Ingrid Brück Bøgh

CONTACT:

+ 45 5383 6655
Mail: ingrid@ibbconsulting.dk

NATIONALITY:
German (permanent Danish residency)

LANGUAGES:
- German, Danish, English: trilingual
- Spanish: basic spoken and written
- Swedish, Norwegian, French: elementary understanding

PROFILE:
Experienced leadership in an ambitious, science-driven environment; result orientated; developing new strategies; driving cross functional collaboration; strong scientific mindset; safety evaluation of drug development projects.

BACKGROUND:
High level scientific education/skills coupled with multicultural work experience within pharmaceutical drug development and toxicology at Novo Nordisk and veterinary clinical research and therapy (Melbourne and Copenhagen Universities). Professional memberships with strategic representative or advisory function.

PERSONAL KEY COMPETENCES:
My leadership and working style is characterised by a good balance of trust, respect, guidance, challenge and acknowledgement. I can contribute with:
- a structured, energetic approach to challenges
- a strong organisational and analytical talent and
- perseverance following tasks through and a track record of reaching ambitious goals.

EMPLOYMENTS:

Since May 2017: CEO and Pre-clinical Safety Consultant at IBB Consulting ApS, Denmark

Since 2014: Vice President of Toxicology and Safety Pharmacology, Non-clinical Development, Novo Nordisk A/S, Denmark

2008-2014: Head of Diabetes Toxicology and Safety Pharmacology, Non-clinical Development, Novo Nordisk

2005-2008: Professor (Full Professorship) and Head of Veterinary Reproduction and Obstetrics at Dept. of Large Animal Sciences, University of Copenhagen, Denmark

EDUCATION:
1986: D.V.M. (cand.med.vet.), Justus-Liebig University, Giessen, Germany
1990: Ph.D. Veterinary Science, University of Melbourne, Australia
2001: Accreditation as **Study Director** for Reproductive Toxicology Studies
2004: D.V.Sc. Doctor of Veterinary Science (habilitation), Copenhagen University
2018: ERT (European Registered Toxicologist)

1. WORK EXPERIENCE

Since May 2017:
Founder, CEO, Pre-clinical Safety Consultant, Toxicology expert at IBB Consulting ApS, Denmark

IBB Consulting provides advice with design and conduct of non-clinical safety programs in the context of regulatory guideline requirements, assists with outsourcing and monitoring of non-clinical safety studies as well as the interpretation of toxicology data and the generation of regulatory submission documents. Substantial preclinical safety experience with small molecule and biologic drug candidates (including peptides, mAbs, bispecific Abs, ADCs, DART, RIT, vaccines) and within a multitude of indications including metabolic diseases, oncology, cancer immunotherapy (CIT), cancer vaccines, fluorescent cancer diagnostics, haemophilia, growth disorder, cardiovascular diseases, inflammation, CNS/pain, calcification, protein misfolding diseases. Moreover, IBB Consulting has extensive expertise with preparing the nonclinical sections of regulatory documents for scientific advice meetings, CTAs, INDs IMPDs, NDAs and marketing applications in EU, USA and various other countries.

See complete list of expertise and services provided on LinkedIn: https://dk.linkedin.com/in/ingrid-brueck-boegh

Achievements:

- Certification as European Registered Toxicologist since 2018
- Complete toxicology packages performed for two oncology mAbs, one approved for marketing by FDA.
- Toxicology packages performed for eight other drug candidates currently in clinical Phase 1-3 (i.e. biologics and NCEs; oncology therapy and diagnostics, haemophilia, metabolic disorder, obesity, pain therapy, cardiovascular disease).
- Design, outsourcing and monitoring of several Phase 1-3 enabling toxicology packages
- Briefing packages prepared for scientific advice meetings with FDA, EMA, PEI, MHRA, DKMA, MPA, AEMPS and TGA
- Writing of nonclinical sections of CTD modules of marketing applications (EMA/FDA) which were approved, and for several CTAs/INDs which allowed progression into clinical trials.

2014-2017:
Vice President of Toxicology and Safety Pharmacology
Non-clinical Development, Novo Nordisk A/S (NN), Måløv, Denmark

The department with 3 subunits had responsibility for safety testing of the entire NN drug portfolio:

- Support to exploratory safety (prior to drug candidate selection)
- Regulatory, mechanistic toxicology and safety pharmacology of drug candidates proceeding towards clinical trials and marketing applications
- Toxicological support to material characterisations for device development and equipment selection in CMC and Product Supply

- Toxicological assessments of impurities and contaminants in drug product
- Occupational Exposure Limit calculations for Product Supply
- Non-conformity assessments in Product Supply

Professional skills:

Organisational leadership:

- Ensure scientific excellence of department and drive deliverables according to ambitious project timelines
- Definition of strategic activities ensuring organisational readiness for the future
- Driving optimal cross discipline collaboration within a project/line matrix organisation and with various stakeholders in a global organisation (i.e. DK, China, USA)
- Initiation of academic collaborations and strategic research Co-chair in External Affairs Consort and participation in relevant international industry fora ensuring company interests e.g. guideline updates, white papers etc.
- Development of internal scientific training courses and knowledge sharing
- Ensuring optimal CRO outsourcing and consultancy relationships

Personnel responsibilities: >35 academic employees, incl. 3 managers, 30 scientists, 2 Lab Techs, 2 PostDocs, 2 Ph.D. students. Budget, hiring, retention, competence development, implementation of organisational changes.

Scientific responsibilities: Chairman of Exploratory Safety Committee (i.e. early assessment of safety signals of new drug targets). Member of Safety Committee for FHD trials (i.e. safety assessments of new drug candidates prior to clinical trials). Review of regulatory documents and marketing applications. Toxicologist/Sponsor´s monitor function on selected projects.

Achievements:

- Initiative and successful implementation of cross-functional collaboration of exploratory safety investigations
- MMPI (Managing Medical Product Innovation), CBS Executive Diploma course. Copenhagen Business School, Copenhagen, Denmark (30 ECTS points)
- Successful integration of new department
- Initiator of 3 Master, 1 Ph.D., 3 PostDoc projects

2008 – 2014:
Head of Diabetes Toxicology & Safety Pharmacology (Team leader/Director),
Non-clinical Development, Novo Nordisk A/S, Måløv, Denmark

Professional skills:
Management of 1-2 units. Total 11-17 academic employees (direct reports). Regulatory toxicology and safety pharmacology of drug candidates within diabetes and obesity portfolio from lead candidate selection to marketing. Toxicological assessments supporting Device R&D, Product Supply and CMC.

Achievements:

- Successful stakeholder management facilitating mutual understanding and alignment of expectations, thereby improving quality of deliverables
- Successful preparations and non-clinical support for FDA´s AdCom leading to successful of marketing authorization
- Considerably increased employee engagement within the first 12 month of employment

---

2005 – 2008:
Professor (Full Professorship) and Head of Veterinary Reproduction and Obstetrics
Dept. of Large Animal Sciences, University of Copenhagen (earlier Royal Veterinary and Agricultural University), Denmark

Professional skills:
Scientific, educational and administrative leadership (incl. budget responsibility) for the Section of Veterinary Reproduction and Obstetrics.

Personnel responsibilities: ~20 employees; 10 academic staff, 6 Lab Techs/Admin, 4 PhD students. Budget, hiring, retention, competence development, implementation of organisational changes.

Scientific responsibilities: Heading the In Vitro Fertilization Research Laboratory. Attraction of major research funds. Initiation, coordination/international collaborations. Hands on participation in below research projects and clinical work at the Large Animal Hospital incl. out-of-hour duties.

Educational responsibilities: Veterinary curriculum and examination of undergraduate students within the discipline veterinary, reproductive physiology, pathology and obstetrics comparative across large and small domestic animals. Supervision of Master and Ph.D. students.

Research projects:
- In vitro production of porcine embryos and diversity in developmental competence
- Neonatal adaptation of cloned porcine offspring and semen quality of cloned boars
- Development of a rat model for human intrauterine growth retardation
- Effect of intrauterine stress on stress susceptibility in adult life – a rat model
- Diagnostics and therapy of ovarian and uterine disorders in the mare

Achievements:
- Production of first cloned transgenic Alzheimer pigs as human disease models worldwide
- Department accredited as educational institution for Diplomats of ECAR (European College of Animal Reproduction)

1990 – 2005:
Assistant/Associate Professor at the Department of Veterinary Reproduction and Obstetrics (13 years) and **Large Animal Surgery** (2 years)
University of Copenhagen (earlier Royal Agricultural and Veterinary University), Dyrlægevej 68, 1870 Frederiksberg C, Denmark

Professional skills:
2004 to 2005 constituted administrative and scientific Head of Veterinary Reproduction and Obstetrics (scientific, educational, organisational, personnel and budget responsibilities).
Coordination of the hospital-related functions. Clinical work at the Large Animal Hospital including out-of-hour duties (e.g. colic surgeries, Caesarean sections, abomasal dislocations, acute trauma treatment). Teaching and examination of undergraduate veterinary students. Supervision of Master and Ph.D. students. Research project management incl. all processes from hypothesis to publication.

Research projects:
- In vitro fertilization techniques
- Bioimaging of the in vitro maturing bovine and equine oocyte
- Transvaginal ultrasound-guided aspiration of follicles and fetal fluids
- Generational effect of compounds mimicking hormones on gonad development and fertility after exposure during fetal life: the pig as a screening model
- Influence of progesterone induced proteins on embryonic glucose metabolism
- Detection of Meiosis-Activating Sterol in follicular fluid of the mare and testicular tissue of the stallion
- Ovarian temperature measurements in pigs

2001– 2002:
Study Director for Reproductive Toxicology (sabbatical leave University of Copenhagen)
Scantox (CRO, now CiToxLab), Hestehavevej 36A, Ejby, DK-4623 Lille Skensved

Professional skills:
Planning, conduction, supervision and reporting of regulatory (GLP) reproductive toxicological studies in different animal species according to ICH and OECD guidelines; writing standard operating procedures (SOP); development and introduction of new toxicological testing methods (e.g. cross fostering of piglets for juvenile toxicity testing).

1987 - 1990:
Ph.D. student, Department of Veterinary Clinical Sciences, University of Melbourne, Australia
Part-time Veterinary Intern (out-of-hour duties) at the University Ambulatory Veterinary Clinic

Responsibilities:
Coordination and conduct of the research projects, teaching of undergraduate veterinary students, attending emergency cases in Large Animal University Hospital.

Research projects:
Glucose metabolism measurements in equine embryos at different developmental stages and the influence of progesterone-induced uterine protein. Analysis of reproductive performance of Australian Thoroughbred mares.

2. PUBLICATIONS, ORAL PRESENTATIONS and RESEARCH GRANTS

Publications

Academic theses: 2 (Ph.D. 1990, D.V.Sc. 2004)
Internationally peer reviewed publications: 50+ (18 first author)
Book chapters/scientific analytical reports: 5
Abstracts of oral presentations or posters: 60+

See complete publication list on Linkedin: https://dk.linkedin.com/in/ingrid-brueck-boegh

Oral presentations at conferences and symposia

1988-2019: 50 scientific oral presentations including 23 invited lectures at national and international scientific conferences, symposia, company workshops or industry fora.

Research Grants and Awards

1987-2007: 29 personal awards and research grants up to 1.5 mio DKK supporting scientific research projects (e.g. Melbourne University Postgraduate Scholarship, Australian Equine Research Foundation, Danish Research Council, OECD, Danish Medical Research Council, Danish National Committee for Pig Production
Since 2008: 3 industry-academia research project grants supporting 1 Ph.D. and 2 PostDocs

3. TEACHING EXPERIENCES

Undergraduate veterinary curriculum (1992-2008)

At Copenhagen University: lectures, practical curses, tutorials and teaching courses for undergraduate veterinary students on various topics related to reproductive function, disorders, diagnostics and therapeutic interventions in domestic animals (cat, dog, sheep, goats, cattle, pigs, horses). Since 2000, practical/oral exams of veterinary students in the field of reproduction and obstetrics, which is mandatory for accreditation as a Veterinarian in Denmark.

Postgraduate supervision (since 1999)

Supervisor or co-supervisor for 34 Veterinary Master students (1999-2014), 4 Ph.D. (2004-2015) students and 2 PostDocs (2015-2017)

Education of veterinary practitioners/industry academics (since 1994)

1994-2008: Contribution to theoretical and practical educational courses in reproductive management arranged for the Danish Veterinary Association, Horse Trainers, Danish Equine Breeders, Nova Postgraduate School, Danish Equine Practitioners.

Since 2008: Lectures and seminars on Non-clinical Drug development, Toxicology and Safety Pharmacology and reproductive, developmental and juvenile toxicology testing at industrial educational courses (e.g. Medicademy, Denmark)

4. MEMBERSHIPS of PROFESSIONAL BODIES

External Professional bodies

- Founding Diplomat of the ECAR (European College of Animal Reproduction (ECAR, since 2000), recertified 2010.
- Editorial Board Member of Reproduction in Domestic Animals (RDA, 2006-2012)
- Member of the Danish Society for Pharmacology, Toxicology, and Medicinal Chemistry (DSFTM, 2009-2021)
- Member of European Association for the Study of Diabetes (EASD, 2011-2016)
- Member of Non-clinical Pediatric Industry Forum (since 2011-2017)
- EUROTOX 2021 Copenhagen/virtual, Member of Local Organizing Committee (2015-2020)
- PhRMA Preclin-KIT Members (2015-2017)
- President (2007-2008) and Board Member (2005-2008) of the Centre for Reproduction and Fetal Development (CRAFT)
- Secretary (2007-2008) and Board Member (2005-2008) of the European Embryo Transfer Association (AETE)
- Board Member of the International Congress of Animal Reproduction (ICAR, 2004-2008)
- Board Member of the European Society of Domestic Animal Reproduction (ESDAR, 1999-2001)
- Editorial Advisory Board Member of Reproduction in Domestic Animals (1999-2001)
- Editorial Board Member of Pferdeheilkunde (1993-2001)
- Various memberships of scientific societies 1992-2008 (e.g. International Embryo Transfer Society; Society for Study of Fertility; European Society of Domestic Animal; Danish Veterinary; Danish Vet. Association for Reproduction of Domestic Animals; European Teratology Society; European Embryo Transfer Association; Danish Embryo Transfer Veterinarians, Danish Society for Reproduction and Fetal Development)

Organisational experience

At Novo Nordisk A/S:

- Chairman of Exploratory Safety Council at Novo Nordisk A/S
- Co-chair of External Affairs Focus Group at Novo Nordisk A/S
- Member of Expert Group Animal Research Ethics at Novo Nordisk A/S
- Member of Non-clinical Department Management team

At Copenhagen University (2003-2008):
Member of the Departmental and Strategic Committees, University of Copenhagen:

- Member of the planning committee of the Biotech-education at University of Copenhagen
- Member of Faculty Committee for Veterinary Research Strategy
- Member of the working group concerning fund raising for improvement of strategic infrastructure at the Veterinary Faculty
- Member of the working group for development of joined Experimental Animal Unit between Veterinary and Medical Faculties at Copenhagen University (Campusstald)
- Co-pilot in the working group concerning establishment of strategic collaboration across faculties of University of Copenhagen
- Member of the building committee of the new Large Animal University Hospital

Other national and international scientific appointments

- External assessor for Chair of Veterinary Obstetrics at the Norwegian Veterinary School (2007)
- Chairman of the assessment committee for Chair in Equine Internal Medicine, Department of Large Animal Sciences, Copenhagen University (2007)
- External assessor for the Chair of Marine Reproduction at the Norwegian Vet. School (2007)
- External assessor for Professorship in Reproduction, Agricultural University, Sweden (2007)
- External assessor of the research qualifications of the Department of Production Animals, Norwegian Veterinary School (2007)
- Chairman of the assessment committee for affiliated professor in reproduction at the Department of Large Animal Sciences, Copenhagen University (2006)
- Member of the local organizing group of the 31st Annual Conference of the International Embryo Transfer Society in Copenhagen (2005)
- Convener of the International Seminar "Equine Oocyte Forum" (2007)
- Scientific Referee for several international journals (Theriogenology, Journal of Reproduction and Fertility, Equine Veterinary J., J. of Equine Veterinary Sciences, Reproduction of Domestic Animals, Animal Reproduction Science, Archives of Medical Research, Acta vet scand, Dansk Veterinær Tidsskrift) and evaluation two book chapters of "Reproductive Physiology"
- Assessor for the British Horserace Betting Levy Board and the Estonian Science Foundation.
- Chair and co-chair of scientific sessions at international and national conferences and meetings (ISER 2006, AETE 2006, CRAFT 2006, 2007, SHARE 2007).
- Advisory function for questions from press, veterinary practitioners, private people, school children concerning reproduction, obstetrics and artificial reproductive techniques, cloning and production of transgenic animal models, including ethical and animal welfare aspects.
- Advisory function in conjunction with the development of new laws and regulations concerning reproductive techniques, ethical considerations in respect to transport and slaughter of pregnant animals and medical treatment of domestic animals with hormones.