europass Curriculum vitae

PERSONAL INFORMATION Simona Badoi

WORK EXPERIENCE

June 2017–Present

Head of the European Procedures Department

NAMMD (Romania)

Management of the marketing authorisation process of medicinal products for human use and related post marketing activities (variations, product information management) through European Procedures; QA management.

Assessment of the clinical trial applications

October 2010–May 2017

Head of the National Procedure Department

NAMMD (Romania)

Management of the marketing authorisation process of medicinal products for human use and related post marketing activities (variations, product information management) through National Procedure; QA management.

Assessment of the clinical trial applications

Participation in development of the national guidelines on authorisation of medicinal products for human use

Participation in transposition of EU Directives regarding medicinal products for human use in national legislation

February 2010–September 2010

Head of National Procedure Evaluation Unit

NAMMD (Romania)

Coordination of the following issues:

- Assessment of the documentation received from the Applicant in respect of quality (drug product only), efficacy, safety and product information, submitted for National Procedure in order to grant the Marketing Authorisation

- Assessment of the documentation for authorisation of the clinical trials on medicinal products for human use and notification of substantial amendments

- Evaluation of documentation for updating of the Annexes of Marketing Authorisation for Romanian and foreign medicinal products submitted for type II variations through national procedure.

- Participation in classifying medicinal products regarding the ATC code and type of prescription.

November 2009–January 2010

Head of Product Information Unit

National Medicines Agency (Romania)

- Coordination of the activity of the Product Information Unit

- Evaluation and review of product information of Romanian and foreign medicinal products (including national, mutual recognition and decentralized procedure).

- Evaluation of documentation for updating of the annexes of Marketing Authorisation for Romanian and foreign medicinal products (including national, mutual recognition and decentralized procedure) submitted for type II variations.

- Review of product information for medicinal products authorised through centralized procedure - post-opinion review (new applications, renewals, line extensions, variations, annual reassessments, referrals, notifications).

- Participation in classifying medicinal products regarding the ATC code and type of prescription.

November 2006–October 2009

Head of SmPCs, PLs Bureau

National Medicines Agency (Romania)

- Coordination of the activity of the SmPC, PLs Bureau

- Evaluation and review of product information of Romanian and foreign medicinal products (including national, mutual recognition and decentralized procedure).

- Evaluation of documentation for updating of the annexes of Marketing Authorisation for Romanian and foreign medicinal products (including national, mutual recognition and decentralized procedure) submitted for type II variations.

- Review of product information for medicinal products authorised through centralized procedure – PALC II and post-opinion review (new applications, renewals, line extensions, variations, annual reassessments, referrals, notifications).

- Participation in classifying medicinal products regarding the ATC code and type of prescription.

January 2006–October 2006

Medical Doctor, Clinical Pharmacologist

National Medicines Agency (Romania)

- Review and editing of the Marketing Authorisation and Annexes (SmPCs, PLs and Labelling) for Romanian and foreign medicinal products (including national, mutual recognition and centralized procedure).

- Evaluation of documentation for update of annexes to Marketing Authorisation for Romanian and foreign medicinal products (including national and mutual recognition procedure) submitted for type II variations.

- Review of product information for medicinal products authorized through centralized procedure – PALC II.

- Participation in classifying medicinal products regarding the ATC code and type of prescription.

January 2002–December 2005

Medical Doctor, Resident in Clinical Pharmacology

National Medicines Agency (Romania)

- Review and editing of the Marketing Authorisation and annexes (SmPCs, PLs and Labelling) for Romanian and foreign medicinal products (including national, mutual recognition and centralized procedure).

- Evaluation of documentation for the update of annexes to Marketing Authorisation for Romanian and foreign medicinal products (including national and mutual recognition procedure) submitted for type II variations.

- Participation in classifying medicinal products regarding the ATC code and type of prescription.

January 1999–December 2001

Medical Doctor

National Medicines Agency (Romania)

- Review and editing of Marketing Authorisation and annexes (SmPCs, PLs and Labelling) for Romanian and foreign medicinal products (including national, mutual recognition and centralized procedure).

- Evaluation of documentation for the update of annexes to Marketing Authorisation for Romanian and foreign medicinal products (including national and mutual recognition procedure) submitted for type II variations.

- Participation in classifying medicinal products regarding the ATC code and type of prescription.

November 1997–December 1998

Medical Doctor, Junior Doctor

“Ionescu-Stoian” State Institute for Drug Control, Bucharest (Romania)

- Assessment of the non-clinical part of the Marketing Authorisation Application

- Control of chemical substances - animal testing

EDUCATION AND TRAINING

September 2012–Present

Senior Clinical Pharmacologist

NAMMD (Romania)

- Assessment of the documentation received from the Applicant in respect of quality (drug product

only), efficacy, safety and product information, submitted for National Procedure in order to grant the Marketing Authorisation

- Assessment of the documentation for authorisation of the clinical trials on medicinal products for human use and notification of substantial amendments

January 2006–September 2011

Specialist Doctor in Clinical Pharmacology

NAMMD (Romania)

- Assessment of the documentation received from the Applicant in respect of quality (drug product only), efficacy, safety and product information, submitted for National Procedure in order to grant the Marketing Authorisation

- Assessment of the documentation for authorisation of the clinical trials on medicinal products for human use and notification of substantial amendments

January 2002–December 2005

Clinical Pharmacologist

Faculty of General Medicine “Carol Davila” Bucharest (1st year); NMA (2nd year), “Marius Nasta” Institute of Pneumology, “Colțea” Universitary Clinical Hospital and “Floreasca” Emergency Universitary Clinical Hospital (3rd year), Obregia Universitary Psychiatric Hospital (4th year) (Romania)

Residency Training Program in Clinical Pharmacology:

- training course and research in Fundamental Pharmacology (1st year)

- training in medicinal products legislation (2nd year)

- training in Intensive Care, Internal Medicine and Toxicology (3rd year)

- training in Clinical Trials (4th year)

November 1997–October 1998

Medical Doctor, Junior Doctor

Drug’s Institute Control “Ionescu-Stoian”, Bucharest (Romania)

Training in non-clinical Toxicology

October 1988–June 1994

Medical Doctor

Faculty of General Medicine at University of Medicine and Pharmacy “Carol Davila” Bucharest (Romania)

General Medicine Courses

ADDITIONAL INFORMATION

Expertise

Regulatory

Clinical Pharmacology

Publications

Projects

Memberships

Member of the National College of Physicians of Romania

July 2012 - December 2014 - National Expert of the UE Council Working Group on Proposal for a Regulation on Clinical Trials on medicinal products for human use

September 2016 - present - National Expert of the UE Council Working Group on Proposal for amending the Regulation (EC) No. 726/2004

July 2017 - present - CHMP Member

July 2017 - present - PDCO Alternate Member

February 2012 - present - Member of the Committee for Advanced Therapies, EMA

December 2010 - December 2014 - Alternate at Management Board, EMA
September 2005 - April 2013 - Member of the Quality Review of Documents Working Group, EMA

Other Relevant Information