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Invitation to a seminar on the new ICH M7 guideline

The National Food Institute (Technical University of Denmark), Saxocon and Leadscope, Inc., co-organise a seminar on the new ICH M7 guideline on assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit a possible human cancer risk. The seminar will take place at the National Food Institute on 23 April 2014.

The National Food Institute invites you to a seminar with a focus on the new draft ICH guideline, ICH M7, on 23 April 2014. The new ICH M7 guideline was prepared by ICH, the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. The guideline is expected to make it possible for companies in the pharmaceutical industry to get approval of impurities in pharmaceuticals with the assistance of SAR expert systems and statistical QSAR computer models. For many years the National Food Institute has worked with developing and applying QSAR models to assess chemical substances.

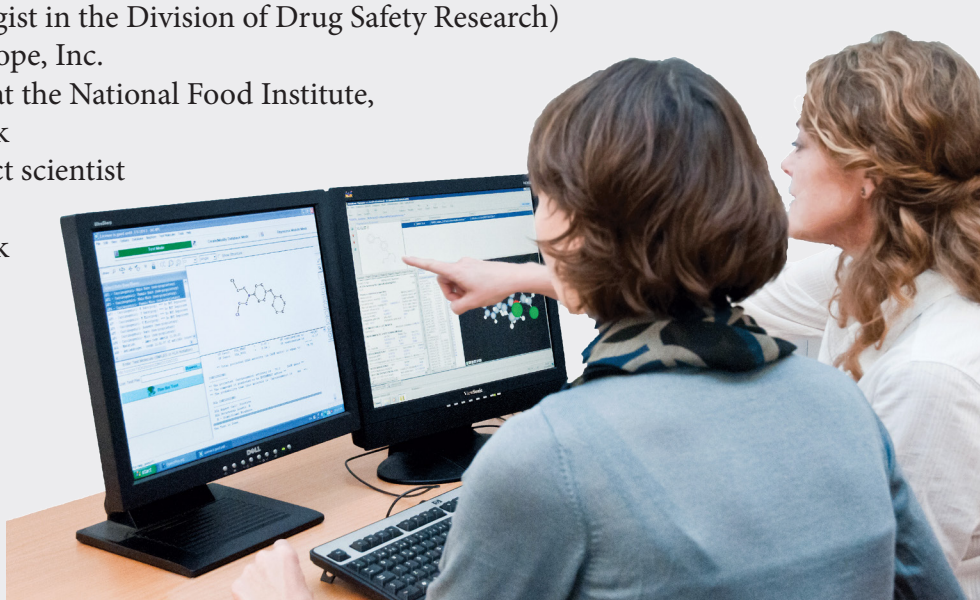
The purpose of the seminar is to provide participants with insight and knowledge on:

- The contents, processes and strategies necessary to support the documentation required by the ICH M7 guideline
- How expert guideline-based and statistics-based in-silico models function
- How you can generate and apply the results from different in-silico systems
- Which tools are available to support chemical and biological assessment of results
- Experience with developing and applying QSAR modelling to assess chemical substances in a regulatory context

The seminar is jointly organised by the National Food Institute, Saxocon and Leadscope. Saxocon is a new biotech company. It offers companies direct access to the National Food Institute's QSAR models, which can predict possible harmful effects of chemical substances with the help of computer simulation. Leadscope is supplier of QSAR modelling software and works closely together with FDA.

Scientific speakers:

- Dr. Daniel Benz, OmniCorp,
  (retired US FDA senior toxicologist in the Division of Drug Safety Research)
- Dr. Glenn Myatt, CSO at Leadscope, Inc.
- Eva Bay Wedebye, chief adviser at the National Food Institute,
  Technical University of Denmark
- Nikolai Georgiev Nikolov, project scientist
  at the National Food Institute,
  Technical University of Denmark



Programme

08:30 – 09:00	Registration, coffee and rolls
09:00 – 09:15	Welcome by Loftus Lucas, president & CEO at Leadscope, and Anders Permin, deputy director at the National Food Institute
09.15 – 09.45	Contents of the new ICH M7 guideline by Dr. Daniel Benz, OmniCorp
09.45 – 10.15	Presentation of the two complementary in-silico methods which are necessary to support the new ICH M7 guideline by Dr. Glenn Myatt, CSO at Leadscope
10:15 – 10:30	Coffee break
10.30 – 11.00	Application, evaluation, consensus creation in regard to predictions and delivery of in-silico model results to FDA by Dr. Daniel Benz, OmniCorp
11.00 -11.30	Experience with developing and applying QSAR models to assess chemical substances in a regulatory context by Eva Bay Wedebye, chief adviser at the National Food Institute, and Nikolai Georgiev Nikolov, project scientist at the National Food Institute
11.30 – 11.45	QSAR as a toxicity tool by Martin Friis-Mikkelsen, CEO at Saxocon
11.45 – 12.15	Round table discussions
12.15 – 13.00	Lunch
13.00 – 14.00	Informal discussions and networking

Venue
The National Food Institute, Technical University of Denmark
Mørkhøj Bygade 19
"The barn"
2860 Søborg, Copenhagen, Denmark

Registration
Participation in the seminar is free of charge, however, there is a no-show fee of 100 euro.
Please sign up at www.food.dtu.dk on 11 April 2014 at the latest.

Contacts
For information about the scientific programme:
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For practical information: Kirsten Becker Hansen, management assistant at the National Food Institute, kirha@food.dtu.dk, tel. 40 19 14 72

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Computational toxicology (QSAR)