

**Dr. rer. nat. Egon P. Amann**

**Professor Emeritus, Consultant in Quality Systems, Medical Devices and Life Sciences**

**Quality Systems Management (Director, 2002-2013)**

- Implementing and maintaining quality management systems in the diagnostic industry (ISO 13485, ISO 9001 & other standards).
- Managing external and internal audits (supplier audits).
- Managing national governmental agency inspections by FDA (USA), ANVISA (Brazil), PMDA (Japan), Notified Bodies (Germany).
- Interacting with national and international agencies concerning product recalls, field corrections and other product issues.
- Decisions on measures to improve the quality of diagnostic products & devices.
- Decisions on product hold, on corrective measures of affected products, and on global dispositions of such products.
- Assignments in diagnostic industry associations (EDMA, IFCC).

**Strategic Planning / Business Development / Technology Assessment (Senior Director, 1996-2002)**

- Identification of portfolio-complementing diagnostic assays, tests and devices.
- Identification of suitable license-in and license-out partners.
- Managing license contract negotiations.
- Assessing the financial value of novel diagnostic products, devices & assays.
- Proposal for and participation in implementing strategic redirections.
- Development of synergy portfolios Rx-Dx (pharmaceutical – diagnostic products).
- Participating in due diligence processes for company acquisitions / mergers.

**Diagnostic product development (Program Director)**

- Project lead “Hemostasis Improvement Program“, Dade Behring Diagnostics (2002-2004).
- Program lead “New serology, coagulation, and tumor marker assays for the OPUS instrument line“, Behring Diagnostics GmbH (1994-1996).

**Pharmaceutical and diagnostic R&D in Japan (Department Head, 1990-1994)**

- Managing “Cell Biology” and “Drug Creation Research“ departments of Hoechst Japan Limited in Tokyo.
- Conceptual design of fermentation facilities in the new “Recombinant Protein Plant” for the manufacture of biological pharmaceuticals.
- Head of biological safety of this plant.
- Manufacture of recombinant human proteins (e.g., coagulation factor XIII, GM-CSF und G-CSF) in cooperation with the head of manufacture.

- Cloning and characterization of new regulatory proteins of the osteoporosis pathway (Osteoblast-specific factors; OSFs).
- Development of a novel diagnostic assay for the detection of autoimmune diseases.

Pharmaceutical and diagnostic R&D in Germany (Laboratory Head, Group Lead, 1982-1990)

- Cloning of novel human proteins with pharmaceutical relevance.
- Development of heterologous expression systems for the manufacture of pharmaceutically relevant proteins (E. coli, yeast, animal cells).
- Vaccine Research (HSV-1, Malaria, FMSE).

### **Academic experiences**

- Professor “Quality Assurance and Product Legislation” at Hochschule Hamm-Lippstadt, University of Applied Sciences, Hamm, Germany (2013-2021).
- Honorary Professor at Philipps-University of Marburg (2005-2013).
- Habilitation and authorization to teach (“Privatdozent”) in Molecular Genetics at Philipps-Universität Marburg (1990).
- Postdoctoral Fellow at Harvard University in Cambridge, MA, USA, in the laboratory of Prof. Dr. Mark Ptashne (1980-1982).
- PhD in Molecular Genetics (MPI Berlin - magna cum laude, 1980)
- Diploma in Biology (Free University Berlin, 1977)

Egon P. Amann is author and co-author of 60 peer-reviewed publications (with more than 4.000 citations) and 18 patents granted in the area of gene expression vectors, vaccine development, cloning and expression of human proteins, osteoporosis regulators, and diagnostic assays.

Egon P. Amann served for many years in the International Federation of Clinical Chemistry (IFCC) and currently is Co-Chair of the Task-Force on Global Lab Quality (TF-GLQ).