PERSONAL INFORMATION

Marcella Albanti
Residence: 47923 Rimini
Italy

POSITION Regulatory Affairs Consultant

WORK EXPERIENCE

26/08/2019- Now Regulatory Affairs Consultant

Vetoquinol

API drugs DMF writing, DMF part of veterinary dossiers, changes submission.

18/10/2017–09/08/2019 Regulatory Affairs Manager

Amino Chemicals Limited, Marsa (Malta)

Lifecycle management of authorized DMF, DMF writing, maintenance old licenses
(API). Preparation of documentation to get a CEP/CEP updating.
ANDAs, ANDS deficiency responses. (EU, US, Canada, China, Korea, Brazil, GCC countries)

Customer regulatory documents Management
In charge of the regulatory compliance role: monitor and provide management with impact of changes in the Regulatory environment.
Establish strong relationship with Health Authorities, including follow-up to check submission status
Florida Permit management
Daily contact with other functions and with same function around the world (customers).
Providing documents for registration of products to several companies around the world.

01/06/2013–13/10/2017 Regulatory Affairs Manager

Sandoz, Rovereto (TN) (Italy)

Lifecycle management of authorized DMF, DMF writing, maintenance old licenses.
Preparation of documentation to get a CEP/CEP updating.
ANDAs, ANDS deficiency responses.
In charge of the regulatory compliance role: monitor and provide management with impact of changes in the Regulatoryenvironment.
Establish strong relationship with Health Authorities, including follow-up to check submission status
Daily contact with global function and with same function around the world inside the company.
Providing documents for registration of products to several companies around the world.
Regulatory representative in several cross-functional cross-site projects.

31/07/2012–31/05/2013 Regulatory Affairs Specialist

Alliance Healthcare, Lavagna (GE) (Italy)

- Management of drug parallel import license (AIP)
- Medical Device (class I) registration (Italy)
- Cosmetic products registration.
- Management of cosmetic products marketing brochures.
- Post marketing assistance medical device as customer service

10/01/2011–31/07/2012 Regulatory Affairs Specialist

Erydel S.p.a, PU (Italy)

- Orphan Drug Designation (ODD) request (EMA)
- Participate to Combined Product (FDA) application,
- development new MAAs OD,
- maintenance old ODD.
- IB and IMPD new Orphan Drug
- Attend Scientific Advice with competent authorities.

04/05/2009–31/12/2010 **Regulatory Affairs Specialist**

Novartis Vaccines and Diagnostics, Siena (Italy)

Flu Franchise, construction module 1 of the CTD and e-CTD, for EU, Swiss, Canada, Kazakhstan, Poland, Hungary, Croatia, Albany, Moldova, Russia, Serbia/Montenegro, Czech Republic. Submission of variations (IA, IB, II) and renewal of MA, support in control of documents of Module 2 and 3 for the submissions. MRP/DCP/National procedures. Daily interaction with CA in EU member states.

14/03/2004–03/05/2009 **Medical Sales Representative**

Astra Zeneca and Allergy Therapeutics (Italy)

Information of the Practitioners and Specialists

03/04/2003–03/10/2004 **Pharmacist**

Municipal Pharmacies

08/1998-11/2002 **Chemical Head Assistant**

Italian Beet Growers Association-ABI (Seasonal)

01/06//1994-1/08/1998 **Waitress**

Bars and Restaurants (Seasonal/weekend)

EDUCATION AND TRAINING

05/06/2018-06/06/2018 **EXTEDO eCTDmanager European eCTDmanager User Group Meeting 2018**

Munich

01/10/2007–27/03/2010 **Second level Master " Regulatory Affairs in drugsand biotechnology"**

University of Novara, Novara (Italy)

01/10/1993-27/03/2003 **Degree in Chemistry and Pharmaceutical Technologies**
(Biotechnology)

PERSONAL SKILLS

Mother tongue(s) Italian

Foreign language(s)

English
French
German

Communicationskills
- good communication skillgainedthroughmy experience as salesrepresentative.

Organisational/ managerial skills
- good organizational skills gained as responsible of regulatory affairs
- good leadership, even if responsible of just one person, gained as sales representative.

Job-related skills
- good command of regulatory registration process
- good control of the working skills under stress
- good motivational capability