

CURRICULUM VITAE



Personal data

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Summary

Consultant with 35 years of technical experience in virology, microbiology, research & development, quality systems, analytical method validation. Having competence to apply this knowledge in the biopharmaceutical industry according to regulatory requirements. Taking a pragmatic approach with no compromise to quality or safety. Sparring partner for scientists, managers, Qualified Persons. Willing to share knowledge. Team player. Writing skills. Enthusiastic, energizing, motivating. Strong communicator. Extensive scientific and social network.

Career

2010-present **EDRA Services, De Meern**

Owner and Senior Consultant

Examples of projects:

- Validation of microbial tests
- Advisor validation adventitious virus and retrovirus tests
- Set-up and validation of new virus, mycoplasma and microbiology laboratories for GMP release testing
- Advisor QC team in a biopharmaceutical company
- Microbiology training for a pharmaceutical company, preparation for FDA inspection
- Evaluation of CMC sections with respect to virology and microbiology testing
- Outsourcing of biological assays, for virus safety testing, mycoplasma, sterility, bioburden, viral clearance studies
- Senior Scientist Quality Control Department
- Risk assessment aseptic filling department
- Project implementation central cell culture laboratory serving analytical departments for R&D and GMP activities
- Root cause analysis in Out of Specifications results for microbiology and virus tests
- Improvement project on Endotoxin testing
- Subject Matter Expert: Auditing Contract Laboratories
- Disinfectant efficacy testing for viruses
- Review and writing Bill of Testing for cell banks and virus seeds

2003-2010 **Progress Project Management & Engineering, Hoofddorp**

Consultant

QC:

- Biological Assay validation, specific for tests for Genetically Modified Organisms
- QC microbiology specialist supporting a documentation and validation project
- Ad interim QC manager biopharmaceutical company
- QC advisor biological assays
- Counseling and training of QC (Microbiology) teams

QA:

- Auditing of GLP toxicology study files
- QA officer change control/validation pharmaceutical company
- Qualification of Contract Research Organizations
- Integration of GXP and ICHQ8-Q9-Q10 principles in the quality system of the R&D department of a biopharmaceutical company

Consultancy projects:

- Validation and documentation projects on aseptic manufacturing: cleanrooms and aseptic filling
 - Writing Biologics Master Files for FDA submission
 - Trouble shooting aseptic processing failures
- Microbiological consultancy services in multiple projects in laboratories, pharmaceutical manufacturing, cell bank qualification, disinfection

- Consultancy services for an aseptic filling department to improve segregation of products

Auditing:

- For cause audits
- Pre-inspection audits for GLP, GMP and FDA inspections
- Auditing of laboratories for compliance with current GMP, GLP, or GMO/biosafety guidelines

Training:

- Development, organization and presentation of courses and training sessions on subjects like GLP, aseptic production, GMP, microbiology, virology, biosafety
- Invited lecturer on several courses and conferences

Biosafety:

- Design of a new BSL-3 laboratory
- Risk assessment design virus/mycoplasma laboratory
- Risk assessment study for use of laboratory equipment with genetically modified organisms
- BioSafety Officer of a BSL-3 production facility

Project management:

- Project manager development, characterization and safety testing of a new cell line
- Study monitor tumorigenicity studies

1993-2003

MicroSafe, Leiden

Co-founder of this international operating CRO with testing activities in mycoplasma, microbiology and virology in compliance with GMP and OECD GLP regulations

Diverse functions, including:

- Laboratory manager
- Study Director responsible for mycoplasma, microbiology and virology testing and multi-site studies for cell bank and virus seed qualification
- Principal Investigator for sub-contracted studies
- BioSafety Officer

1990-1993

Centocor (currently Janssen Biologics), Leiden

Associate Scientist at the QC Microbiology department

- Responsible for the development and validation of assays for the detection of adventitious virus and murine retroviruses in cell products
- Supervising QC virus laboratory

1981-1990

Utrecht University, Veterinary Faculty

Department of Infectious Diseases and Immunology

Analyst and technical assistant to Prof. Dr. M.C. Horzinek

- Research subjects include:
 - Pathogenicity of feline and porcine Corona viruses
 - Characterization of Berne virus, resulting in the classification of a new genus within the *Coronaviridae* (Torovirus)
 - Isolation of Feline Immunodeficiency Virus (FIV) strains and subsequent characterization, cloning and sequencing
- Practical courses in virology for 3rd/4th year veterinary students

1980-1981 Organon (currently MSD), Oss
Trainee, biochemical analyst
 Development of diagnostic assays for Hepatitis B virus.

Professional Courses and Training

2015	GMP and Raw data training (PCS), Leiden
2014	Seminar Environmental Monitoring & Risk Analysis in Pharmaceutical Industry (heipha Dr. Muller), Eindhoven
2014	Annual Global Conference on Pharmaceutical Microbiology (PDA) Bethesda MD, USA
2014	Conference Biopharmaceutical Raw Materials and Viral Safety for Biologicals (Informa), Cologne, Germany
2013	Conference 4 th Virus & TSE Safety Forum (PDA), Berlin, Germany
2012	Vaccines Conference (PDA/FDA), Bethesda MD, USA
2012	Good Manufacturing Practise (PCS), Leiden
2012	Workshop Biological Waste Management and Decontamination and attending Annual Conference European BioSafety Association (EBSA), Manchester, UK
2011	Conference Adventitious Agents and Novel Cell Substrates, Emerging Technologies and New Challenges (PDA/FDA), Rockville MD, USA
2009	Conference Rapid Microbiology Methods (ECA/Concept Heidelberg), Vienna, Austria
2008	BioSafety testing: The Changing Requirements for Vaccines and Gene Therapy Products (Management Forum), London, UK
2007	Virus Testing for the Next Generation of Biologics (Management Forum), London, UK
2006	The Auditing Course (BARQA), Cambridge, UK
2004	Course Sterile Manufacturing-GMP/FDA compliant Qualification/Validation (ECA/Concept Heidelberg), Berlin, Germany
2002-2003	Courses Validation of Microbial Test Procedures (ECA/Concept Heidelberg), Barcelona, Spain and Berlin, Germany
2001	Workshop: Pestivirus Contamination of Bovine Sera and Other Bovine Virus Contamination (EDQM), Paris, France
2001	Informal Working Group: Biological Standardization in Gene Therapy (NIBSC), South Mimms, UK
1998	GLP training (PCS), Leiden
1998	Conference: Viral Safety and Regulatory Aspects of Animal Sera, Derivatives and Substitutes Used in the Manufacture of Pharmaceuticals (EDQM/IABS), Strasburg, France
1998	GMP course: Practical Aspects of Sterile Product Manufacturing (David Begg), York, UK
1996	Course on Biological Safety in Agriculture and Industrial Biotechnology, basis and application (TNO/COGEM/NIABA), Vianen/Zeist
1990	Virological Aspects of the Safety of Biological Products (IABS/Ares Serono), London, UK

1990	Symposium HIV and AIDS: Pathogenesis, Therapy and Vaccines (UCLA), Keystone CO, USA
1988	Workshop on Molecular Biology and Recombinant-DNA Technology (University Utrecht)
1983	Course on Radioactivity and Radiation (NRLW/University Wageningen)

Personal Development and Leadership

2015	Course Transactional Analysis TA101 (Corael), De Bilt
2013	Licensed Practitioner of Neuro-Linguistic Programming®, personally trained by Richard Bandler and John LaValle (NLP Life Training), London, UK
2012-2013	Personnel Development Using the Enneagram (HCA) Leusden
2012	Training Communication and NLP (Anker & Kompas), Houten
2010	Workshops Communication and Advising (Boertiengroep), Hoofddorp
2008	Training Personal Efficacy (DMS), Eindhoven
2008	Presentation Training Conviction Strength (Boertiengroep), Hoofddorp
2000	Continuous Management Training (Krauthammer), Leiden
2000	Communication Training NLP (Arcturus), Leiden

Education

2016-2020	Executive Modular MBA, Nyenrode Business University, Breukelen
2009	Assignment BioSafety Officer for GMOs up to ML-III/MI-IV/DM-III, VROM, The Hague
1996-1997	Middle Management (ISW/IBW), Utrecht, diploma 1997
1978-1981	Polytechnic School, HBO-B Biochemistry, Oss, diploma 1981
1971-1978	Secondary School Athenaeum, Doetinchem, diploma 1978

Memberships

BVF Platform	Dutch Association for BioSafety Officers
DARQA	Dutch Association for Research Quality Assurance
PDA	Parenteral Drug Association
VOL	Association of Female Entrepreneurs in Leidsche Rijn

Languages

Dutch	Native language
English	Fluent
German	Good
French	Fair

External publications

- J. Ederveen. A Practical Approach to Biological Assay Validation. A report for the Ministry of Housing, Spatial Planning and the Environment (VROM), The Hague (2010).
- J. Ederveen. Risico-evaluatie gebruik laboratorium apparatuur binnen en buiten de inperkende ruimte. RIVM, bureau GGO, Bilthoven (2007).
(<http://bggo.rivm.nl/Documenten/Documenten%20IG/Progress%20rapport.pdf>)
- S.B. Ebeling, E.R. Simonetti, H.P. Borst, A. Blok, A.M. Schelen, E. Braakman, J. Ederveen, A. Hagenbeek. Human primary T lymphocytes have a low capacity to amplify MLV-based amphotropic RCR and the virions produced are largely noninfectious. *Gene Ther.* (2003) 10, 1800-6.
- E.J. Verschoor, E.G. Hulskotte, J. Ederveen, M.J.M Koolen, M.C. Horzinek, P.J.M. Rottier. Post-translational Processing of the Feline Immunodeficiency Virus Envelope Precursor Protein. *Virology.* (1993) 193, 433-438.
- H.F. Egberink, J. Ederveen, R.C. Montelaro, N.C. Pedersen, M.J.M. Koolen, M.C. Horzinek. Intracellular Proteins of Feline Immunodeficiency Virus and their Relationship with Equine Infectious Anaemia Virus Proteins. *J. Gen. Vir.* (1990) 71, 739-743.
- H.F. Egberink, J. Ederveen, M.J.M. Koolen, H. Lutz, M.C. Horzinek. Infecties met het feline T-lymfotrope lentivirus (FTLV). *Vlaams Diergeneeskundig Tijdschrift.* (1988) 21, 252-263 en *Tijdschrift Diergeneeskunde.* (1988) 113, 937-43.
- R.E. Krebber, J. Ederveen. Besmetting van celcultures met Mycoplasma. *Histotechniek.* (1988) 2, 92-93.
- B. Kaeffer, P. van Kooten, J. Ederveen, W. van Eden, M.C. Horzinek. Properties of Monoclonal Antibodies against Berne Virus (Toroviridae) *Am. J. Vet. Res.* (1988) 50, 1131-1137.
- Y. Zhou, J. Ederveen, H. Egberink, M. Pensaert, M.C. Horzinek. Porcine Epidemic Diarrhea Virus (CV 777) and Feline Infectious Peritonitis Virus (FIPV) are antigenically related. *Arch. of Virology.* (1988) 102, 63-71.
- H. Egberink, J. Ederveen, P. Callebaut, M.C. Horzinek. Characterization of the Structural Proteins of Porcine Epizootic Diarrhea Virus (CV 777). *Am. J. Vet. Res.* (1988) 49, 1320-1325.
- E.J. Snijder, J. Ederveen, W.J.M. Spaan, M. Weiss, M.C. Horzinek. Characterization of Berne Virus Genomic and Messenger RNA's. *J. Gen. Vir.* (1988) 69, 2135-2144.
- M.C. Horzinek, M. Weiss, J. Ederveen. Toroviridae: a proposed new family of enveloped RNA viruses. *Ciba Found.Symp.* (1987) 128, 162-174.

M.C. Horzinek, J. Ederveen, H. Egberink, H.E.L. Jacobse-Geels, T. Niewold, J. Prins. Virion Polypeptide specificity of Immune Complexes and Antibodies in Cats Inoculated with Feline Infectious Peritonitis Virus. *Am. J. Vet. Res.* (1986) 47, 754-761.

M. Koopmans, J. Ederveen, G.N. Woode, M.C. Horzinek. Surface Proteins of Breda Virus. *Am. J. Vet. Res.* (1986) 47, 1896-1900.

M.C. Horzinek, J. Ederveen, B. Kaeffer, D. de Boer, M. Weiss. The peplomers of Berne Virus. *J. Gen. Vir.* (1986) 67, 2475-2483.

M.C. Horzinek, J. Ederveen, M. Weiss. The Nucleocapsid of Berne Virus. *J. Gen. Virol.* (1985) 66, 1287-1296.

M.C. Horzinek, M. Weiss, J. Ederveen. Berne Virus is not 'Coronavirus-like'. *J. Gen. Vir.* (1984) 64, 645-649.