## **ISPE NORDIC AFFILIATE ANNUAL MEETING 2018**

## Quality Risk Management in Pharmaceutical Industry

Comwell Conference Center, Center Blvd. 5, 2300 København, Danmark Wednesday November 21 2018

08:30 - 09:00	Registration, coffee & Visit table top exhibition
09:00 - 09:10	Welcome and setting the scene, ISPE Nordic intro Anders Widov (Interim Vice Chair of ISPE Nordic Affiliate)
09:10 - 9:50	Keynote speaker Lars Guldbæk Karlsen, Novo Nordisk, Denmark
9:50 – 10:30	Quality Risk Management Mette Kraemmer Hansen and Hanna Kviat Antonsen, Novo Nordisk, Denmark
10:30 – 11:10	Risk-MaPP - implementation Lena Fahlqvist Kozicic, AstraZeneca, Sweden
11:10 – 11:40	Coffee break – Visit table top exhibition
11:40 – 12.20	Risk-MaPP - case study Pete Marshall, AstraZeneca, UK
12:20 -13:20	Lunch - Visit table top exhibition
13:20 -14:00	Implementation of Quality Risk Management including involvement of
	Management (case study) Evamarie Juul Mathiesen, Lundbeck, Denmark
14:00 – 14:40	<b>GAMP5</b> and Quality Risk Management – an approach to daily operation Anders Vidstrup, NNIT, Denmark
14:40 – 15:20	ТВА
15:20 - 15:40	Coffee break – Visit table top exhibition
15:40 – 16:20	ISPE Nordic Affiliate Annual General Meeting – election of new board Ylva Ek, Chair of ISPE Nordic
16:20 –16:50	ISPE – Global perspective on the Industry Association Gert Moelgaard, Moelgaard Consulting, Denmark
16:50 -17:00	Round up and adjourn
17:15 -18:30	Networking & refreshments
18:30 -22:00	Dinner