CURRICULUM VITAE

PERSONAL SKILLS AND EXPERIENCE

Over 30 years' experience within the pharmaceutical industry in clinical research and development with strong experience in project management

- project planning, budgeting, tracking and reporting
- contacts with preclinical scientists
- optimizing the laboratory process for the production of the compound
- CMO selection and management
- local and international CRO selection and management for toxicology program and clinical studies
- regulatory affairs management (meeting regulatory requirements and managing contacts with the authorities)
- team leadership, management and training, managing team meetings
- project budgeting and management
- production and presentations of project documentation material

Strong experience in planning and executing clinical studies

- expertise in protocol writing, mainly Phase I/II but also Phase III in numerous indications including RA, Dermatology, Immunology, Hematology, Oncology, Cardiovascular, Respiratory
- initiating, auditing and reporting of international clinical trials phase I-IV (including orphan drug indications and compassionate use/ named patient programs)

- since 1998 responsible for
  - Phase I/II Study in Glioblastoma: Germany, Russia, India
  - Phase III Study in Renal Cell Carcinoma: USA, Europe, Russia
  - Phase I Studies for NCEs and Biologics in Oncology : Germany
  - Phase II Studies for NCEs in Prostate Cancer: Germany, France
  - Phase I Study in Severe Brain Injury (Biotech Product): Germany
  - Phase I Studies in Oncology (Biotech Products): Germany
  - Phase III Study for NCE in Chronic Heart Failure: USA, Europe
  - Phase III Study for NCE in Pulmonary Arterial Hypertension (PAH): Mexico, Europe
  - Phase II studies for NCEs in Duchenne Muscle Dystrophy, Friedreich's Ataxia and in Leber's Hereditary Optic Neuropathy: USA, Canada, Europe
  - Phase II Study for NCE in Traumatic Brain Injury (TBI): USA, Europe, Australia

- strong negotiating and representative skills (with medical, financial and regulatory parties, at board meetings, congresses)
- organization of opinion leader meetings
- managing clinical development with strategic alliance partners
- international scientific lecturing
- ambitious, excellent leading and communication skills, analytical thinking, team player, goal oriented, highly organized, international network

PROFESSIONAL AFFILIATIONS

- Member of the Swiss Society of Hematology
- Member of the Swiss Society of Immunology
- Member of European Hematology Association

PERSONAL EXPERIENCE

December 2020
until May 2022 **Clinical Program Leader, Immunology at Sobi,**
Swedish Orphan Biovitrum AG, Solna, Sweden
Responsibilities:
-ensuring cross functional coordination
-adherence to timelines, budget
-operational strategy within the indication

July 2020 until
September 2017 **Project Manager at Saiba Biotech Zürich**
Responsible for organizing the team for development of a Corona vaccine

September 2017
until April 2020 **Head of Clinical Operations, PresSura Neuro, Melbourne, Australia**
Responsible for selecting the CRO for Phase II study and implementation and conduct of the trial together with the CRO, responsible for the management of clinical sites, laboratories and other relevant study vendors.
Accountable for the implementation and execution of the clinical trial according to ICH GCP and other applicable regulations.
Responsible for the coordination of the study team allocated to the project to ensure that project activities and trial deliverables are achieved according to timelines, quality standards, budget and contractual agreements.

September 2019
until Nov 2019 **Senior Clinical Project Manager, Virometix, Schlieren, Schweiz**
Successfully supporting and managing the team for the next steps from preclinical phase to Phase I for a new vaccine.

September 2016
until Oct 2017 **Snr Global Project Manager in pRED**
F. Hoffmann-La Roche, Basel, Switzerland
Supporting and Managing the team for the next steps from preclinical phase to Phase I
by providing operational leadership, communication and facilitation skills in partnership with the PTL to create and maintain high performing project teams and ensure highly effective Meeting Management.
Effectively managing the budget and milestone projection to ensure timely and coherent forecast. Keeping the teams on track to reach their

deliverables by illustrating short-term, mid-term and long term activities to achieve team objectives.

March 2016-
September 2016 **Compassionate Use /Pre-Approval Access Coordinator at F. Hoffmann-La Roche, Basel, Switzerland**
Organizing and coordinating drug supply for patients worldwide either in compassionate use programs or investigator initiated trials.

July 2015-
March 2016 **Clinical Project Manager Asthma at Novartis, Basel, Respiratory Franchise**
Responsible for all operational aspects of organizing and controlling global IITs (negotiating with CPOs, legal, finance, DSM, investigators), Grants (negotiating with CPOs, legal, finance, compliance department, payments); budget control of the team budget, organizing finance approvals, payments as well as supporting the team for any other operational aspects of activities.

March 2015-
June 2015 **Senior Project Manager Santhera AG, Switzerland**
Responsible for vendor selection (CROs) for clinical studies and starting a clinical trial in USA (organizing and leading the kick-off meeting) until the new Head of Clinical Operations could join the company.

June 2014-
Dec. 2014 **Clinical Scientific Associate Director at Novartis, Basel, Primary Care Franchise**
Responsible for data review and cleaning of a global registration study and supporting the team in all aspects of preparation of the study report

April 2014-
May 2014 **Expert Clinical Manager at Novartis, Basel, Oncology Business Unit**
Responsible for supporting the international team in all aspects of starting a new global trial, mainly writing the clinical study protocol and defining the CRF and PDs.

June 2013-
March 2014 **Clinical Scientist at Novartis, Basel, Primary Care Franchise**
Responsible for starting 2 new global studies in COPD in close relationship with the study manager and the medical person, mainly writing the clinical study protocol and defining CRFs and PDs with statistician and data managers

2007 - 2013 **Project Manager**
From laboratory to clinic for new compounds (NCEs and recombinant proteins) in small biotech companies
BD Manager
For CROs (phase I units and full service companies)

Since 1998 **Independent Consultant for the pharmaceutical industry**

Mainly for emerging biotech companies
- Co-founder of the CRO Hesperion Ltd.
- Managing Director of Hesperion Germany GmbH
- Managing Director of Actelion Germany
- Director of Project Management and Director of Business Development at Hesperion until 2008, when Hesperion was sold to Averion International Ltd.

1995 - 1998 **F. Hoffmann-La Roche Ltd., Basel, Switzerland**
Business Development & Strategic Marketing
Pharmaceutical Division
International Medical Manager for Neupogen® Senior Scientist
Responsibilities:
- leading the Medical Team for Neupogen® reporting to the Amgen-Roche Joint Development Team
- management of clinical trials phase III and phase IV;
- coordination of international study centers and groups;
- clinical trials reporting; auditing;
- scientific lectures at national meetings in Europe, Middle- and Far East

1986 - 1995 **Sandoz Pharma Ltd, Basel, Switzerland.**
Clinical Research and Development
Clinical Expert
Responsibilities:
- development (phase I to phase III) and registration of GM-CSF (Leucomax®) in cooperation with Schering-Plough Ltd.
- international lecturing at conferences and launch meetings
- life cycle management after registration
- clinical development of anti-viral monoclonal antibody; lipid A analogue as cytokine stimulator; novel anti-rheumatic, oncological, dermatological and anti-infectious agents from phase I to phase IV

1983 - 1986 **University of Medicine, Inselspital, Bern, Switzerland,**
Scientific Assistant at the Central Hematology Laboratory
Head of the Laboratory of the Autologous Bone Marrow Transplantation Unit

1981 - 1983 **University of Medicine, Basel, Switzerland, Institute of Microbiology,**
(Prof. Dr. P. Erb)
Scientific Assistant

EDUCATION

1977 - 1981 **University of Basel, Switzerland (Biocenter)**
Ph.D. in Cell-Biology and Immunology

1971 - 1977 **Ludwigs-Maximilian University, Munich, Germany**
Diploma in biology

Main subjects: physiology, biochemistry, genetics, cell-biology, molecular biology

1968 - 1970 **Study of Biochemistry at the Chemieschule Dr. Elhardt, Munich**
Certificate as a licensed senior technician

1967 **Diploma from German secondary school**
Pestalozzi Gymnasium, Munich, Germany

PROFESSIONAL TRAINING

Internal Company Courses

1989 - 1997 **Strategic Marketing Course, F. Hoffmann-La Roche Ltd. Basel,**
DRRA International Workshop (Drug Registration & Regulation Association)

Basic Management Training Course; Project Management Course, Basic Leadership Training Courses; Course in Clinical Trial Statistics; Clinical Trial Monitoring Course, Sandoz Ltd. Basel, Switzerland

External Courses

1997 **The Interpersonal Effectiveness Course, Management Centre Europe, Brussels, Belgium**

HONOURS

1981 - 1983 **Research grant of Deutsche Forschungs -Gemeinschaft (DFG)**