eatris TRANSVAC

TRANSVAC E-LEARNING COURSE

10 hours
Investment time

Online self-paced course on Regulatory aspects of vaccine development

Introduction

Find out how to navigate the regulatory maze, plan a regulatory strategy and prepare a dossier for National Competent authorities or EMA

CMC development

Learn about Chemistry, Manufacturing and Control (CMC) aspects of vaccine development, along with regulatory guidance on production process and validation assays

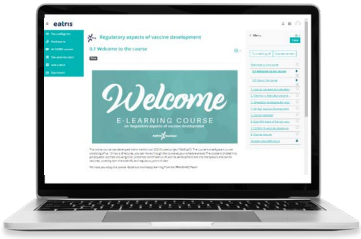
Preclinical & clinical

Explore the regulatory landscape for preclinical and clinical testing, including relevant animal models, clinical trial design, efficacy endpoints and clinical trial application

Cancer vaccines & ATMPs

Understand the scientific basis and regulatory landscape for cancer vaccines and ATMPs with highlights on CMC, nonclinical and clinical aspects for cancer vaccines

- The course is designed for professionals working on vaccine development who are in need of an introduction to the (EU) regulatory requirements associated with the field.
- The course covers mainly prophylactic vaccines including CMC, preclinical and Phase I-II of vaccine development, and touches on therapeutic and cancer vaccines as well, both from the scientific and regulatory point of view.



Sign Up

Speakers:

Dr. Giovanni Migliaccio
EATRIS / CVBF

Dr. Christopher Mann
Asphalion

Dr. Leo van der Pol
Intravacc

Dr. Lucia Gabriele
Istituto Superiore Di Sanita

Dr Rosan Kreeftmeijer-Vegter
EATRIS

1. How to navigate the regulatory maze

In this first learning unit, you will be introduced to regulatory science, the development pathway of a vaccine, how to plan for drug development and the relevant competent authorities operating in the field of vaccine development.

After completing this learning unit you will be able to

- Describe the relevant competent authorities overseeing the safety and efficacy of vaccines
- Understand where to get technical guidance
- List the different Good practices applicable to vaccine development
- Define the most important components of a drug development pathway
- Understand how Reverse planning and a Target Product Profile can help draft your development plan
- Plan a regulatory strategy for your product
- Use EATRIS Regulatory Database to support vaccine development

Speakers:

Dr. Giovanni Migliaccio
EATRIS / CVBF

Dr. Jitka Rychlíčková
Masaryk University/ St. Anne's University Hospital Brno

2. Chemistry, Manufacture and Control

In this Chemistry, Manufacturing and Control Unit, you will get an overview of the key concepts of CMC and the available regulatory guidance for production process and validation assays.

After completing this learning unit you will be able to

- Distinguish between the different types of vaccines
- Recognize and describe the basic GMP principles required for vaccine production
- List the steps of the vaccine manufacturing process
- Understand where to get regulatory guidance for CMC development
- Recall important aspects of the CMC process validation and relevant analytical assays used in CMC
- Appreciate the importance of monitoring relevant Critical Quality Attributes (CQA), Critical process parameters (CPP) and Critical Material Attributes (CMA) of vaccines

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EATRIS

3. Regulatory landscape for preclinical testing

In this unit, we will look at regulatory landscape for preclinical testing of vaccines. You will get an overview of the main preclinical requirements to qualify the product for first-in-human (FIH) clinical trials, which are intended to identify possible risks, pre-emptively identify any toxicity, and facilitate the transition to clinical studies

After completing this learning unit you will be able to

- Understand what regulations apply to vaccine animal testing
- Differentiate between the 3 critical phases of non-clinical development (PD, PK and toxicity)
- Define the purpose of animal testing
- Identify key questions for the non-clinical development path
- List the types of studies and relevant animal models used for vaccine testing
- Recall important alternatives to animal testing
- Understand the relationships between non-clinical testing and CMC development and clinical testing

Speaker:

Dr. Christopher Mann
Asphalion

4. Clinical Vaccine Development

This learning unit will focus on the key clinical questions that a vaccine will need to address as well as the regulatory procedure and documentations for the initial clinical trial application (CTA) through to the end of its lifecycle.

After completing this learning unit you will be able to

- Understand what regulations apply to vaccine clinical testing
- Differentiate between the different phases of clinical development
- Identify key questions for the clinical development path of a vaccine
- Recognize and describe the basic GCP principles required
- Understand the impact of the Clinical Trial Regulation (CTR) and the Clinical trials Information System (CTIS) on how clinical trials are managed in the EU
- List clinical trial types and aspects of the clinical trial application (CTA) process including required documentations and timelines
- Recall important alternatives to standard efficacy trials in vaccine development

Speaker:

Dr. Christopher Mann
Asphalion

5. Cancer vaccines and ATMPs

This learning unit will overview the main regulatory requirements for the development of vaccines for cancer indications including preclinical and clinical requirements that will need to be taken into account even from an early stage.

After completing this learning unit you will be able to

- Differentiate between classical vaccines, cancer vaccines and Advanced Therapy Medicinal Products (ATMPs) from a regulatory point of view
- Understand the relationships between EU legislation, Good
- Practices and applicable guidelines for cancer vaccines
- Describe the specific regulatory considerations and developmental issues of cancer vaccines as compared to regular vaccines
- Recall important aspects and constraints when establishing a manufacturing workflow for ATMPs
- List the most important differences in non-clinical and clinical study types between cancer vaccines and regular vaccines.

Speaker:

Dr. Christopher Mann
Asphalion

6. Scientific basis of Cancer vaccines

In this unit, we will highlight the great potential of cancer vaccines in the era of personalized medicine. We discuss the intertwined relationship between the immune system and the different types of cancer vaccines while highlighting their (dis)advantages and strategies to improve their performance.

After completing this learning unit you will be able to

- Understand how the immune response to cancer vaccines works
- Identify the key immune elements responsible for inter- and intra-individual variations in the antitumor immune response
- Understand the interactions and dynamics between immune and cancer cells at the Tumor Microenvironment level
- List the advantages and disadvantages of the different cancer vaccine platforms
- Describe strategies to improve the performance of cancer vaccines
- Understand the role of immune biomarkers for a successful cancer vaccination
- Recall the definition of personalized medicine

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