

Workshop On
DRUG DEVELOPMENT: CONCEPTUALISATION TO COMMERCIALISATION
(D2@C2) – 2012

Module-II: Medical Writing, Regulatory Affairs & Pharmacovigilance

Day – 1 (27th September, 2012)

09:00 am – 09:15 am	Opening Remarks By Dr. Shashidhar Rao, Novartis
9:15 am – 10:00 am	Medical Writing as a Profession - Key skills, Qualification and Future Prospects Speaker – 1 (Dr. Priyadarshini Roy, Novartis)
10:00 am – 10:45 am	How to write a publication – Views from an editor Speaker – 2 (Dr. Rao Vadlamudi, Hyderabad)
11:15 am – 12:00 pm	overview of Regulatory medical writing Speaker – 3: (Mr. Mayur Kherdikar, Novartis)
12:00 pm – 12:45 pm	Panel interaction (all speakers) with the participants
02:00 pm – 06:00 pm	Workshop on Writing Abstracts and Posters (Dr. Priyadarshini Roy, Mr. Mayur Kherdikar and team, Novartis)

Day – 2 (28th September, 2012)

09:00 am – 09:15 am	Opening Remarks , By Dr Amit Khanna, Novartis
9:15 am – 10:00 am	Global Regulatory Landscape Speaker – 1 (Dr. Sushil Choubey, Novartis)
10:00 am – 10:45 am	Electronic Submission Standards Speaker – 2 (Ms. Rajashri Ojha, Mumbai)
11:15 am – 12:00 pm	Emerging Trends in Regulatory Affairs Speaker – 3 (Ms. Bharti Khanna, Delhi)
12:00 pm – 12:45 pm	Panel interaction with the participants
02:00 pm – 06:00 pm	Workshop - Review of Product Labels in line with the CTD sections (Dr. Sachin Wani /Mr. Syam Musuvathi, Novartis and Ms. Rajshri Ojha, Mumbai)

Day – 3 (29th September, 2012)

09:00 am – 09:15 am	Opening Remarks By Dr Rajesh Ghosh, Novartis
9:15 am – 10:00 am	History and Evolution of Pharmacovigilance Speaker – 1 (Mr. Promit Roy, Novartis)
10:00 am – 10:45 am	Identification and reporting of adverse events Speaker-2 (Dr Shobha Rani, Al-ameen College of pharmacy Bangalore)
11:15 am – 12:00 pm	Analysis and Reporting of the AEs Speaker – 3 (Dr. Sibin Kurien, Novartis)
12:00 pm – 12:45 pm	Panel interaction with the participants
02:00 pm – 05:00 pm	Workshop on Pharmacovigilance – Case Processing, Seriousness Assessment and Medical Analysis (Dr. Mangesh K and team, Novartis)