ACADEMIC TOOL – METHODS

Elementary
Advanced
Postdocs

Information Seminar - Drug Approval & Regulatory Affairs

Trainer

Dr. Bettina Klug, MSc

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Graduation in Medicine at the Johannes Gutenberg University, Mainz (Germany). Degree in Immunology from the Pasteur Institute, Paris and a Master Degree in Infectious diseases of the London School of Hygiene and Tropical Medicine.

Objective

The course provides an oversight of the regulation of medicines for human use in the European Union (EU).

Description

The course provides an overview of the key aspects of the European regulatory system, and the key players.
A brief introduction into the current clinical trial application procedures (CTA) and the dossier requirements to support a CTA-submission is provided, followed by an outlook on the future European CTA procedure according "Clinical trials - Regulation EU No 536/2014".
The different regulatory pathways for a marketing authorization for new medicines in Europe, i.e. national procedure, decentralized procedure and centralized procedure, are presented with a special emphasis on the centralized marketing authorization procedure which is mandatory for biotechnological medicinal products.
Finally a brief overview of the incentives, including the support for small and medium-sized enterprises to encourage the development of new medicines, is provided.

Organizational Information

Language	Englisch
Target group	Doctoral Candidates at all stages and Postdocs from Natural and Life Sciences
Date	Tuesday, 14 November 2017, 14:00-17:00
Registration	**For registration click here**