



Doris Weber Rügger

Brief profile

Born 1972 in Glarus
Resident in Canton Thurgau

Director of PHARCONS Pharma Consulting GmbH

Diploma of Advanced Studies in Pharmaceutical Medicine
MSc Biomedical Engineering
Chemist FH

Main working responsibilities

Regulatory Affairs

New applications in diverse therapeutic areas (incl. oncology), fast track, regular and article 13 procedures. New and known active substances, Orphan-Drug Status etc.
Life-Cycle Management (extensions, all types of variations, PSUR, renewal, labelling changes etc.).

eCTD

Complete compilation incl. publishing and validation of sequences incl. baseline.

Pharmacovigilance

Experience as Drug Safety Officer (DSO) and DSO Deputy; handling of reports from and to authorities as well as internal party, maintenance of database.

Quality

Establishment/maintenance QMS, "Responsible Person", PQR review etc.

Training

eCTD training for eCTD beginners and experienced users, internal trainings/presentations on Swiss authorisation procedures etc.

Medical Affairs

Review of promotional materials, training of sales forces, medical writing.

Professional basis

Education

DAS Pharmaceutical Medicine (17-19)
MSc Biomedical Engineering (08-10)
Chemist FH (01-04)
„Technische Berufsmatur“ (00-01)
Medical laboratory technician (95-98)
Degree in music, apprenticeship and orchestral diploma (89-93).

Employment history

Director PHARCONS Pharma Consulting GmbH, responsibility of Regulatory Affairs dept., senior position Regulatory Affairs, Regulatory Affairs Manager (consultancy), head of laboratory, medical lab technician, music teacher.

Professional training

Various internal and external trainings in the area of Regulatory Affairs, eCTD, Pharmacovigilance, Medical Affairs, Pharma and Legislation etc.

Memberships

Megra (central European association of Regulatory Affairs)
SwAPP (Swiss Association of Pharmaceutical Professionals)
Swiss Engineering (professional association of engineers and architects in Switzerland).