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## Dr. Ingrid Bause

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### Scope

### Curriculum Vitae/ Qualification Profile

### Professional Experiences

Starting October 15, 2009 Novartis Vaccines & Diagnostics  
Marburg, Germany

Head Quality Engineering, QA Compliance

- Main Function: Manage Quality optimization initiatives within a process orientated structure to continuously ensure harmonization of implemented Quality Systems on the basis of significant deviations.

2000 to October 15, 2009 Novartis Vaccines & Diagnostics/  
Chiron Vaccines, Marburg, Germany

Release Responsible Person/ Qualified Person, Operational  
Quality Assurance

- Manage a QA organization responsible for compliance to quality and regulatory requirements for a multiple vaccine product stream. Responsibilities include:
- Oversight of major quality systems associated with manufacture, quality control testing, and release of these commercial as well as developmental, clinical products (viral/ bacterial vaccines, therapeutics). Specifically this includes and is not restricted to:
  1. Deviation Management
  2. Product Release (European Authorities, FDA, Health Canada, RoW Countries)
  3. Master and Batch Production Records/ Laboratory Test Records (establishment and review)
  4. Validation of production processes including aseptic processes/ Media Fills, Media Runs, Media Simulations, Validation of analytical test methods, Transport validations
  5. Change Control Management
  6. Annual Product Review/ Product Quality Review (trending of process parameters, IPCs, release test results)
  7. Recalls, BPDRs, PTCs, AEs
  8. Stability Programs
  9. Process Control including Environmental Monitoring/ FMEA, HCCAP Analysis/ Change-over process
  10. Contract Manufacturing/ Quality Agreements
  11. Secondary Manufacturing (visual inspection/ labeling and packaging)
  12. Technology Transfer (transfer of production processes as

well as analytical test method transfer)

### 13. Self Inspection and Audit Program

Within this position and time period 5 to 9 Direct Reports were managed.

Within this time period focus was also set to the development and training of personal soft skills. Specifically this includes management and coaching of direct reports as well as providing feed back to superiors, development of social competence, awareness of the 'art of communication', actively develop a change culture (respective certificates may be provided).

Professional Experiences cont.      1995 to 2000      Hoechst Roussel Vet      Marburg, Germany  
Regulatory Affairs Manager

- Establishment and maintenance of registration dossiers for viral Veterinary Vaccines (small and large animals)
- Responsibility for the submission and processing of applications for marketing authorization within the EU and East European countries as well as Japan/ routine personal contacts with all of the respective regulatory authorities
- Establishment of 'Expert Reports' on safety as well as efficacy according to EU requirements

Professional Experiences cont.      1995      Justus-Liebig University Gießen      Germany  
Scientific Associate

- School of Veterinary Medicine, Institute of Virology
- Research: Biochemical characterization of Borna Disease Virus specific proteins
- Publications (may be provided on request)

Professional Experiences cont.      1994      Robert-Koch-Institute (RKI)      Berlin, Germany  
Freelance

- Federal Ministry of Health, RKI
- Evaluation of validation studies on viral inactivation procedures in human blood products as manufactured by the 'Behring Werke AG', Marburg, Germany

- 1990 to 1993                      Berlin / Marburg                      Germany  
Maternity Leave
- Professional Experiences cont.
- 1985 to 1989                      Free University Berlin                      Berlin, Germany  
Hochschulassistentin (Research and Teaching Associate)
- School of Veterinary Medicine, Institute of Virology
  - Research: Biochemical characterization of Borna Disease Virus specific proteins, characterization of the BDV genome
  - Teaching: Basic and advanced virology, planning and execution of virological / immunological courses
  - Coaching of graduate students aiming for their diplomas and PhD, respectively.
  - Publications (may be provided on request)
- Professional Experiences cont.
- 1981 to 1984                      University of Wisconsin                      Madison, WI, USA  
Postdoctoral Research Fellow / Research and Teaching Associate
- Department of Veterinary Science: Research in the field of Enzootic Bovine Leukosis
  - School of Veterinary Medicine: Development and performance of virological/ immunological assays as applied for routine diagnostics to detect viral diseases in small and large animals
  - Teaching: Basic and advanced virology
  - Publications (may be provided on request)
- 1978 to 1981                      Georg-August-University                      Göttingen, Germany  
Research Associate at the Institute of Veterinary Medicine and at the University Clinics for Human Medicine / Department of Hematology and Oncology
- Routine diagnostics and research in the field of Enzootic Bovine Leukosis
  - Co-working in the Federal Public Poultry Health Service
  - Research in the field of circulating immune-complexes of tumor patients
  - Publications (may be provided on request)

Education	1973 to 1980	Georg-August-University Göttingen, Germany School of Agriculture Sciences
		<ul style="list-style-type: none"> <li>▪ Specialization in animal husbandry, nutrition, housing, and hygiene</li> <li>▪ <b>1978 Diploma</b> in Agriculture Sciences (<b>Dipl. Ing. agr.</b>): Thesis: 'Hygiene during the raising of calves' at the Institute of Veterinary Medicine</li> <li>▪ <b>1980 PhD</b> in Agriculture Sciences (<b>Dr. sc. agr.</b>); Thesis: 'The persistence of precipitating antibodies in bovines infected with Enzootic Bovine Leukosis' at the Institute of Veterinary Medicine.</li> </ul>
Language Proficiencies/ English French		<ul style="list-style-type: none"> <li>▪ Nine years of education at school (English)</li> <li>▪ Three years as a research and teaching associate in Madison, WI, U.S.A.</li> <li>▪ Since 1995 working in global pharmaceutical industry/ vaccines in a bi-lingual environment fluent in speaking, reading, and writing</li> <li>▪ Seven years of education at school (French): Basics, reading and understanding of scientific documents</li> </ul>
Private Interests		<ul style="list-style-type: none"> <li>▪ Ball room dancing as high performance sports</li> <li>▪ Human and animal behavior (psychology, social competence, coaching and leading)</li> <li>▪ Spending time with family and friends</li> </ul>