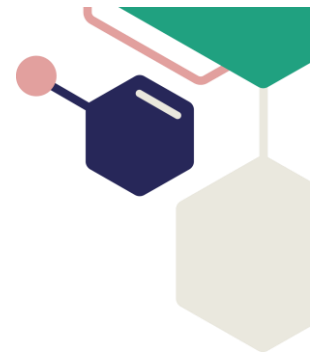




Date: October 1, 2025

Time: 09.00 - 17.00

Venue: Carolina Tower, Hagastaden, Stockholm

Conference room: Röntgen

Nordic Regulatory Affairs Meeting 2025

Program

from 08.30

Registration and coffee

09.00 – 09.05

Welcome

Sandra Trost, Läkemedelsakademin

09.05 – 09.15

Introduction to the day

Moderators:

Helena Björkman, Avia Pharma

Henrik Fant, Gedeon Richter

09.15 – 10.00

Updated EU variation guideline

Authority perspective

Hanna Holst, Swedish Medical Products Agency

Natascha Johansen, NOMA

10.00 – 10.30

Corporate perspective

Sini Eskola, Takeda

10.30 – 10.40

Time for questions

10.40 – 11.00

Pause with refreshments

11.00 – 11.45

Joint Nordic project with English PLs

Cecilia Ulleryd, Swedish Medical Products Agency

11.45 – 12.15

Icelandic ePL project – an update

Gunnbjört Þóra Sigmarsdóttir, Icelandic Medicines Agency

12.15 – 13.15

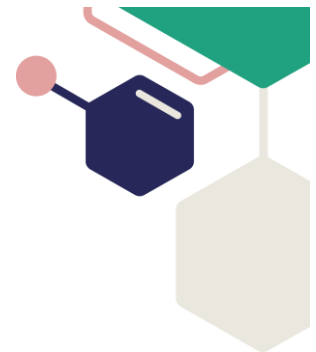
Lunch

13.15 – 13.30

The Regulatory Affairs role

How it all started...until now and forward...

Thomas Fockter, Balder Pharma



13.30 – 14.15	AI in Regulatory Affairs Authority perspective – REGULUS, the newly launched internal MPA generative AI system to support our assessors <i>Samuel Fransson and Sofia Bosdotter Enroth, Swedish Medical Products Agency</i>
14.15 – 14.45	Corporate perspective - Insights into the effectiveness of using AI to draft and manage eCTD submissions – from a digital innovation and CMC perspective <i>Harry Rowland, PharmaLex</i>
14.45 – 15.00	Time for questions
15.00 - 15.30	Networking fika
15.30 - 16.00	PICs new VNR hub Practical demo of new and coming functionalities <i>Riikka Manninen, Pharmaca Health Intelligence</i>
16.00 – 16.30	Current issues on the availability of medicines <i>Riikka Holthöfer, Fimea</i>
16.30 – 16.45	Time for questions
16.45 – 16.55	Meeting wrap-up reflection Today's and tomorrow's most important regulatory challenges – and opportunities in the Nordics? <i>Moderators:</i> <i>Helena Björkman, Avia Pharma</i> <i>Henrik Fant, Gedeon Richter</i>
16.55 – 17.00	Thank You! <i>Sandra Trost, Läkemedelsakademin</i>

Speakers in alphabetical order:

Cecilia Ulleryd, Swedish Medical Products Agency
Gunnbjört Þóra Sigmarsdóttir, Icelandic Medicines Agency
Hanna Holst, Swedish Medical Products Agency
Harry Rowland, PharmaLex
Helena Björkman, Avia Pharma
Henrik Fant, Gedeon Richter
Natascha Johansen, NOMA
Riikka Holthöfer, Fimea
Riikka Manninen, Pharmaca Health Intelligence
Samuel Fransson, Swedish Medical Products Agency
Sini Eskola, Takeda
Sofia Bosdotter Enroth, Swedish Medical Products Agency
Thomas Fockter, Balder Pharma