QUALITY SYSTEMS AND SOP's IN CLINICAL TRIALS

Day: Saturday

Date: May 2nd, 2015

Time: 11:15 a.m. to 12:15 p.m.

Venue: Convention Hall, Symbiosis International University, Lavale campus, Pune

Speakers: Dr. Ganesh Divekar

Dr. Ganesh Diwekar is a clinical research professional, qualified in medicine, management, clinical strategy and inputs, medical writing, project coordination and management, vendor management, and practical hands-on management of phase 1, 2, and 3 clinical trials.

Dr. Diwekar began the session with the case study of Symptom Diary—the "Asthma Trial" done by Pfizer Company a few years ago. He pointed out that random errors do not matter much and are unavoidable, whereas systems errors do matter and are avoidable.

He talked about the purpose of quality systems, which is to ensure consistent delivery. The activities you choose to perform must result in consistent goods or services. He stated that data can never be 100% error free.

He gave a brief introduction to the basis of clinical research, which is that there should be clinical trial in sample population, followed by product approval in entire population. He also discussed "quality clinical study," its elements, methods of improvement, and the systemic approach to quality.

Some of the other subjects that the speaker discussed were as follows: stakeholders in clinical research, quality management system, procedure of clinical trial, training records, difference between quality assurance and quality control, benefits of QMS in the form of PDCA cycle (Plan, Do, Check, and Act), rational approach to QMS, and SOPs.