

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

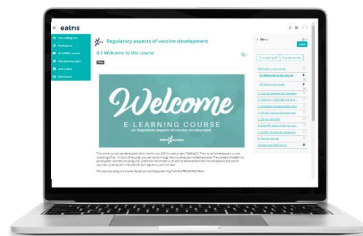
Explore the regulatory landscape for preclinical and clinical testing, including relevant animal models, clinical trial design, efficacy endpoints and clinical trial application



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.



Speakers:



Dr. Giovanni Migliaccio
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Dr. Leo van der Pol
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