

## Job Objective

Freelance collaborator offering support in the field of Regulatory Affairs

## Professional Summary

- More than 5 years experience in the sector of Regulatory Affairs
- Experience in the field of oncology and other medical disciplines
- Used to work unsupervised
- Solution-oriented and structured approach to work, even if the workload is high
- Excellent communication skills, flair for interacting with people

## Work Experiences

Since 12/2013

**Büro & und Vertriebs-Service, Peißenberg;** Freelancer

- Redacting of spc, pal and labeling texts
- Conforming of german informative texts to english demands (in connection with MRP/DCP proceedings)
- Adapting of texts to QRD templates
- National implementation of approvals in MRP/DCP proceedings
- Providing and submitting of variations
- Competent contact partner to cooperate with national authorities (DE and AT)

2012-2013

**Registered german distance school: sgd Darmstadt**

course: Psychotherapy HP; final grade: testimony

10/2011-07/2013

**Oncocorp GmbH, Weilheim;** Assistant of medical scientific department

- Composition and monitoring of e.g. approvals, variations
- Controlling of informative texts regarding to form and content
- Maintaining the establishment of a Quality Management System
- Supporting the preparation of scientific training materials
- Sales representative for oncological products

11/2006-09/2011

**NeoCorp AG, Weilheim;** Assitstant of medical scientific department

- Compiling of national and european approvals
- Monitoring all time lines according to authority
- Independently handeld correspondence to authority (BfArM)
- Authoring of pal, spc and labeling
- Administrating the Pharmacovigilance System
- Reviewing and adapting of Standard Operation Procedures
- Training of Sales representatives
- Answering to client requests

seit 05/2003

**„medinfo-onkoserv“, Penzberg**

- Maintaining of a literature data base (ca. 2 hours/week)

- 05/1997-10/2006: **Bristol-Myers Squibb, München**; Sales Representative
- Scientific advising of practicebased and clinicalbased Oncologists and Internists
  - Planning and organisation of special seminars
  - Participation in national and international congresses
- 10/1994-04/1997: **Dr. August Wolff Arzneimittel GmbH & Co, Bielefeld**; Area Sales Manager
- Responsible for offering original- and generic products in different branches of medical science
- 03/1992-09/1994: **Forschungszentrum Jülich, Institute of Biotechnology**; Assistant
- Investigation of a Multi-Enzyme complex with genetical methods
- 1992-1994 **Registered german distance school: medidact Pharma GmbH, München**  
final grade: IHK certified Area Sales Manager
- 12/1991-02/1992: **Labormedizinischen Praxis Dr. Hoeverer, Dr. Cornely, Aachen**;  
Assistant
- Implementation of microbiological tests
- 07/1989-09/1991: **Heinrich-Heine-Universität Düsseldorf, Institut of Biochemistry**;  
Assitstant
- Examination of molecular-genetic work

## Education

- 1987-1989 Berufsfachschule für technische Assistenten, Köln  
Final Grade: **state certified Biological Technical Assistant**
- 1978-1987 Gymnasium in Eschweiler  
Final grade: **University-entrance diploma**

## Additional skills

- 05/2014 Workshop: electronic submission: basic principle and eCTD; MEGRA
- 03/2014 Presentation: electronic submission via CESP; P.S.S.T
- 02/2014 Presentation: pharmaceutical, medical product, cosmetic product, biocidal products; definition, characteristics, differences; P.S.S.T
- 09/2010: InDesign course
- 03/2010: Labeling & Package leaflet (legal requirements belonging to. 15.AMG-Novelle; user testing, usefull tipps)
- 06/2009: Seminar: Variations (variations on basis of 15. AMG-Novelle) FORUM Institut
- 01/2008: Seminar: Drug approval in Germany and Europe; FORUM Institut
- 11/2007: Office practice: excel XP course; Institute 2F
- 11/2007: Seminar: Common Technical Document; FORUM Institut
- 06/2007: Seminar: official auxiliary in Regulatory Affairs; FORUM Institut
- 07/2001: English language course in London for one week; Language Studies International
- EDV Very good knowledge in MS Office (word, excel, powerpoint, outlook)
- Languages German mother tounge  
English proficient w/s