

Work Experience Dr. med. Ann Baumann, Fluentis GCP

Head of the GCP Inspectorate and department of clinical trials, Swissmedic, Bern, Switzerland June 2007 – March 2011

- Planning, preparing and conducting inspections of clinical trials
- Notification of clinical trials with drugs
- Writing standard operating procedures and checklists
- Training of new medical reviewers and GCP inspectors
- Networking with ethical committees and pharmaceutical industry
- Networking with EU GCP Inspectors, member of the EMA Inspector working group
- Workshops on GCP inspections and notification of clinical trials in Switzerland

Medical reviewer and GCP Inspector, Swissmedic, Bern, Switzerland March 2005 – June 2007

- Performed assigned GCP inspections
- Notification of clinical trials with drugs (evaluation of protocol, informed consent, insurance certificates, contracts, IMP documentation, etc.)

Project Manager, Geistlich Pharma AG, Wolhusen, Switzerland March 2000 – February 2005

- Writing of study protocol, informed consent, CRF for clinical trials with medical devices
- Submission of clinical trials to ethical committees and authorities
- Established Design Control Processes in cooperation with regulatory affairs for all medical devices of the company
- Training of principal investigator in ISO guidelines and GCP

Assistant doctor, different hospitals in Belgium, London, Switzerland July 1996 – February 2000

Summary of Qualifications

- Remarkable experience working in a clinical, regulatory and quality assurance environment
- Excellent knowledge of GCP inspections and the swiss regulations on clinical trials
- Skilled in inspection of swiss and EU clinical trials
- Sound knowledge of ICH guidelines
- Sound ability to prioritize
- Ability to work under pressure and independently
- Excellent communication and intrapersonal skills
- Excellent report writing capabilities

Education

- Doctor in medicine, University Leuven, Belgium, 1996
- Master of surgery, University London, 2000
- Continuous training in GCP, swiss regulation and inspection skills