HERMANN LEHN, PH.D.
Consultant
LehnConsulting

EDUCATION:

1985 — **German Cancer Research Center/University of Heidelberg, Germany**
Ph.D.-Thesis: Organization and expression of papillomavirus genomes in human genital tumors

1982 - 1985 — **German Cancer Research Center, Heidelberg, Germany**
Post-graduate studies on tumor virus gene expression in human tumors

1982 — **University of Nice, France**
Short-term fellowship of the European Molecular Biology Organization

1976 - 1982 — **University of Heidelberg, Germany**
Graduate student, diploma examination and senior thesis (Biology)

PROFESSIONAL EXPERIENCE:

Since June 2015 — **Quality Consultant at LehnConsulting**

- ✓ Successful preparation for and support during inspections by GLP Monitoring Authorities from EU and from US FDA
- ✓ Conduct of CRO audits and internal audits In European countries, in North America, in Russia and in China
- ✓ Development, successful implementation and maintenance of a quality system for GLP and GCLP at a CRO
- ✓ Conduct of several full-day in house trainings on GLP and GCLP
- ✓ CSV guidance and support

September 2012 - May 2015 — **Global Head of Operations and Quality**
F. Hoffmann-La Roche Ltd, Basel (Switzerland), VP Pharmaceutical Sciences
Member of Roche's Quality Steering Committee

- ✓ Managed and guided the GLP QA group at the sites in Basel and Nutley, NJ
- ✓ Managed and guided the groups responsible for all outsourcing of toxicology and safety pharmacology studies, for reporting and IND/NDA submissions, for planning and resource allocation, and for archiving of study materials (internally and at contract archives)
- ✓ Ensured, together with local QA, the GLP compliance during 2 inspections of the Swiss GLP Monitoring Authorities in Basel, and during one inspection of the Nutley, NJ, site by US FDA
- ✓ Strategically developed and implemented the first quality system within Roche research areas at the Roche Innovation Center Shanghai

- ✓ Prepared the Roche Innovation Center Shanghai for an inspection by Chinese FDA which was successfully passed
- ✓ Ensured GCP compliance of laboratories which conducted bioanalysis of samples from clinical trials
- ✓ Further improved the global Roche nonclinical outsourcing strategy by implementing best operational practices
- ✓ Maximized the support of Pharmaceutical Sciences departments by introducing globally harmonized and optimized operational processes, and by implementing new concepts in order to improve quality and best practices
- ✓ In addition to the CRO inspection activities from May 2005 to September 2012, coordinated about 80 GLP inspections of CROs globally used on behalf of Roche. Review of all CRO inspection reports. Conducted about 20 CRO inspections himself, 4 thereof in China.
- ✓ Ensured the timely availability of fully compliant final GLP study reports
- ✓ As member of Roche´s Quality Steering Committee, contributed to the global Roche quality strategy, together with the global QA Heads of GCP, GMP, IT and Diagnostics

May 2005 - September 2012

Global Head Quality Assurance GLP
F. Hoffmann-La Roche Ltd, Basel (Switzerland), VP Nonclinical Safety
Member of Roche's Quality Steering Committee
Member of Roche's Sustainability Working Group

- ✓ Managed and guided the GLP QA groups at the sites in Basel, Nutley, NJ, and Palo Alto, CA
- ✓ Ensured, together with local QA, the GLP compliance during 3 inspections of the Swiss GLP Monitoring Authorities in Basel, and during 3 inspections of the North American sites by US FDA
- ✓ Ensured GCP compliance of laboratories which conducted bioanalysis of samples from clinical trials
- ✓ Project leader (project duration: 4 years) of the Roche Pharma Research *GLIMS* project where more than 20 LIMS systems were replaced by a small number of fully GLP and 21 CFR Part 11 compliant global LIMS. This also encompassed the GxP compliant decommissioning of more then 14 LIMS
- ✓ Ensured the timely availability of fully compliant final GLP study reports
- ✓ Coordinated about 250 GLP inspections of CROs globally used on behalf of Roche. Review of all CRO inspection reports. Conducted about 40 CRO inspections himself, 10 thereof in China
- ✓ Delivered strategic input and co-developed the new GLP study outsourcing strategy of Roche
- ✓ Project leader of the GLP closure projects of the Roche Nutley and Roche Palo Alto sites. Both projects were retrospectively inspected by US FDA without any objections and therefore considered fully compliant with 21 CFR Part 58
- ✓ As member of Roche´s Quality Steering Committee, contributed to the global Roche quality strategy, together with the global QA Heads of GCP, GMP, IT and Diagnostics
- ✓ Contributed to the successful sustainability strategy of Roche

April 1999 - April 2005

Global Head Quality Assurance GLP
Bayer Health Care AG, Wuppertal (Germany)

- ✓ Managed, in a newly created function, the GLP QA groups at the sites in Wuppertal, in West Haven, CT, in Raleigh, NC, and in Berkeley, CA
- ✓ Ensured compliance during 2 inspections of German GLP Monitoring Authorities and one joint US FDA/German GLP inspection
- ✓ Supported/guided the joint US FDA/German GLP inspection of the West Haven site in September 2001
- ✓ Ensured the timely availability of fully compliant final GLP study reports
- ✓ Conducted most GLP inspections of CROs globally used on behalf of Bayer
- ✓ Implemented new processes in order to meet OECD GLP Consensus and Advisory Documents
- ✓ Developed the strategy for computer system validation, in the GLP area, together with the company IT experts
- ✓ Ensured regulatory compliance of the sample analysis from clinical trials (Bioanalytics, Clinical Chemistry, Hematology)

May 1990 - March 1999

Head of Quality Assurance GLP
Business Group Pharma, Bayer AG, Wuppertal (Germany)

- ✓ Led up to 5 teams of GLP QA inspectors with a total of <20 staff
- ✓ Ensured compliance during 3 inspections of German GLP Monitoring Authorities and one joint US FDA/German GLP inspection
- ✓ Ensured the timely availability of fully compliant final GLP study reports
- ✓ Conducted most GLP inspections of CROs globally used on behalf of Bayer
- ✓ Implemented the GLP regulations according to German Chemical Act from 1990 as well as the revised OECD GLP regulations from 1997
- ✓ Implemented new processes in order to meet OECD GLP Consensus Documents

May 1986 - April 1990

Toxicology Study Director
Institute for Toxicology, Bayer AG, Wuppertal (Germany)

- ✓ Implemented cell culture models in genotoxicity, such as HPRT test, UDS test
- ✓ Executed regulatory genotoxicity studies in compliance with GLP regulations
- ✓ Outsourced GLP genotoxicity studies to CROs

April 1986

Ludwig Institute for Cancer Research, Sao Paulo (Brazil)
Advisor in advanced techniques of gene expression detection methods

April 1985 - April 1986

German Cancer Research Center, Heidelberg (Germany)
Post-doctoral research associate

OTHER:

- Founder Member of the German Quality Management Association (GQMA; formerly DGGF)
- Fellowship of the British Association of Research Quality Assurance (RQA)
- Active Member of the American Society of Quality Assurance (SQA)
- Representative of the German Pharmaceutical Industry at OECD GLP Workshops between Industry and Authorities
- Invited Speaker at international conferences on a regular basis