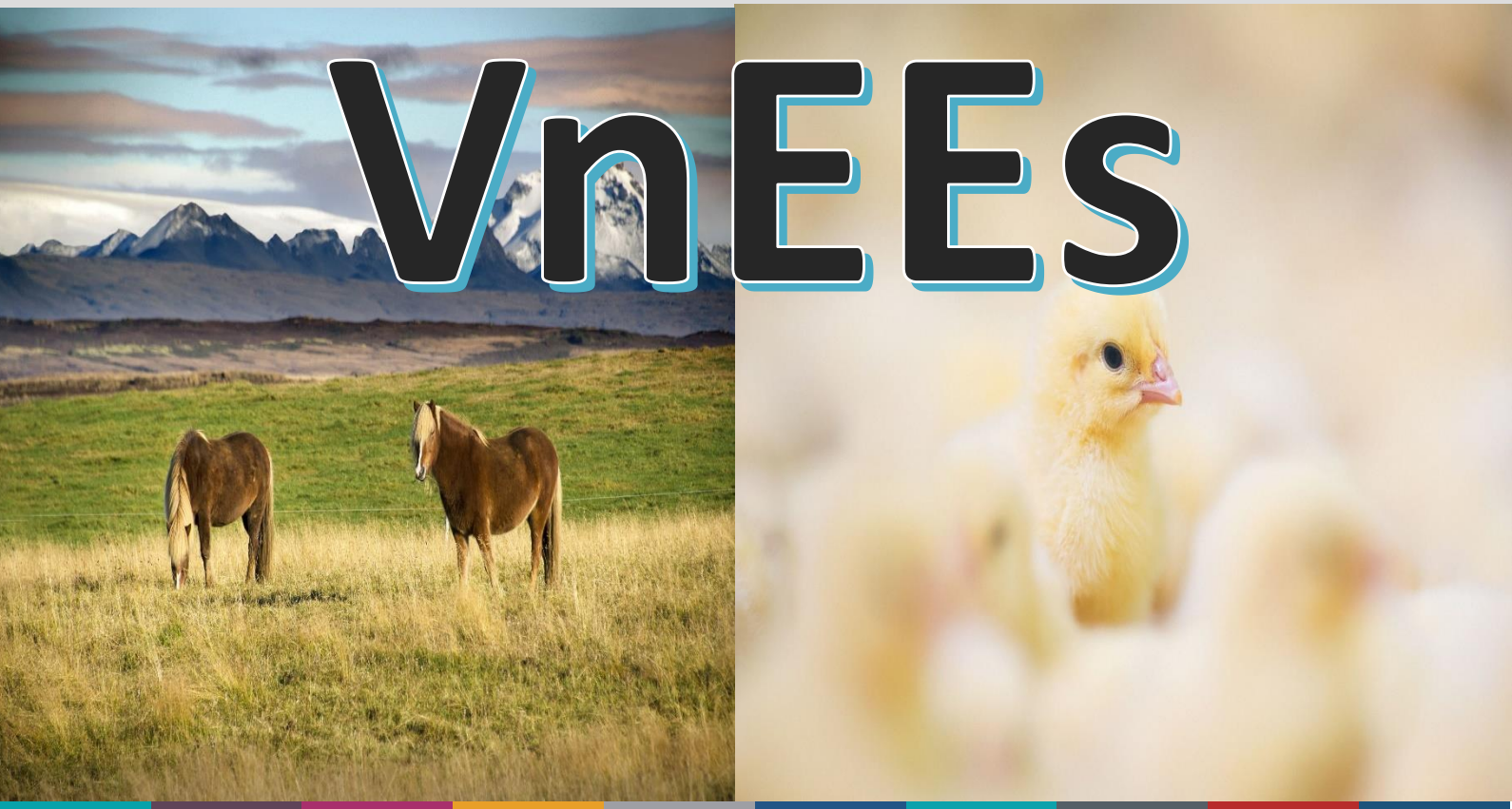
مركز د. صالح عبدالله باوزير للاستشارات الصيدلية

Prof. Bawazir Pharma Consulting Center

Preparing VNeeS Submission

11 April 2021

Riyadh, Saudi Arabia



Presents

Training Workshop on

Preparing VNeeS Submission

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

11 April, 2021
Riyadh, Saudi Arabia

OVERVIEW

This course will offer insight into the compilation of the VNees, share experience and best practices gained during VNees submissions to SFDA.

LEARNING OBJECTIVES

Every regulatory professional should have a solid understanding of the standards, groundwork, expertise and technology required to submit compliant VNees 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 VNees mandates.

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

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

KEY TOPICS

- Overview of VNees readiness at the agencies
- Impact of the VNees on regulatory processes and procedures
- VNees compilation and life cycle management
- VNees 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

The 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.

The Bawazir Pharma offers professional services to complete all aspects of an VNees 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.

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Program Details

DAY 1

09:00 -10:00 SESSION1

INTRODUCTION TO VNeeS

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

10:00 - 11:00 SESSION 2

VNees Data Requirements

- Granularity
- Root Folder
- Administrative Information Folder
- Veterinary Folder structure
- Response to Questions
- Roadmap

11:00 - 11:30 COFFEE BREAK

11:30 - 13:00 SESSION 3

Hands on Experience of the software

- General Principles
- VNees Backbone
- NeeS Specifications
- Validation criteria differences

13:00 – 14:00 LUNCH

Session 3 Continued 14:00 – 15:30

15:40 END OF TRAINING COURSE

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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 (VNees) 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)

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REGESTRATION

Program in Riyadh, Saudi Arabia, 11 April, 2021

REGISTRATION FEES

Registration fee including refreshment breaks and lunches and training course material

FEES	SAUDI RIYAL
ADMISSION FEES	SAR 2000.00
EARLY BIRDS REGISTRATION FEE PAY YOUR FEE BEFORE 10 April, 2021	SAR 1500.00

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Payment can be made by telex transfer or Bank Transfer

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- SAR 1000.00
- If you do not cancel one week prior to the event start date and do not attend, you will be responsible for the full registration fee.
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