and is involved in the company's global inclusive leadership and diversity program. She has a professional development certificate from the European Medical Writers Association (EMWA) and an educational background in medicine, medical law and ethics. Roopa is based in Bengaluru, India.

Dr. Rajesh Pandey is a Physician with MBA in Healthcare and has over 17 years of industry experience. He has vast experience in writing and review of clinical documents in Regulatory writing, Safety writing as well as Scientific Publications. Currently, he is working as Head of Medical Writing at Tata Consultancy Services and is responsible for establishing and growing the Medical writing partnerships, competency development and driving automations in medical Writing.

Dr. Payal Bhardwaj, presently working with TCS as an SME and Medical and Scientific Communications Lead, earned a PhD degree in Gastroenterology from the prestigious All India Institute of Medical Sciences, New Delhi. She has over 17+ year experience in academics, pharmaceutical industry, which encompasses medical writing, clinical research and patient education.

Shivanand Jigajinni, presently working with IQVIA, is an Ayurvedic Physician by education and has a master's degree in Clinical Research. He has over 10 years of experience in medical writing, and is presently heading the Global Narrative Writing group at IQVIA.

Dr. Jitendra Sharma is physician by profession and has completed his MD in pharmacology and Ph.D. in clinical pharmacology. He has over 10 years' experience in academic research, clinical research, pharmacovigilance, market research and medical writing. He currently heads the global QC team for medical writing for IQVIA.

Shalini Dwivedi is currently working as Associate Director (Development Operations) in Kinapse Ltd. She has about 14 years of cumulative experience in academia and medical writing. Shalini is Masters in Pharmacy (Chemistry of Natural Products) from Jamia Hamdard, New Delhi.

Anushila Vaishali, presently working with Novartis Healthcare Pvt Ltd, is a molecular biologist by education and holds MPhil degree in Biotechnology from University of Delhi South Campus. She has over 2 years of experience in Molecular Biology Research and 8 years of experience in Medical Writing. She is currently working as a Senior Medical Writer in Novartis Regulatory Writing Team. She is passionate about medical writing as a profession, mentors new joiners into the writing team and works as an SME for the CVM portfolio.

Vani Rana, presently working with NovoNordisk (Bangalore), is a Medical Writer and has a master's degree in Clinical Research. She has a spent 9 years in the Regulatory Medical Writing field and has been working as an SME in the field. She has worked on an investigational site and also in companies like GVK bio, Kinapse and Novartis in the past. She has worked on variety of regulatory deliverables spread across different therapeutic areas.

Eti Srivastava is currently working as Senior Associate Medical Writer in Kinapse Ltd. She has around 6 years of cumulative experience in academia and medical writing. Eti is post graduate of pharmacy with specialization in Pharmaceutical Chemistry. She has also experience of working on SAS for statistical data management.