Toxicologist at Novo Nordisk tasks, educational background and perspectives

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European registered toxicologist (ERT)
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Principal Scientist Toxicology,
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Professional career and education

2015. European registered toxicologist (ERT)

2011. Master in Applied Toxicology, University of Surrey, UK.

2001. Master of Science Biology/Ecotoxicology.
Syddansk University, Odense.

2012. Principal Scientist. Toxicologist. Toxicology, Novo Nordisk A/S

- Performing non-clinical studies supporting the safety assessment of drug candidates
- Provide toxicological assessments to Product Supply
- CRO outsourcing specialist

2011. Non-clinical assessor/Toxicologist, Danish Medicines Agency

- Responsible for assessing the non-clinical part of Marketing Authorisation Applications submitted via the EMA or the Danish Medicines Agency.

2006. Senior Toxicologist and Program Manager Preclinical Development, NeuroSearch A/S

- Responsible for safety evaluation of new compounds prior to clinical testing.

2001. Study Director, Lab Scantox

- Responsible for designing study protocols, liaison with clients, study conduct, interpretation of data and preparation of reports.

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What is toxicology at Novo Nordisk?

- **Toxicology**
  - Study of adverse effects of chemicals on living organisms

- **The role as Toxicologist at Novo Nordisk**
  - Responsible for performing non-clinical (toxicology) studies supporting the safety assessment of drug candidates throughout development
  - The role involves extensive interaction with other scientists and clinicians both within and outside the company and internationally, designing and implementing the programs of work necessary for submission to national drug regulatory bodies.
  - Provides toxicological support and assessments to Product Supply
  - CRO coordinator - responsible for ensuring high quality and cost effective outsourcing to CROs

- **At Novo Nordisk we are performing animal studies to evaluate safety risk in man**
  - Studies are mainly performed at external CROs
  - Toxicologists and safety pharmacologists = Sponsor monitor (SM)

labcorp

scantox

charles river

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Using animals to support different areas/disciplines in drug development

- Support early safety assessment (exploratory safety studies) (various species)
- Safety pharmacology (rodent: mouse, rat, non-rodent: dog, minipig, monkey)
- Repeat dose toxicity (rodent: mouse, rat, non-rodent: dog, minipig, monkey)
- Reproductive and developmental toxicity (rodent: rat, non-rodent: rabbit)
- Genotoxicity /Carcinogenicity (2 rodent species; rat and mouse)
- Mechanistic studies to address identified safety concerns (case-by-case designs)





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Nonclinical development activities

- All activities to be considered for all types of compounds

Timing of nonclinical studies

		Phase I	Phase II	Phase III
Tox DRF/MTD	4-week tox	13-week tox	26/39-week tox	
Genotox screen	Genotox	Metabolism and Drug-Drug-Interaction		
Safety Pharm screen	Safety pharm	Reproductive toxicity (EFD)	Reproductive toxicity (Fertility, EFD)	Reproductive toxicity (PPND)
			Juvenile tox (if relevant for PIP)	
			Carcinogenicity (2-year / 26-w)	