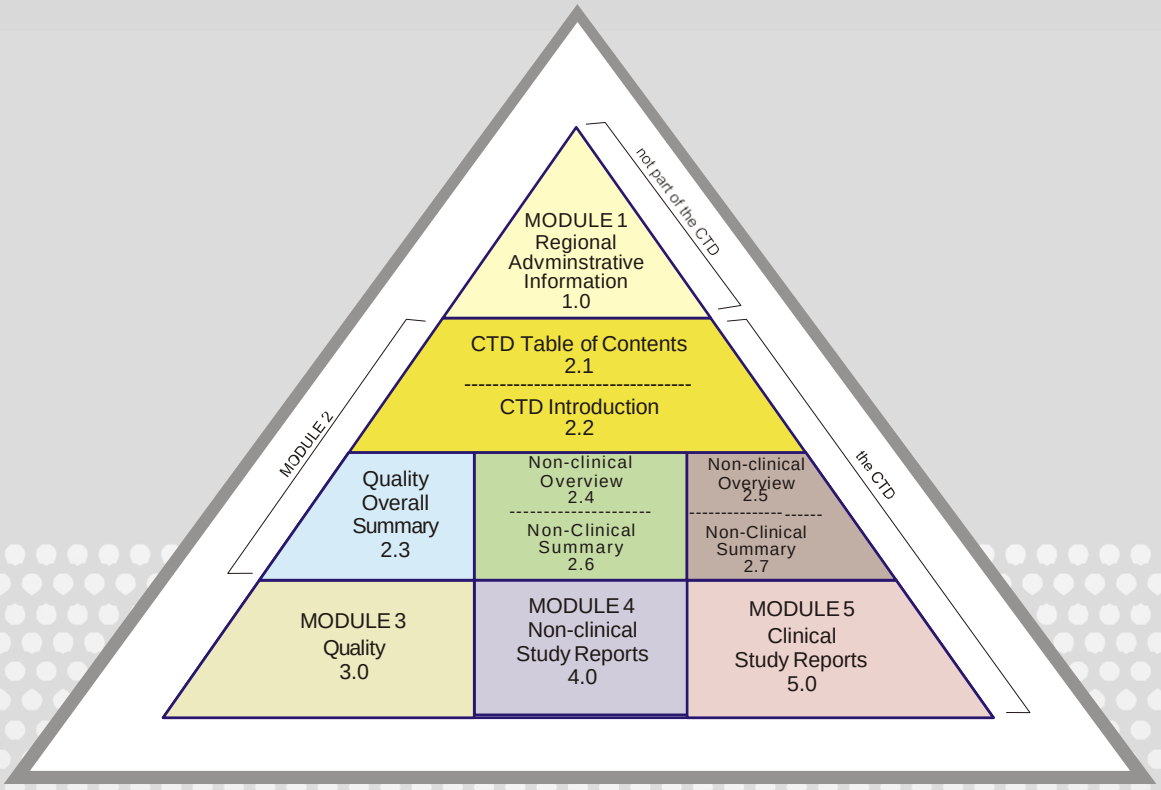
مركز صالح عبدالله باوزير للاستشارات المهنية

Prof. Bawazir Pharma Consulting Center

Common Technical Documents (CTD) and eCTD preparation

9 March 2022

Riyadh, Saudi Arabia



Presents

Training Workshop on

Common Technical Documents (CTD) and eCTD preparation

For online Registration please visit https://www.bawazirpharma.com/

2022
Riyadh, Saudi Arabia

OVERVIEW

This course will offer insight into the compilation of the eCTDs, share experience and best practices gained during eCTD submissions in the GCC, explain the eCTD review and lifecycle process and the upcoming eCTD requirements.

LEARNING OBJECTIVES

Every regulatory professional should have a solid understanding of the standards, groundwork, expertise and technology required to submit compliant eCTD submissions. This begins with understanding what will be accepted and what will not. Put yourself and your company a step ahead of competitors by understanding the technical skills and regulatory requirements necessary to meet the impending eCTD mandates.

At the conclusion of this course, participants will be able to:

- Participate in the preparation of the eCTD including "submission ready documents"
- Recognise eCTD requirements on a regional and ICH basis
- Create and submit technically valid GCC eCTDs
- Prepare to move from a paper to eCTD process
- Describe technology used for eCTD compilation, validation and review
- Understand the difference between eCTD and NeeS submission
- Have an overview on future eSubmission development

KEY TOPICS

- Overview of eCTD readiness at the agencies
- Impact of the eCTD on regulatory processes and procedures
- Practical experience of submitting an eCTD in the GCC
- eCTD compilation and lifecycle management
- eCTD Validation
- Document granularity and readiness
- Technical issues
- Specifications and standards

WHO WILL ATTEND

Professionals working in:

- Pharma Regulatory Affairs
- Scientific Office Managers
- Regulatory Authorities.
- Dossier Management
- Pharmacist
- Compliance
- Submission Management/Electronic Publishing
  Data Management / IT

Bawazir Pharma Approach

Bawazir Pharma approach is grounded in the belief that compliance and quality should be managed as any other critical business issue. Proper quality management and a state of regulatory compliance will result in a decrease in direct costs such as rejects, and indirect costs such as adverse events and recalls.

Bawazir Pharma offers professional services to complete all aspects of an eCTD submission. The depth of our experience and knowledge acquired from our work with the Regulatory authorities, ICH, International Standards Organization is made available to our partners. Our team can guide your organization through compilation of an original submission, perform submission maintenance and step in to support your internal staff during workload peaks.

Building Trust Between
Regulators and Industry

EXPERT TRAINER

Prof. Saleh A Bawazir

CEO, Bawazir Pharma Consulting Center
EX-Vice President for Drug Sector (SFDA)

Professor Bawazir worked for eight years as an advisor to the Minister of Health for pharmaceuticals. During his work he chaired the committee that revised and updated the pharmacy law, updated drug registration procedures and established pharmaceuticals pricing guideline. He also represented the Ministry of health in the national committee that negotiate Saudi Arabia accession to the World Trade Organization (WTO) and the committee that establish the Saudi Food and Drug Authority (SFDA).

For the last nine years Professor Bawazir worked as vice president for drug affairs and advisor at the SFDA. During his work he led the drug sector development through a strategic plan and managed to establish a state of the art drug regulatory system that ensure quality, safety and efficacy of the pharmaceutical products and contributed positively to overall publichealth. Underprofessor Bawazir supervision the SFDA built many electronic databases and regulatory framework that implement electronic Common Technical Document (eCTD) for drug submissions and established a strong regulatory framework for clinical trials and construct the Saudi Clinical Trial Registry (SCTR) Database. Under professor Bawazir leadership the drug sector at the SFDA is recognized as a leading drug authority in the region and worldwide. Furthermore, Professor Bawazir represented the GCC for the last eight years in the Global Cooperation Group under the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)

Program Details

8:45 INTRODUCTION, LOGISTIC

09:00 – 10:30 SESSION1

INTRODUCTION TO ICH, CTD AND eCTD

- Background on the ICH
- Outline the basic CTD format
- Brief Overview on CTD Content
- ICH guidance documents
- Approach of Health Authorities
- The eCTD Language
- Terms Definition
- eCTD characteristics & terminology
- Differences between CTD and eCTD

10:30 – 11:00 Coffee BREAK

11:00 – 12:30 SESSION 2

FRAMEWORK FOR REQUIRED ELECTRONIC SUBMISSIONS

- Requitements (Infrastructure)
- Mandatory Document
- Modularity of submission components
- eCTD specifications
- Regional Specifications
- Validation Products
- Best Practices
- The eCTD Language

12:30 – 13:30 LUNCH BREAK

13:30 – 15:30 SESSION 3

Hands on experience continued.

- General Principles of eCTD.
- Backbone eCTD Vs. NeeS
- Validation criteria
- Overview of the eCTD Software

16:00 END OF TRAINING COURSE

FOR REGESTRATION CLICK LINK BELOW

https://www.bawazirpharma.com/

Payment can be made Online or by Bank Transfer

FEES	SAUDI RIYAL
Registration fees	2000.00
Early Birds Registration Fee Pay Your Fees Before 6 _March_2022	1500.00

Bank Account Details

NAME :Saleh Abdullah Bawazir Pharma Consulting Center

مركز صالح عبدالله باوزير للاستشارات المهنية

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- SAR 1000.00
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