Curriculum Vitae

Personal information

Heinrich Scheiblauer

Work experience

Currently Head of the IVD Testing Laboratory at the Paul-Ehrlich-Institut (PEI), Germany. Thirty years experience in virology, more than 20 years in the assessment of diagnostics, knowledge since then in related national and EU directives/ regulations and in quality management systems, proficient in viral safety of blood and plasma products. Extensive technical IVD expertise gained through assessment of several hundred IVD products (mainly Annex II of IVDD, but not limited to) from multiple manufacturers and of various technologies through review of technical documentation, own clinical evaluations; batch testing protocols and on-site assessments. Involved in the WHO Collaborating Center at PEI for blood products and IVDs (development of international standards), and participation as an expert in the WHO prequalification program for IVDs (review of technical dossiers and on-site evaluations). At present, working on laboratory evaluation of SARS-CoV-2 antibody and antigen assays. The above activities have resulted in more than more than 26 scientific publications.

18/10/2000 – CURRENT – Langen, Germany

Head IVD Testing Laboratory at PEI

Paul-Ehrlich-Institut

Work in the IVD Testing Laboratory mainly in cooperation with notified bodies within the framework of the IVD Directive (IVDD) 98/79/EC. First

as deputy, from 01.01.2020 as head.

Description of the individual working activities:

- Expert for evaluation of the performance of high risk IVD devices according to Annex II of the IVDD in the context of conformity assessment according to Annex IV and V/VII of the IVDD (review of technical documentation) in cooperation with Notified Bodies.
- Batch testing according to the IVDD to Annex IV 6. and Annex VII 5.on behalf of Notified Bodies.
- Regulatory tasks within PEI related to the safety of blood and plasma products (assessment of plasma master files, plasmapool testing, working group on blood saftey).
- Appointed WHO Expert for the Advisory Panel on Health Laboratory Services.
- Assessor for WHO IVD prequalification (WHO/EMP/RHT/PQT), in particular for rapid test devices for detection of HIV, HBV and HCV.
- PEI-IVD WHO Collaborating Center for Blood Products and in vitro Diagnostic Devices. Establishment of biological standards (lead in the establishment of standards for anti-HBc, anti-HBe, HBeAg, HBsAg, HCV antigen, CMV).
- Assessment and testing of diagnostics towards competent authorities to clarify vigilance issues and test failures etc.

01/08/1998 – 17/10/2000 – Langen, Germany

Senior Scientist, Project manager in the Section Marketing Authorization of IVDs

Paul-Ehrlich-Institut

Tasks were the national approval of IVDs and project manager to set up the Testing Laboratory at PEI under the IVDD.

Description of the individual working activities:

- Licensing of viral diagnostics according to the German provisions, i.e. diagnostics for HIV, HBV, HCV, HAV, Rubella, Cytomegalovirus, Rotavirus and Poliovirus.
- Official batch release testing of the above mentioned diagnostics.
- Permanent comparative testing of the licensed tests in particular e.g. to determine the seroconversion sensitivity of blood screening test devices.
- Development of reference materials and reference methods for in vitro diagnostics.
- Development, testing and application of new diagnostic methods, e.g. HIV sub-types and sub-type distribution, HBsAg mutants.
- Testing of plasma pools as starting material for blood and blood products (virus burden, antibody titer).
- Assistance in the working out of legislative regulations and directives.

01/08/1993 – 31/07/1998 – Langen, Germany

Deputy Head in the Section Viral Safety

Paul-Ehrlich-Institut

- Evaluation of dossiers on the viral safety of blood products, plasma derivatives and cell culture products (MAbs) in the context of their medicinal product approval.
- Own investigations on the efficacy of virus inactivation and virus removal methods.
- Participation in the development of the EMEA Plasma and Virus Safety Guidelines.

01/04/2008 – 31/03/2009 – Geneva, Switzerland

Project Manager, Technical Officer at the World Health Organisation (WHO)

WHO Headquarters Geneva/Switzerland

Management and Development of WHO Biological Reference Preparations.

Coordination of the various Collaborating Centers for coordination of the development of standards, set up of the internet catalog in WHO on the Biological Standards.

Education and training

01/10/2000 – CURRENT

Regular training courses since 2000 on the IVDD 98/79/EC, IVDR 2017/746, CTS (2009/886), related technical standards, and QM- systems.

Paul-Ehrlich-Institut, Notified Bodies, other organizations

01/01/2003 – 31/12/2018 – Kriegerstraße 6, Stuttgart, Germany

Lead auditor and quality auditor according to ISO 9001, ISO 13485 and IVDD 98/79/EC

Lloyd's Register Quality Assurance Limited (LRQA) and mdc medical device certification GmbH

01/01/1997 – 31/12/1997 – Ludwigstraße 23, Gießen, Germany

Special Degree in Microbiology ('Fachtierarzt für Mikrobiologie')

University of Giessen, Germany

01/10/1981 – 31/12/1990 – Ludwigstraße 23, Gießen, Germany

Study on Veterinary Science, Doctorate in Virology

University of Giessen, Germany

LANGUAGE SKILLS

MOTHER TONGUE(S): German

OTHER LANGUAGE(S):

English

Listening	**Reading**	**Spoken production**	**Spoken interaction**	**Writing**
C2	C2	C2	C2	C2

Spanish

Listening	**Reading**	**Spoken production**	**Spoken interaction**	**Writing**
C2	C2	C2	C2	C2

Additional information

Publications

26 own scientific publications as attached.

Projects

Memberships

01/01/2020 – CURRENT

EU Commission

MDCG Subgroup on IVD

MDCG Subgroup on Standards

Other Relevant Information