LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

BIO PEOPLE
Denmark's Life Science Cluster

Workshop on Scientific Advice

Open Space Lab on Informal Scientific Advice to Entrepreneurial "Newcomers" and Companies (SMEs) in the Development of Medicinal Products

"What you need to know to understand"

The Danish Medicines Agency and Denmark's Life Science Cluster, Biopeople, are pleased to announce this event. It is open to entrepreneurial researchers and employees in companies that are in need to know more about the regulatory pathways and opportunities for medicines development. Participation is free of charge and includes any material, water, coffee, tea and a lunch sandwich. Registration is mandatory at www.biopeople.eu. The no-show fee is 5.000 DKK. The event is limited to ca. 50 participants; the organisers decide potential overbooking.

Thursday 21 November 2019

Maersk Tower, University of Copenhagen, Blegdamsvej 3B, 2200 Copenhagen

Room 7.15.92, 15th floor

Tentative programme:

9:00 Arrival and registration, welcome by Per Spindler (Director), Biopeople, Denmark's Life Science Cluster

9:30-10:30 Anja Schiel (Senior Advisor and Statistician), Norwegian Medicines Agency. Chair the Scientific Advice Working Party of the Committee for Medicinal Products for Human Use

- *An introduction to scientific advice and protocol assistance at the European Medicines Agency*
- *European Medicines Agency's assistance to small pharmaceutical companies*
- *Orphan medicinal products*

10:30-10:45 Break

10:45-11:05 - Louise F.S. Bang-Lauritsen (Non-Clinical Assessor), Danish Medicines Agency

- *Non-clinical safety*

11:05-11:30 - Pernille Sterling (Senior Preclinical Assessor) & Louise Jørgensen (Clinical Assessor), Danish Medicines Agency

- *Clinical trials and First-In-Human*

11:30-12:30 Lunch

12:30-13:30 Sinan B. Sarac (Chief Medical Officer), Danish Medicines Agency, Member of the Committee for Medicinal Products for Human Use, the European Medicines Agency

- *National Scientific Advice at the Danish Medicines Agency*
- *Clinical safety and efficacy, methodology and statistics*
- *Cases*

13:45-14:45 Networking and QA session on the European Medicines Agency, National Scientific Advice, Non-clinical safety and First-In-Human

15:00 Farewell