

KATIA AMERICI

Date of birth: September 7, 1969

Place of birth: Sezze (Latina)

Contact address. Via L. Da Vinci 5

04011 Aprilia (Latina).



Work experiences

ACRAF SPA Angelini Group

From Nov 2020 – till now

Global Regulatory Affairs Pharma Head.

Coordinate the planning and monitoring of team member's activities for regulatory activities on global level with affiliates and partners worldwide.

Design regulatory strategies for submitting registration dossier.

Collaborate in Due Diligence for the acquisition of new products or companies.

From Oct 2012 – till Nov 2020

Responsible in International Regulatory Affairs in European and non EU countries.

Coordinate the planning and monitoring of team member's activities for regulatory activities on global level with affiliates and partners worldwide.

Design regulatory strategies for submitting registration dossier.

Collaborate in Due Diligence for the acquisition of new products or companies.

From Jan 2007 till Sep 2012

I was hired at the ACRAF SPA Angelini Group as the ***Head of Regulatory Affairs Business Generic Italy*** where I dealt with the evaluation of the dossiers and the preparation of the marketing authorization applications in agreement with the national procedure, the mutual recognition and decentralized. Preparation of variation the types of AIC IA-IB-II. Preparation of the application for the renewal of the AIC - ownership transfers - dealership, due diligence. I had the management of the patient information, implementation and monitoring of the material packaging.

I managed the local archives (paper and electronic) Regulatory Office.

Tubilux Pharma S.p.A.

From Sep 1999 till Dec 2006

I was hired at the Tubilux Pharma S.p.A. as ***Regulatory Affairs Manager*** where I dealt with the evaluation, preparation and management of the dossier (CTD format) and documents for registration purposes to both national and foreign (European and non-European area). Verification for the patient information and their compliance with the ministerial authorizations and by the law.

Relationship with the health authorities in the management of regulatory and authorization procedures. Collaboration with other business functions for the drawings of SOPs regarding the Regulatory Affairs relevant topics. I followed the pharmacovigilance activities; I supported the Technical Direction and pharmaceutical development for the technical documentation necessary for registration purposes.

WorldWide Clinical Trials

From Jan 1999 till Aug 1999

I was hired at the WorldWide Clinical Trials as a ***Clinical Research Associate***, where I was involved in a multicentre study of Eli-Lilly in oncology.

Novo Nordisk Farmaceutici S.p.A.

From Feb1995 till Dec 1998

Hired as a ***Clinical Research Associate at the Medical Management / Regulatory*** Novo Nordisk Farmaceutici S.p.A. In this position I was responsible for the online endocrinology and paediatric endocrinology (phase III and IV). I had collaborated with many "opinion leaders" of the Italian paediatric and endocrinology areas. I gained considerable experience in organizing Italian and international multicentre clinical trials, interacting with the Head office

Novo Nordisk in Copenhagen, in agreement with the EEC legislation on 'Good Clinical Practice'

The trials were run from the beginning protocol drawing of the related data-acquisition card and the operating manual, the assessments of the costs and the collection of the "Pre-Study Documentation" (exequatur, approval of the Ethics Committee, etc.) till their closing. For this reason, in addition to monitoring the studies at the centres (comparison of the data with the "Source Documentation" control "Drug Accountability", etc.) I was devoted to the input of the data and I worked till their validation with the "Clinical Quality Assurance". Also I helped the Regulatory Manager in the preparation of the dossier registration especially for the clinical part.

Lastly, I was in charge of the pharmacovigilance and SOPs on clinical trials.

Educational Background

UNIVERSITY 'OF ROME "La Sapienza"

Degree in Biological Sciences entitled "Preliminary research on the spleen differentiation in normal chicken embryos and partially brainless". Speaker: Prof. Harry Manelli, director of the Institute of Zoology ", with 105/110.

Post-graduate internship at the Laboratory of Clinical Analysis dell'A.S.L. Rm / H "Hospital Regina Apostolorum"

HIGH SCHOOL ANTONIO MEUCCI located in Aprilia (Latina)
scientific maturity diploma with the vote of 53/60 vote.