19 – 23 AUGUST 2019, 9:00 – 16:30	EUR 2,680 / DKK 19,900 EXCL. DANISH VAT

Copenhagen Summer University

REGULATORY ISSUES IN PHARMACEUTICAL DEVELOPMENT

Regulatory legal issues in the area of pharmaceuticals are rapidly growing in importance, not only because the legal framework is in a seemingly constant state of flux, but also because this area of the law is increasingly proving itself one of the crucial elements in the toolbox of pharmaceutical and biotechnological companies when launching new products and drugs onto the market.

"Very well structured and organized"

Jasmina Lovric, Associate Professor, University of Zagreb

Data and market exclusivity and orphan drug market exclusivity, for example, constitute powerful incentives for pharmaceutical companies to invest in new drugs and other forms of treatment. These incentives have increased so much in importance that they are sometimes perceived as being just as fundamental to a pharmaceutical company as traditional patent protection. Moreover, in cases where such patent protection is not always available, such exclusivities take on even greater relevance.

This course offers an exciting update on the most critical and relevant changes in legislation and case law over the last few years, providing an "unmissable" opportunity to bring yourself up to speed with recent challenging developments in this vital legislative area.

WHAT YOU WILL LEARN

After the course, you will:

– Have learned about the most recent developments in the regulatory space in pharmaceuticals and biotechnology

– Be able to apply the knowledge acquired to your day-to-day work

– Be acquainted with the most recent developments in the area of big data, Artificial Intelligence and personalized medicine and their legal implications

– Have increased your awareness of the evolving competition law issues relating to pharmaceuticals

– Get deep insight into the recent developments in the area of data and market exclusivity, including orphan drug designations

COURSE CONTENT

Life sciences regulatory practice is currently undergoing a series of major changes, resulting in a large number of challenges for companies operating in this area of law and practice. The course will cover: ATMP's (Advanced Therapy Medicinal Products), Pricing and Reimbursement, competition law issues, and Personalized Medicine (PM). PM not only considerably shapes and influences the legal areas mentioned, but also presents a number of fresh challenges, such as the issue of big data in the context of PM and the rapidly growing development of Artificial Intelligence (AI) solutions in this area, which raises many (new) questions in its own right. The following topics will be covered on the course:

– Marketing authorization issues, including data and market exclusivity

– Orphan drug designation

– Clinical trials and transparency, clinical trials and GDPR

– Early access schemes

– Medical devices approval

– Pricing and reimbursement

– Personalized medicine, big data and the regulatory framework

– ATMP's (Advanced Therapy Medicinal Products)

– Artificial Intelligence and the digitization of medical care in general

– Pharmacovigilance

– Competition law issues, such as alleged excessive pricing, discounts, rebates and bundling

– Marketing of pharmaceuticals, such as Pharma advertising, On-line advertising, etc.

The course will be rounded off with an introduction to and update of IP issues for regulatory lawyers in the area of pharmaceutical and biotechnological inventions. These two legislative areas of the law are likely to become increasingly intertwined, so it is essential that today's regulatory lawyers are well up to date with the various IP issues and challenges in this particular technological area.

The course will be taught by experts from both the University of Copenhagen and by independent practitioners and in-house lawyers from Denmark and abroad.

PARTICIPANTS

The course is targeted at in-house legal counsel working in pharmaceutical and biotech companies, lawyers in private practice (law firms), judges, employees from the 'Danish Medicines Agency' (or from any national Medicinal Products Agency and the EMA), employees from the 'Danish Competition and Consumer Authority' with pre-knowledge of regulatory law aspects of life sciences (or from any national Competition Authority), academics who want to bring themselves up to date with recent and topical issues in the regulatory law aspects of life sciences, and any other civil servants at ministries who are interested in taking the course.

For more information and registration

W	COPENHAGENSUMMERUNIVERSITY.DK	✉	csu@adm.ku.dk	📱	+45 35 33 34 23

"Thank you for an excellent course"

Participant on Market Access

The course is relevant for people from any country within the EU, as well as for those people living outside the EU, but who would like to gain a detailed and up-to-date insight into the world of regulatory issues in pharmaceutical development in Europe.

The course fulfills the formal requirements for compulsory training for lawyers and associates in Denmark. When registering, you can request to receive course certificates on completing the course. Please note, however, that the Danish Bar Association does not issue approvals of continuing education courses - either to providers, lawyers or attorneys. Therefore, the Faculty of Law cannot guarantee that such approval will be given in the event of a random sample inspection

COURSE DIRECTORS

Sven Bostyn, Associate Professor, JUR Centre for Advanced studies in Bio-medical Innovation Law, University of Copenhagen

COURSE FEE

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

For more information and registration

W	COPENHAGENSUMMERUNIVERSITY.DK		csu@adm.ku.dk		+45 35 33 34 23