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2-Day In-Person Seminar:

eCTD Submissions of IND and NDA/BLA to the US FDA

By: **Dr. Mukesh Kumar**, PhD, RAC, Senior Director, Regulatory Affairs, Amarex Clinical Research

Location: May 12-13, 2016 | San Diego, CA

SPEAKER

Dr. Mukesh Kumar, PhD, RAC, Senior Director, Regulatory Affairs, Amarex Clinical Research

Dr. Mukesh Kumar leads the Regulatory Affairs and Quality Assurance departments at Amarex, a full service pharmaceutical product development company based in Germantown, MD (www.amarexcro.com). Mr. Kumar's key expertise is in regulatory affairs, clinical trials and multi-national project management for medicinal and diagnostic products. He has written more than 40 new INDs for FDA submission and reviewed more than 100 INDs. He has been involved in about 100 clinical trials in more than 40 countries, has made several hundred US FDA submissions, and arranged a number of meetings with the US FDA.

In addition, he has had made regulatory submission in the EU and India. He has conducted GCP, GLP, GMP and GACP audits in the US and several countries in Europe and Asia. He has conducted numerous training workshops in FDA compliance related issues. He has authored numerous articles in peer-reviewed journals. He is a well-known expert in global regulatory affairs and has been an invited speaker at several professional and academic organizations worldwide. He is a certified regulatory affairs professional by the Regulatory Affairs Professional Society, USA.

COURSE DESCRIPTION

Soon FDA will stop accepting paper submissions of all kinds of applications. Despite there being extensive information available from FDA and other regulatory bodies regarding eCTD submission, creating one and submitting it through the electronic submission gateway (ESG) of the FDA, is a daunting task even for those proficient in computer systems and coding languages. The off-the-shelf software and consultations available are prohibitively expensive not only in the capital investment required but also in terms of the time needed for getting a submission ready.

This 2-day workshop is designed to address all these and provide the attendees with step-by-step instructions in creating and submitting eCTD submissions for IND, NDA, BLA, and ANDA applications without the need for expensive tools or unreasonable efforts. This no-frills workshop aims to train in the minimum skills needed and provide hands-on practical tips to create eCTD submissions. The trainers will use their own case studies of how eCTD submissions were created and successfully submitted to the FDA using indigenous tools and expertise. Also discussed will be logistical issues associated with managing and maintaining eCTD compliance with regards to all regulatory submissions. This workshop will be beneficial to both the novices and experienced in the field.

AGENDA

Day 1 (8:30 AM – 4:30 PM)

8:30 – 9:00 AM: Registration

9:00 AM: Session Start Time

9:00 – 10:30 AM: Lecture 1: Introduction to eCTD

- The difference between CTD and eCTD
- FDA and ICH guidance documents
- Technical resources needed to get started: IT, regulatory and medical writing
- Programmable versus purchased elements
- Overview of a CTD: Modules 1-5
- Practical rules for modular creation components
- Planning for hyperlinking, cross-linking and understanding XML, DTD, SPL, etc.

10:30 – 10:45 AM: Break

10:45 – 12:30 Noon: Lecture 2: Ground Rules for Writing, Formatting and Updating Content

- Formatting and version control for content intended for electronic submission
- Using MS Office and Adobe elements to create e-ready documents
- Hyperlinks and cross-links in an XML environment
- Best practices for MS Word and Adobe PDF in an eCTD environment
- Off-the shelf software versus manual editing

12:30 – 1:15 PM: Lunch

1:15 – 2:45 PM: Lecture 3: Module 1 of an eCTD

- Organization of Module 1
- IT & Regulatory Responsibilities
- Forms, certifications, and other components of Module 1
- Application fees, waivers, and correspondence
- NDA pre-submission number requests, secure email set-up
- National and multi-national applications
- Handling Amendments to M1

2:45 – 3:00 PM: Break

3:00 – 4:30 PM: Lecture 4: Module 2: Summaries in an NDA

- Descriptions of each section of Module 2
- Granularity requirements
- Cross-linking Module 2 with Modules 3-5
- Writing styles for summaries and review of information
- Use of Tables, lists, figures and flow-charts
- Handling Amendments to M2

Day Two (8:30 AM - 3:30 PM)

8:30 – 10:00 AM: Lecture 5: Module 3: CMC Information Presentation

- Organizing the CMC information in an NDA
- Granularity and limitations of each section
- Minimum requirements for reports, testing data, and other documents
- Managing large files
- Content duplication and reference limitations
- Handling Amendments to M3

10:00 – 10:15 AM: Break

10:15 – 12:00 Noon: Lecture 6: Modules 4 and 5: Bulk Data from Non-Clinical and Clinical Studies

- CTD/ICH format for study reports
- General organization of study reports in Modules, Study Tagging Files, Study Data Specifications
- Linking Module 2 with Modules 3 and 4: Micro-summaries verses Macro summaries
- Managing different PDF files: scanned verses de novo
- Cross-linking and hyperlinking: pivotal verses non-pivotal studies
- Handling Amendments to M4 and M5

12:00 – 12:45 PM: Lunch

12:45 – 2:15 PM: Lecture 7: Putting the Whole Submission Together

- Cross-Referencing between Submissions
- Compiling the full eCTD, Submission Lifecycles, Singular vs. Grouped Submissions
- Validation of Submission Materials
- Acknowledgment and tracking submissions

2:15 – 2:30 PM: Break

2:30 – 3:30 PM: Lecture 8: Introduction to the FDA's ESG

- What is the Electronic Submission Gateway (ESG)
- Submitting to the electronic document room versus ESG
- Stepwise instructions in creating an ESG account: Hardware and software, ESG Checklist
- Set-up, validation, and testing of ESG accounts
- Virus scanning requirements and uploading to ESG
- Direct versus Web-trader accounts

WHO WILL BENEFIT

- Regulatory affairs professionals preparing IND, DMFs, NDAs and other submissions
- Medical and Technical writers
- Project Managers, Directors
- Supervisors, and lead workers in Regulatory Affairs
- Quality Assurance and Quality Control
- IT professionals looking to make eCTD submissions

Registration Form

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Seminar Topic: eCTD Submissions of IND and NDA/BLA to the US FDA

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