Two Day in Person Seminar on eCTD Submissions of IND and NDA/BLA to the US FDA: Hands-on Workshop

Washington DC | July 13-14, 2015

Creating and submitting eCTD submissions for IND/NDA/BLA applications

WORKSHOP SUMMARY

In the wake of FDAs decision to stop paper submissions of all kinds of applications, 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.

For additional information on the workshop agenda and logistics, call 410-501-5777 or email: info@fdamap.com

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, and IT professionals looking to make eCTD submissions.

HOW TO REGISTER FOR THE WORKSHOP:
To register online and avail up to 40% discount please visit: http://bit.ly/19kasL4

Conference material will be given on the spot if it is available after distributing to other attendees. In case it is not available we will send the material after the conference is over. After we receive the payment from the registered attendee an electronic event pass will be sent to the email address associated with the registrant before 5 working days from the seminar date. Please bring the pass to the venue of the event.

YOU WILL ALSO GET:
- The opportunity to ask individual questions
- Encapsulated information all at one place
- Case-studies to highlight best practices

USEFUL AND UNIQUE GIVEAWAYS:
- Templates of and step-by-step instructions for successful eCTD submissions for IND/NDA/BLA applications
- One hour of one-on-one personalized consultation with the trainer free for all registrants on a first-come, first-serve basis
AGENDA

Day 1: 8:30AM - 3:30PM

- **Session I: 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.

- **Session II: 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, off-the-shelf software versus manual editing

- **Session III: 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

- **Session IV: 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, and flow-charts.

Day 2: 8:30AM - 3:30PM

- **Session V: 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 Module 3

- **Session VI: 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 versus Macro summaries, managing different PDF files: scanned verses de novo

- **Session VII: 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

- **Session VIII: Introduction to the FDA’s ESG**
  What is the Electronic Submission Gateway (ESG), submitting to the electronic document room versus ESG and instructions in creating an ESG account.

VISIT DETAILED AGENDA: For detailed workshop agenda, please visit [http://bit.ly/1LVLzHP](http://bit.ly/1LVLzHP)

SPEAKER

Dr. Mukesh Kumar, PhD, RAC
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Amarex Clinical Research, Germantown, MD USA

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). His key expertise is in regulatory affairs, clinical trials and multi-national project management for medicinal and diagnostic products. He has conducted more than 200 successful meetings with FDA. He has also conducted numerous training sessions for implementing eCTD submissions for IND applications.

View Detailed Agenda  |  FDAmap.com  |  Forthcoming Workshops
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