About Our Company

Study Mario is an online learning platform that has enabled every learner to grow in their professional career while upgrading their skill set. This is possible while attending college, working on the job, or searching for a job opportunity. We have made this possible by designing an integrated system of live and recorded sessions that considers every need of our learners. All the videos and course content have been developed by experienced industry experts and faculty from prestigious universities in India.

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Introduction to Regulatory affairs, regulatory guidelines and various regulatory bodies(USFDA, EMEA, MHRA, PMDA, CDSCO etc).

Basics of Clinical Trial, types, methods, phases and drug development process.

Understanding of Regulatory approval pathways involved in the approval of drug and other products .

Detailed study of regulatory guidelines as per their applicability to different regulatory bodies (ICH, 21 CFR, WHO, Cgmp, GLP, GCP etc).

Preparation of Technical documents required for regulatory submissions including SOPs, specifications, Modules, administrative applications, SmPC, PIL, clinical summaries etc.

Compilation and filling of dossier as per CTD/ eCTD/ACTD format.

Post-Marketing Regulatory Compliance and Life Cycle Management.

Handling of complaints, queries, product recalls

Regulatory Affairs for Medical devices, Gene and Cell Therapies, and other advanced therapies.

Advanced Regulatory Affairs Case Studies Practical training through real time projects.

Preparation for regulatory affairs job interviews, covering various roles.

*Above sections will be taught by industry experts, who will provide practical insights based on their experience in the field.

PROFESSIONAL CERTIFICATE AND DIPLOMA COURSES ON DRUG REGULATORY AFFAIRS

COURSE BROCHURE

Course Name	Duration
Certification in Regulatory affairs	3 months
Diploma in Regulatory affairs	6 months