Lecture Series

„Regulatory Science and Translational Research"

Dr. Christian K. Schneider, Head of BioPharma Excellence and Chief Medical Officer (BioPharma) at PharmaLex GmbH

Who is Christian Schneider?

Head of BioPharma Excellence and Chief Medical Officer (BioPharma) at PharmaLex GmbH since September 2021.

Interim Chief Scientific Officer at the Medicines and Healthcare products Regulatory Agency (MHRA) in Great Britain, 2020 - 2021.

Director of the National Institute for Biological Standards and Control (NIBSC) in Great Britain 2016 – 2020

Medical Head of Division Medicines Licensing and Availability, Danish Health and Medicines Authority, 2013 - 2015.

Chair of the Committee for Advanced Therapies (CAT); European Medicines Agency, 2009 – 2013.

Chair of the CHMP Working Party on Biosimilar Medicinal Products (BMWP), 2007-2016.

Before:

Member of the Committee for Medicinal Products for Human Use (CHMP).

Senior Medical Officer at the Danish Medicines Agency

Head of Division EU Co-operation/Microbiology at the Paul-Ehrlich-Institut.

4. Lecture:

Title: "Risk-based approaches in translational medicine"

- Definition
- Case studies

Date: Monday, 27 February 2023

Time: 11:00 a.m.

Where: Online via Zoom

Target audience: advanced students (1. state exam medicine and life sciences) as well as interested audience from the fields of clinical and translational research

Background

„Regulatory Science" or „regulatory research" aims at assisting translational research and medicinal product development by systematically analysing and evolving existing regulatory frameworks (including both requirements and possibility for assistance for commercial and non-commercial developers). This evolution of regulatory frameworks should happen alongside the needs of translational medicine. The role of the regulator and the regulatory agency is changing: The regulator is not only a „gatekeeper", but also an „enabler" of medicinal product development – and thus of translational medicine.

Regulatory science is also an enrichment for basic science, since virtually every research project in basic science can find a translational application, e.g. intracellular signaling pathways for the future development of biomarkers, which can then lead to further projects, e.g. definition of patients responsive to certain treatments etc. Regulatory science can therefore help continuing and expanding basic science projects.

The lecture curriculum „Regulatory Science and Translational Medicine" provides training in regulatory science for advanced students and colleagues in translational and basic science who wish to receive further training and in-depth knowledge in this field.

Lecture series contents

Why is knowledge in regulatory science important for translational medicine and basic science?

- The role of regulatory agencies in translational medicines
- Medicinal product development in research project (often without knowing it!)
- Non-clinical science (in-vitro test systems and animal models) – regulatory science helps in optimization.

First-in-human clinical studies with biotechnology-derived medicines

- Basic principles
- What is special for vaccines?
- What is special for gene therapies?
- What to do if non-clinical approaches are limited?

Non-clinical development of gene and cell therapies as a paradigm of translational research

- Basic principles
- Regulatory check lists or individualized and focused development?

Risk-based approaches in translational medicine

- Definition
- Case studies

Interaction with regulators, e.g. in preparation of a first clinical study

- What are the possibilities?
- How does one plan this interaction optimally? What to do as an academic group?
- Which special possibilities does one have when developing „Advanced Therapies“ (gene therapies, cell therapies, tissue engineering products)?
- From practice: How does a Scientific Advice meeting with regulators look like? What happens there? How to prepare?