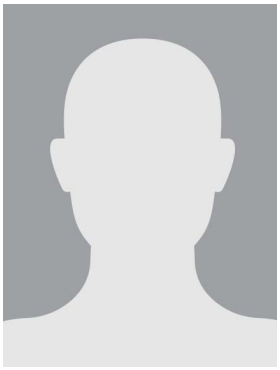

NN
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Toxicology and Biosafety

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Competences

- Regulatory toxicology and product safety
- Biological Evaluation Report
- Clinical Evaluation Report
- Medical Writer
- Biological Evaluation Plan and testing strategy
- Toxicological exposure and safety assessment
- Regulatory compliance for industrial chemicals, biocides and medical devices
- Planning, execution and evaluation of biocompatibility and chemical characterisation studies
- Risk/safety assessment of chemicals, impurities, migrating substances etc.
- Specialist in toxicology and development of new medicines and biotechnological products
- Publication of more than 60 peer-reviewed papers
- Scientific writer/medical writer experience

Key results

- Head of department of a group of 30 toxicologists
- Development of toxicological courses at post graduate level
- Submission of several non-clinical reports to authorities
- Head of Danish group for development of ISO standards for safety evaluation nanoparticles
- Danish representative at advisory board for EFSA
- Preparation and leadership to ensure marketing of consumer products to markets in EU and USA.

Regulations/Standards

Extensive knowledge in:

- ISO 10993 for biosafety of medical devices
- Toxicological support for material selection or substitution projects
- ICH guidelines for non-clinical testing for safety of biotech, pharma, medical devices, food and feed ingredients and foods.
- International submissions and approvals in: EU (EMA, EFSA, ECHA), FDA, Health Canada, China
- Safety assessment of cosmetic products

Personal Characteristics

He is a pragmatic, enthusiastic, extrovert, resourceful, constructive and straight forward person that believes in an open and honest dialogue, and enjoys working with others.

He has many years hands-on experience in Regulatory Affairs in relation to the non-clinical area and has been working with many different products.

He spends his free time with family, friends, biking, running and reading novels.

References

Medicologic A/S (2018-
Senior consultant Regulatory toxicology and Clinical Evaluation Report

Værløse Dyreklinik:

- General veterinary practioner & consultant in development of biotechnological products.
- Consultancies within safety assessment of products

DTU: Senior executive officer and Deputy director

- Responsible for translational research and innovation within life science at DTU
- Responsible for contact and exposure of DTU projects
- Created several spin-outs at DTU

DHI Environment and Toxicology: Head of Department,

- Managed biotech projects from innovation to market for clients.
- Safety assessment of Life-science projects within pharma, food, feed, medical devices, chemicals, cosmetics etc.
- Responsible for safety assessments of Johnson & Johnson products.

H. Lundbeck A/S: Medical writer

- Writing of non-clinical and clinical reports for relevant authorities (EMA, FDA)
- Written several non-clinical and clinical reports
- Initiated development of publication strategy for clinical department at H. Lundbeck.

University of Copenhagen, Department of Veterinary Microbiology: Associate Professor and director

- Responsible for development of a cross disciplinary approach to use of research results in development projects
- Developed a model for cross disciplinary approach to improve small livestock.
- Developed a cross disciplinary MSc for animal scientists and veterinarians.
- Publication of research results in peer-reviewed journals