



## 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).