Regulation of Biologics

This learning journey is designed to introduce the regulation of biologics, applicable guidelines, considerations, challenges, and information on the approval process. Both the US and EU regulatory schemes are discussed in this journey.

Legal evolution of drug approval and definition of terms

Extract from:
'Development of a cancer drug'
Prof. Martin Edelman
Fox Chase Cancer Center, USA

3 mins

ICH guidelines including safety

Extract from:
'Overview of nonclinical safety assessment'
Dr. Claudette L. Fuller
Merck Research Laboratories, USA

4 mins

Regulatory considerations for cellular and gene therapy products – opportunities for interaction with FDA

Extract from:
'Development and regulation of cellular and gene therapy products: FDA perspective'
Dr. Larissa Lapteva
Center for Biologics Evaluation and Research, FDA, USA

4 mins

Advanced therapy medicinal products – route of approval in Europe

Extract from:
'Regulation of ATMPs in Europe: present and future'
Dr. Ana Hidalgo-Simon
European Medicines Agency, The Netherlands

4 mins

Regulation of medical device combination product

Extract from:
'Biological safety testing: supporting medical device combination products'
Dr. Christine L. Lanning
Merck & Co., Inc., USA

3 mins

Regulatory challenges of accelerated vaccine development

Extract from:
'Challenges of accelerated vaccine development'
Dr. Jakub Simon
Director of Clinical Research, Vaccines, Merck Research Laboratories, USA

3 mins

Drug approval tracks and New Drug Application

Extract from:
'Development of a cancer drug'
Prof. Martin Edelman
Fox Chase Cancer Center, USA

6 mins

New Drug Approval package and activities after submission

Extract from:
'Drug development: from discovery to manufacture'
Prof. Michael Kinch
Washington University in St. Louis, USA

3 mins

FDA review and approval

Extract from:
'Development of a cancer drug'
Prof. Martin Edelman
Fox Chase Cancer Center, USA

2 mins