Europass Curriculum Vitae

Personal information

First name(s) / Surname(s)	**Vanessa Bonomi**
Address(es)	Via dei Mille 5 – 25046 Cazzago San Martino (BS)
E-mail	bonomi.v@libero.it
Nationality	Italian
Date of birth	24/03/1979
Gender	Female

Work experience

Dates: 02/2022 → up to date

Occupation or position held: **Chief Quality & Regulatory Officer**

Main activities and responsibilities:

As Head of Regulatory Affairs:

- Coordinates product authorization processes and changes in the various regulatory areas
- Definition of regulatory strategies for the market access of company products
- Provides input to planning activities for regulatory aspects (R&D, QA)
- Manages product technical files
- It is responsible for the market surveillance activities (handling complaints, notifications, advisory notices, recall).
- Coordinates the Post Market Surveillance process

As Head of Quality Dept:

- Documents the activities of the company QMS, updates the documents and archives the records in accordance with the defined documentation control procedures
- Supports the Management in the Review of the QMS
- Supports the Management in defining the evaluation criteria of company processes and with it evaluates the results with a view to pursuing the improvement of the QMS
- Participate in process and product risk management processes
- Supports the correct implementation and management of CAPA processes
- Supports the management and implementation of internal and external auditing activities

Name and address of employer: **Greenbone Ortho SpA -** Via Albert Einstein, 8 48018 Faenza (RA), Italy

Type of business or sector: Medical Device Company

Dates: 04/2019 → 01/2022

Occupation or position held: **Senior Regulatory Affairs Manager**

Main activities and responsibilities:

- Relationship with Competent Authorities, NB and distributors in order to manage regulatory processes in compliance with local requirements where products are sold (EU, MDSAP, UK, Latin America, Asia Pacific);
- Definition of regulatory strategies for the market access of company products
- Evaluation of relevant guidelines and international standard to update and support the involved departments;
- Monitoring and coordination of a regulatory team (5 people)
- Managing of the QMS documentation related to regulatory processes
- MD/ IVD Vigilance (EU, US eMDR, Health Canada…): complaint managment
- MDR/IVDR Post-Market surveillance activities (PMS plan, PSUR…)
- Support to Biocompatibility, Risk Analysis and Clinical Evaluation activities
- US pre-market approval (Pre-Submission, 510(k))

- Collaboration with QA and PJ dept for CAPA and DESIGN change assessment
- Collaboration with QA and CS for the finalization of QA/RA agreement with economic operators
- Currently in charge to coordinate the transition from MDD/IVDD to MDR/IVDR

Name and address of employer **Copan Italia SpA- via F.Perotti, 10 - Brescia**

Type of business or sector MD and IVD Medical Device Company

Dates 05/2013 → 03/2019

Occupation or position held **Regulatory Affairs Manager**

Main activities and responsibilities
- Relationship with Competent Authorities and distributors in order to manage regulatory processes (new registration, renewal, products modification) in compliance with local requirements where products are sold (EU, US, Canada, Latin America, Asia Pacific);
- MD and IVD Vigilance (EU, US eMDR, Health Canada…)
- Risk Analysis support
- Managing of Technical Documentation for CE marking
- US pre-market approval (Pre-Submission, 510(k))
- Labeling and marketing material approval
- MD Clinical Evaluation Report
- Collaboration with the internal departments and subsidiaries to plan new registrations or modifications
- Evaluation of relevant guidelines and international standard in order to update and support the involved departments.

Name and address of employer **Copan Italia SpA- via F.Perotti, 10 - Brescia**

Type of business or sector MD and IVD Medical Device Company

Dates 12/2012 → 05/2013

Occupation or position held **Clinical Research Associate** (*certified according to Italian Decree -D.M. November, 15th 2011)*

Main activities and responsibilities CRA for international and domestic multi-centre clinical trials (oncology and infectious disease observational studies). Main activities performed:
-Preparation of the documentation and material needed for the start-up , monitoring and final visits of the clinical trials.
-Organisation and carrying out the monitoring visits: source data verifications from the clinical records Support to the investigators to correctly fill in the CRFs and implementation of the procedures of the protocol.
- Preparation of the relevant monitoring reports.
-Collaboration with the Medical staff in in the design of the Case Report Form (CRF).
- Check of the CRF consistency, including Pharmacovigilance data

Name and address of employer **Medepha- via Aosta 4/a- Milano**

Type of business or sector CRO

Dates 05/2010 → 11/2012

Occupation or position held **Regulatory Market Specialist**

Main activities and responsibilities
- Set up of all files (English language used) necessary for worldwide registration (Latin America, Asia Pacific e Emerging Markets) and international tender of biomedical products.
- Relationship with Competent Authorities and distributors in order to manage regulatory processes (new registration, renewal, products modification) in compliance with local requirements where products are sold.;
- Collaboration with the internal departments and subsidiaries to plan new registrations or modifications
- Evaluation of relevant guidelines and international standard in order to update and support the involved departments.
- Scientific support on biocompatibility studies

Name and address of employer **Orthofix SRL– Via delle Nazioni, 9 – 37012 Bussolengo (Vr) -Italy**

Type of business or sector Multinational Orthopedic biomedical Company

Dates 08/2006 - 05/2010

Occupation or position held **Regulatory Affairs Officer**

Main activities and responsibilities	- Set up of all files (in Italian, English and sometimes French) necessary for registration, renewal and type I and II modification of immunological products (vaccines), for both domestic and International markets; - Relationship with National and Extra-European Regulatory Authorities in order to manage and to update each regulatory process; - Collaboration with other Company Departments in order to evaluate and to manage all situations whose revisions can affect regulatory issues - From 2007 to 2010 attendance to the bimestrial meeting of the working group "Regulatory" of AISA (Associazione nazionale Imprese Salute Animale)-FEDERCHIMICA
Name and address of employer	**IZO S.p.A. – Via Bianchi, 9 – 25124 Brescia**
Type of business or sector	Veterinary Pharmaceutical Company
Dates	02/2005 – 07/2006
Occupation or position held	**Research Grant**
Main activities and responsibilities	Laboratory activities. Research project followed "The role of transcriptional factors Aire and Foxp3 in the development of autoimmunity".
Name and address of employer	Institute of Molecular Medicine "A. Nocivelli" – Children's Hospital of Spedali Civili di Brescia, under the direction of Professor L.D. Notarangelo.
Type of business or sector	National Institute for the genetic diagnosis of primary immunodeficiency diseases and Center of Research in paediatric immunology.
Dates	11/2002 – 12/2004
Occupation or position held	**Apprenticeship**
Main activities and responsibilities	Laboratory activities for a sperimental dissertation titled "Heterozygous mutations altering the C-terminal region of protein CXCR4 in patients affected by Whim Sindrome: molecular characterization and functional study"
Name and address of employer	Institute of Molecular Medicine "A. Nocivelli" –Children's Hospital of Spedali Civili di Brescia, under the direction of Professor L.D. Notarangelo.
Type of business or sector	National Institute for the genetic diagnosis of primary immunodeficiency diseases and Center of Research in paediatric immunology.

Education and training

Dates	05-2012 / 03-2013
Title of qualification awarded	**Master (II level) "Research and preclinical and clinical development of drugs"**
Name and type of organisation providing education and training	Università degli Studi di Milano-Bicocca

Dates	09/1998 – 12/2004
Title of qualification awarded	Diploma conferring the right to practice the profession of Biologist
Name and type of organisation providing education and training	Università degli Studi di Milano

Dates	09/1998 – 12/2004
Title of qualification awarded	**Degree in Biological Sciences**
Principal subjects/occupational skills covered	Major in Biomolecular Biology (genetics, molecular biology, biochemistry)
Name and type of organisation providing education and training	Università degli Studi di Milano – Faculty of Mathematical, Physical and Natural Sciences
Level in national or international classification	Five-year degree.

Dates	09/1993 – 07/1998
Title of qualification awarded	Scientific High-School Diploma
Principal subjects/occupational skills covered	Major in P.N.I. "National Plan Computer Science" (maths, physics, computer science, latin, english as a second language)
Name and type of organisation providing education and training	Liceo Scientifico Statale "A. Calini" di Brescia
Level in national or international classification	Scientific High-School diploma

Languages:

Mother tongue(s)	**Italian**
Other language(s)	English and French

Aware of the consequences of making false statements, falsehood of acts and use of false facts, punishable by law according to art. 76 D.P.R. n. 445/2000 and of the Italian Penal Code and special laws, the undersigned declares that the information is true.

The undersigned hereby authorize the processing of personal data present in the CV pursuant to Legislative Decree .Lgs. 101/2018 and of art.13 GDPR (EU Reg. 2016/679)."

Firma *12/02/2024*
Vanessa Bonomi