TRANSPARENCY AND TRUSTWORTHINESS IN DRUG DEVELOPMENT

Over the last few decades, complex systems of accountability have been designed to increase transparency and build trustworthy relations between healthcare institutions, the pharmaceutical industry, patients and society as a whole. However, many of these systems have had the converse effect and do not always work as intended.

Dilemmas of transparency and trustworthiness are unavoidable when working in drug development. This course provides a space where you can debate real life cases with relevant stakeholders.

Pharmaceutical ethics awareness enables you to develop innovative ways to increase transparency and trustworthiness throughout the whole life cycle of a medicinal product. Understanding the different stakeholders’ perspectives and dilemmas, will provide you with better tools and arguments to put together a trustworthy regulatory dossier.

WHAT YOU WILL LEARN
After the course you will be able to:

• Understand and deal with contemporary issues affecting transparency and trustworthiness in the development, approval, accessibility and use of pharmaceutical products
• Develop innovative ways to increase transparency and trustworthiness throughout the whole life cycle of drug development using pharmaceutical ethics awareness
• Understand how the values embedded in pharmaceutical ethics, beyond simply complying with legislation, will enable you to prepare a more sound and trustworthy regulatory dossier.

COURSE CONTENT
This course centres around five real life cases illustrating contemporary dilemmas affecting transparency and trustworthiness in the development, approval and use of pharmaceutical products. Moreover, we will cover the viewpoints of the main stakeholders involved in these processes.

Module 1: Ethical dilemmas linked to data-intensive healthcare: a nationwide comparison about the public and professionals’ distrust of the public administration of healthcare data.
Module 2: Adapting the regulatory framework towards the patient’s needs: ethical challenges faced when making regulatory decisions based on scarce scientific evidence.
Module 3: Revisiting the paradigm of autonomy and informed consent in the light of the ever-increasing globalization of clinical trials.
Module 4: Ethics after post-authorization: communicating benefit/risk proactively and transparently.
Module 5: When drugs are available but not affordable: ethical dilemmas on unequal access to pharmaceutical treatments.

The course combines group work, lectures, and panel discussions with experts, decision-makers, patients’ representatives and industry professionals.

“Good course. Well-selected and relevant topics.”

Mikhail Kalinichev, Director, Ipsen Innovation on the course Market Access for Pharmaceutical Products, 2017
PARTICIPANTS
The course is intended for professionals working with the development, approval and reimbursement of pharmaceuticals.

The course is preapproved as a compulsory course in the Master of Medicines Regulatory Affairs (MRA) programme and as an elective course in the Master of Industrial Drug Development (MIND) programme.

Participants must:
• Hold a relevant bachelor’s degree or equivalent
• Have a minimum of 2 years of relevant job experience
• Be proficient in English

COURSE DATES
5 days, August 20 – 24, 2018, 9:00 – 16:30 at the University of Copenhagen, South Campus.

COURSE DIRECTORS
Lourdes Cantarero-Arévalo, Associate Professor, Department of Pharmacy, University of Copenhagen.

OTHER COURSE TEACHERS
Marieke De Bruin, Professor, Director of the Copenhagen Centre for Regulatory Science (CORS), University of Copenhagen
Klemens Kappel, Professor, Department of Media, Cognition and Communication, University of Copenhagen
Dr. Mark Flear, Senior Lecturer, School of Law, Queens University, Belfast
Sofia K. Sporrong, Associate Professor in Social and Clinical Pharmacy, University of Copenhagen
Sinan Badakci Sarac, Chief Medical Officer at the Danish Medicines Agency, member of the European Medicines Agency, CHMP
Birthe Ryskov, European Rare Diseases, Eurordis Denmark
Henrik Harksen, External Associate Professor, Department of Pharmacy, University of Copenhagen
Dr. Rosemarie Bernabe, Marie Curie Postdoctoral Fellow, Centre for Medical Ethics, University of Oslo

Karen Brøndum-Nielsen, Professor, Chair of the National Committee on Health Research Ethics, Denmark
Karim Friis-Bach, Danish Politician, Copenhagen Capital Region
Vibeke Bjerregaard, Former Senior Regulatory Affairs Project Manager, Novo Nordisk
Dr. Jonathan Ives, Senior Lecturer, Deputy Director - Centre for Ethics in Medicine, Bristol Medical School, University of Bristol

The course will also include additional speakers.

COURSE FEE
EUR 2,680/DKK 19,900 excl. Danish VAT. Fee includes teaching, course materials, examination and all meals during course.

Students following Master’s programmes are entitled to a price discount. Please contact csu@adm.ku.dk for details.

EXAMINATION
Course participants have the option of acquiring 4 ECTS credits by submitting a written essay based on a real life case of their choice or provided by the course convener. The essay should be written using the reference list provided as compulsory reading material and has to be submitted at the latest by 7th September 2018 at 14:00. The submission of the written essay is compulsory for students enrolled in the Master of Medicines Regulatory Affairs.

FOR MORE INFORMATION AND REGISTRATION:
copenhagensummeruniversity.ku.dk

“Very educational. Teachers are very passionate and knowledgeable.”
Wendy van Loon, Quality Assessor, Medicines Evaluation Board on the course Quality by Design in Pharmaceutical Development, 2017