"Regulatory Science: The Present and Future"

Annual Conference of the Copenhagen Centre for Regulatory Science

November 23rd and 24th, 2016

University of Copenhagen
Ceremonial hall, Frue Plads 4, 1168 Copenhagen

Program for

CORS 2nd Research Seminar

Inauguration of Marie L De Bruin, Professor in Regulatory Science, University of Copenhagen

Copenhagen Centre for Regulatory Science Annual Conference*

Register for the events [here](#)

*For Industry participants there is a registration fee of 3000 DKK (400 EUR) for participation in the annual Conference on the 24th of November
Day 1 - November 23\textsuperscript{rd}

13:00-15:30  RESEARCH SEMINAR – an update of ongoing regulatory science projects

Welcome: CORS Research Seminar
Christine E. Hallgreen, assistant professor, Copenhagen Centre for Regulatory Science, University of Copenhagen

Pharmacy student driven collection of adverse drug reactions and off-label use in the community pharmacy setting
Ole J. Bjerrum, Professor Emeritus, Department of Drug Design and Pharmacology, Faculty of Health and Medical Sciences, University of Copenhagen

Regulatory Information - future trends and vision
Niels Grønning, Managing Consultant, NNIT A/S

Break

A qualitative study to address how patients evaluate rare serious adverse events: Implications for the involvement of patients in regulatory decisions
Mikkel Lindskov, PhD candidate, Copenhagen Centre for Regulatory Science, Faculty of Health and Medical Sciences, University of Copenhagen

The Regulation and Rise of Statin Use in Denmark: Studying Medical-Historical Developments from an Anthropological Perspective
Sofie Rosenlund Lau, PhD candidate, Department of Anthropology, Faculty of Social Sciences, University of Copenhagen, and Bjarke Oxlund, PhD, Associate Professor. Department of Anthropology, Faculty of Social Sciences, University of Copenhagen

16:00-18:00  INAUGURATION

Welcome and inauguration by Professor Sven Frøkjær, on behalf of the Dean of Faculty of Health and Medical Sciences, University of Copenhagen

Inaugural lecture by Marie L De Bruin, Professor in Regulatory Science

Closure by Flemming Madsen, head of Department of Pharmacy

Reception/Informal buffet
Day 2 - November 24th

CONFDENCE
8:30-9:00 Morning coffee and tea, registration

9:00-9:15 Welcome Address
Ulla Wewer, Dean, Faculty of Health and Medical Sciences, University of Copenhagen

9:15-9:30 The importance of regulatory science in a societal and industrial perspective
Marianne Kock, Senior Vice President, Ferring Pharmaceuticals

9:30-9:45 Conference Opening and Setting the Scene
Merete Schmiegelow, Novo Nordisk A/S, Industrial Ambassador for Regulatory Science, University of Copenhagen

9:45-10:15 The Empowered Patient in the Regulatory Science Framework
Terkel Andersen, President, EURORDIS

Break (Coffee and refreshments)

Morning session: Health authorities’ current activities and perspectives in regulatory science of medical products – balancing the “affairs” with the “science” (Moderator: Janne Lehmann Knudsen)

10.45-11.00 Introduction by Janne Lehmann Knudsen, Director of Division Pharmacovigilance & Medical Devices at the Danish Medicines Agency

Speakers:

11:00-11:30 Maria Isaac, Senior Scientific Officer, Scientific Advice at the European Medicines Agency (EMA), UK

11:30-12:00 Carolyn Wilson, Associate Director for Research at the FDA’s Center for Biologics Evaluation and Research, US Food and Drug Administration (FDA), USA

12:00-12:30 Yoshiaki Uyama, Director, Office of Medical Informatics and Epidemiology, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

12:30-13:00 Panel discussion

Lunch
Afternoon session: Regulatory science leading into the future of medical product innovation with focus on the role of research and academia (Moderator: Christian Schneider)

14:00-14:15 Introduction by Christian Schneider, Director, The National Institute for Biological Standards and Control (NIBSC), UK

Speakers:

14:15-14:45 Hans Hillege, Professor in Cardiology, University of Groningen, and Member of the Committee for Medicinal Products for Human Use (CHMP) for The Netherlands

14:45-15:15 Maria Beatriz Da Silva Lima, Professor of Pharmacology and Pharmacotoxicology, Lisbon University, and Chair of the IMI Scientific Advisory Committee, Portugal

Break (Coffee and refreshments)

15:45-16:15 Bert Leufkens, Professor of Pharmacoepidemiology, Utrecht Institute for Pharmaceutical Sciences, Utrecht University, and Chair of the Medicines Evaluation Board (MEB), The Netherlands

16:15-16:45 Panel discussion

16:45-17:00 Conclusions and Adjournment Marie L De Bruin, Professor and Director, Copenhagen Centre for Regulatory Science, University of Copenhagen

The Copenhagen Centre for Regulatory Science (CORS) aims at being the international partner for the regulatory framework that will make innovative medicinal products available to patients academic leadership in regulatory science, research and education and to participate in building http://pharmacy.ku.dk/research/cors