FACULTY OF HEALTH AND MEDICAL SCIENCES
UNIVERSITY OF COPENHAGEN

Copenhagen Centre for Regulatory Science (CORS)
Medical Product Innovation - Research & Education

Annual CORS Conference 2018

Impact of drug regulation on health and society

19.11.2018	
9:00 – 9:30	*Arrival of the participants. Registration and coffee.*
9:30 – 9:45	*Welcome: Professor Marieke De Bruin, Director of the Copenhagen Centre for Regulatory Science, University of Copenhagen, Denmark*

9:45 – 11:45	**Session 1. Impact of innovation on drug regulation**
9:45-10:15	*Louise Druedahl,* Copenhagen Centre for Regulatory Science "Putting the drivers and the evolution of the European regulation of biosimilars in perspectives"
10:15-10:45	*David Martin,* Associate Director for Real World Evidence Analytics, Office of Medical Policy, FDA CDER "U.S. Food and Drug Administration Real World Data and Evidence Initiatives"
10:45-11:15	*Bert Leufkens,* Utrecht University, Affiliate Professor at CORS "A responsive regulatory system, myth or reality?"
11:15-11:45	*Discussion:* **What will the future regulatory system look like?**

Session chair: Nikolai Brun, Medical Evaluation and Biostatistics, Danish Medicines Agency

11:45 – 12:45	*Lunch*

12:45 – 14:15	**Session 2. How and why to measure the impact of regulation on society and public health?**
12:45-13:15	*Mette Gørtz*, Centre for Health Economics and Policy, UCPH, Denmark "Health, innovations and economic behavior."
13:15-13:45	*Christine E. Hallgreen*, Copenhagen Centre for Regulatory Science "Use of complexity science methods in regulatory science."
13:45-14:15	*Discussion:* **Are we geared up to evaluate regulatory systems?**

Session chair: Nancy Pire-Smerkanich, Regulatory & Quality Sciences, University of Southern California, USA

14:15 – 14:45	*Coffee break*

14:45 – 16:45	**Session 3: How do policy instruments affect society and public health?**
14:45-15:15	*Mathias Møllebæk*, Copenhagen Centre for Regulatory Science "How do Danish GPs read regulatory safety advisories? A rhetorical protocol analysis."
15:15-15:45	*Per Sindahl*, Danish Medicines Agency "Added value of pharmacovigilance instruments."
15:45-16:15	*Mads B Axelsen,* Chief Medical Officer, Vaccibody A/S "Personalised medicine: Are the regulators really ready? An SME perspective"
16:15-16:45	*Discussion:* **Drug regulation - does it really matter?**

Session chair: Jens Heisterberg, Regulatory Intelligence, Novo Nordisk, Denmark

16:45-17:00	Closing remarks: *Professor Marieke De Bruin, Director of the Copenhagen Centre for Regulatory Science, University of Copenhagen, Denmark*
17:00	*End of the conference*