Dr. Angelika C.Stern, Immunologist/ Hematologist

www.sternconsult.ch

EXPERIENCE

Over 30 years' experience within the pharmaceutical industry in clinical research and development

- 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 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 II Study in sHLH (Still's disease, Hemophagocytic): USA, Canada, Europe, Russia
  - Phase I/II Study in Glioblastoma: Germany, Russia, India
  - Phase III Study in Renal Cell Carcinoma: USA, Europe, Russia
  - Phase I Studies for New Chemical Entities (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
  - Phase II Leber's Hereditary Optic Neuropathy: USA, Canada, Europe
  - Phase II Study for NCE in Traumatic Brain Injury (TBI): USA, Europe, Australia
  - pre-clinical : Hepatitis C protease inhibitors
  - Phase I-IV Autologous and Allogeneic Bone Marrow Transplantation

- 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: Key Highlights

At present: **Consulting activities for several (undisclosed) Biotech Companies**

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

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.

March 2016-
until Oct 2017 **F. Hoffmann-La Roche, Basel, Switzerland**

Snr Global Project Manager in pRED

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.

Compassionate Use /Pre-Approval Access Coordinator
Organizing and coordinating drug supply for patients worldwide either in compassionate use programs or investigator initiated trials.

June 2013-
until March 2016 **Novartis, Basel**

Clinical Project Manager Asthma at 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.

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

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.

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-
Until – 2013 **Pieris, Munich, Germany**
Project Manager From Bench to Bedside : (Anticalin: recombinant anti-vegfr protein:), phase 1, Oncology

1998-2008 CRO Hesperion Ltd.
- For CROs (phase I units and full service companies)
- Managing Director of Hesperion Germany GmbH
- In 2008, Hesperion was sold to Averion and eventually to ICON

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

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

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)**