



Sushma Yedunuri

Regulatory Associate

EXPERIENCE:

- Regulatory Associate, Emergo (India) Consulting Private Limited – 2011 to Present
- Clinical Research Coordinator Intern in Phase II & III studies of Clinical Trials, Yashoda Hospital, Secunderabad – 2010 to 2011

AREAS OF EXPERTISE:

- Clinical Trial Regulations
- Ethics Committee Submissions and Approval
- Drugs & Cosmetics Act
- Maintenance and storage of test drugs
- Audits, Gap Assessments and Risk Assessments
- Coordinating clinical trials
- Training in clinical trial regulations
- AE's, SAE's, ADR's, Unexpected ADR's, SAR's, SUSAR's
- Preparation and documentation of source documents and other clinical trial reports
- CRF and EDC completion
- Investigational Product Accountability

EDUCATION:

- Bachelor of Technology (B.Tech) in Biotechnology, Jawaharlal Nehru Technological University, Hyderabad, India
- Master of Science (M.Sc) in Clinical Research Management, Prist University, Thanjavur, Tamil Nadu, India