OSLO CANCER CLUSTER INCUBATOR

Läkemedelsakademin
Swedish Academy of Pharmaceutical Sciences

It is our pleasure to invite biotech companies and researchers to Oslo Cancer Cluster Incubator's training seminar:

Development of a new anti-cancer drug product – What do you need to know?

March 20th, 2014 – Auditorium, 2 etg., Pfizer Oncology, Lilleakerveien 2B, Oslo

Please register here before 18 March, 2014!

For more information please contact Susanne Werner, sw@oslocancercluster.no. Please note, due to limited space, Oslo Cancer Cluster members will have priority.

Registration fee
Non-members of Oslo Cancer Cluster: 2500 NOK
Members of Oslo Cancer Cluster: no fee, but 500 NOK no-show-fee.

Oslo Cancer Cluster Incubator together with the Swedish Academy of Pharmaceutical Sciences (SAPS) kindly invite employees of early stage biotech companies, hospital employees involved in designing clinical trials, interested PhD/master students within oncology and others interested in the topic, to learn more about the drug development process. This one-day training course includes regulatory perspectives, metabolism, safety, formulation, general clinical development and business perspectives.

Welcome!

The organizers

Oslo Cancer Cluster Incubator AS will be an integrated part of the new Oslo Cancer Cluster Innovation Park, opening May 2015. The incubator will help young, promising oncology biotechs to successfully commercialize, and is already open for tenants. This training seminar is the first activity in a series to support biotech companies. Read more at **www.oslocancercluster.no.**

PROGRAM

Development of a new anti-cancer drug product

– What do you need to know?

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Seminar content

The seminar starts with registration and Coffee from 08:30.
The program begins at 08:50 and finishes with Q&A around 17:30.

- **The drug discovery and development process – an overview**
  Benjamin Pelcman, BeePCo
- **Regulatory Affairs in drug discovery and drug development**
  Marie Gårdmark, Sofus
- **Biologics, Immunotherapy, Vaccines**
  Anki Malmborg Hager, Avena Partners
- **Drug metabolism and Pk/Pd**
  Magnus Halldin, ADMET
- **Preclinical Toxicity Testing and Safety Assessment**
  Lars Wiklund, RegSafe
- **Pharmaceutical formulation**
  Mats E Johansson, Mattis Galenik
- **Clinical Trials**
  Bengt Dahlström, Clinical Trials Consultances

Questions the training seminar should answer

- *What are the essential choices I have to make in the initial process of clinical studies that can save me both time and money?*
- *Do I have the right quality of preclinical information to be able to start clinical studies?*
- *Why could good knowledge of the drug substance and product be important?*
- *Which is the right timing to start dialog with regulatory authorities?*
- *What level of control do I need to hav e of the development process and what are the different consequences?*
- *What are the regulatory requirements of the FDA/ EMA for development of cancer drugs and how can I take advantage of SME and / or Orphan Drug Status?*
- *Who should apply for SME- or Orphan-drug-status?*
- *How can I seek preclinical and clinical advice at FDA and EMA? Which advantages will that have for my product?*