

GIRA Introduces
Certificate Program in eCTD
Submission



Electronic Submission The New Age Regulatory
Submissions for
Marketing Authorization
across the world.

Course background

Many countries have started adopting the eCTD standard and are accepting eCTD submission. EMEA has started accepting eCTD Submission for all centralized procedure from 1st January 2010 as a step to mandate eCTD submission, paper submission for centralized procedure are no longer accepted.

The Course guides through various aspects of eCTD giving a complete understanding of what eCTD is and how companies can move from paper base to eCTD. The Program focuses on European and US eCTD Submission and help participants compile and submits and eCTD application.

The Course is designed for students and Pharma professionals who have no or little knowledge in regards to eCTD and its submission. The Course is best suited for Regulatory Affairs professionals or aspiring participants who are looking to enter the Regulatory Affairs Industry

Learning Outcome

- Basic Understanding of CTD & eCTD
- Assist in Compiling & filing an eCTD Application
- Identify EU & US Requirement for eCTD
- Help Companies to move to eCTD from paper based application
- Review eCTD Application.
- Discuss the Technology involved in eCTD Application.

Course Structure

- Introduction and Overview
- CTD Fundamentals & Overview
- eCTD Fundamentals & Details
- Best Practice in preparing eCTD
- Submissions using the eCTD Format
- Life Cycle Management for eCTD
- eCTD Software for Compilation & Validation
- Key Points for Successful eCTD Submission

Course Name	Course Mode	Duration
Certificate Program in eCTD Submission	Part Time Program	3 Months

Who Will Benefit

- Chemists (Research, Quality Control, and CRO) involved in documentation
- Regulatory affairs chemists responsible for CTD/DMF preparation & Submission
- QC/QA Managers and Staff
- Documentation department
- Regulatory Consultants

Eligibility

Life Science Graduate with Experience or Knowledge of Regulatory Affairs

Teaching Methodology

- You will be provide with course & Study material
- You will be provided links to specific reading on eCTD for quick understanding (Links to Power Point presentations, Rules, Guidelines, and Examples on eCTD)
- You will be free to ask any questions/query to the instructor during the course
- **Practical training will be provided at the end of the course for eCTD**

Program Fees – A Small Investment for a better Career

GIRA Program Participation fee for this program is Rs 20,000/- Payment is to be made in the form of Demand Draft/Cashiers Cheque or telegraphic transfer in favor of Global Institute of Regulatory Affairs payable at Pune.

****Early Bird Registration Discount of 20% subjection to registration till 30th April 2012**

How to Join

- Get the Admission Prospectus from GIRA office in Pune by visiting personally or call us at 020-46704472 and email at info@regulatoryinstitute.com
- Fill up and submit the same by prescribed date.
- Pay the fees for admission before the prescribed date

Contact Us

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*If You can't Fly, run.... If you can't
run, walk... If you can't walk, crawl...
But Keep Moving towards your GOAL...*