Curriculum Vitae

Personal information

Simona Badoi

Work experience

1. Employer: NAMMDR
   - Start date: 29.08.2025
   - End date: present
   - Position: Coordinator of the European Procedures Directorate
   - Activities: 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. Participation in development of the national guidelines on authorisation of medicinal products for human use
   - Country: Romania
2. Employer: NAMMDR
   - Start date: 042018
   - End date: 28.08.2024
   - Position: Coordinator of the European Procedures Direction
   - Activities: 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. Participation in development of the national guidelines on authorisation of medicinal products for human use
   - Country: Romania
3. Employer: NAMMD
   - Start date: 062017
   - End date: 032018
   - Position: Head of the European Procedures Department
   - Activities: Management of the marketing authorisation process of medicinal products for human use and related post marketing activities (variations, product information management) through European Procedure; QA management. Assessment of the clinical trial applications Participation in development of the national guidelines on authorisation of medicinal products for human use
   - Country: Romania
4. Employer: NAMMD
   - Start date: 102010
   - End date: 052017
   - Position: Head of the National Procedure Department
   - Activities: 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
   - Country: Romania
5. Employer: NAMMD
   - Start date: 062017
   - End date:
   - Position: Head of the European Procedures Department
   - Activities: 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
   - Country: Romania
6. Employer: NAMMD
   - Start date: 022010
   - End date: 092010
   - Position: Head of National Procedure Evaluation Unit
   - Activities: 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.
   - Country: Romania
7. Employer: National Medicines Agency
   - Start date: 112009
   - End date: 012010
   - Position: Head of Product Information Unit
   - Activities: _ 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.

- Country: Romania

8. Employer: National Medicines Agency
   - Start date: 112006
   - End date: 102009
   - Position: Head of SmPCs, PLs Bureau
   - Activities: _ 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.
   - Country: Romania
9. Employer: National Medicines Agency
   - Start date: 012006
   - End date: 102006
   - Position: Medical Doctor, Clinical Pharmacologist
   - Activities: _ 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.
   - Country: Romania
10. Employer: National Medicines Agency
    - Start date: 012002
    - End date: 122005
    - Position: Medical Doctor, Resident in Clinical Pharmacology
    - Activities: _ 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.
    - Country: Romania
11. Employer: National Medicines Agency
    - Start date: 011999
    - End date: 122001
    - Position: Medical Doctor
    - Activities: _ 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.
    - Country: Romania
12. Employer: "Ionescu_Stoian" State Institute for Drug Control, Bucharest
    - Start date: 111997
    - End date: 121998
    - Position: Medical Doctor, Junior Doctor
    - Activities: _ Assessment of the non_clinical part of the Marketing Authorisation Application _ Control of chemical substances _ animal testing
    - Country: Romania

Education and training

1. Subject: NAMMD
   - Start date: 092012
   - End date:
   - Qualification: Senior Clinical Pharmacologist
   - Organisation: _ 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
   - Country: Romania
2. Subject: NAMMD
   - Start date: 012006
   - End date: 092011
   - Qualification: Specialist Doctor in Clinical Pharmacology
   - Organisation: _ 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
   - Country: Romania
3. Subject: Faculty of General Medicine "Carol Davila" Bucharest (1st year); NMA (2nd year), "Marius Nasta" Institute of Pneumology, "Colţea" Universitary Clinical Hospital and "Floreasca" Emergency Universitary Clinical Hospital (3rd year), Obregia Universitary Psychiatric Hospital (4th year)
   - Start date: 012002
   - End date: 122005
   - Qualification: Clinical Pharmacologist
   - Organisation: 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)
   - Country: Romania
4. Subject: Drug's Institute Control "Ionescu_Stoian", Bucharest
   - Start date: 111997
   - End date: 101998
   - Qualification: Medical Doctor, Junior Doctor
   - Organisation: Training in non_clinical Toxicology
   - Country: Romania

5. Subject: Faculty of General Medicine at University of Medicine and Pharmacy “Carol Davila” Bucharest
   - Start date: 101988
   - End date: 061994
   - Qualification: Medical Doctor
   - Organisation: General Medicine Courses
   - Country: Romania

Additional information

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 _ past _ Member of the Committee for Advanced Therapies, EMA December 2010 _ December 2020 _ Alternate at Management Board, EMA September 2005 _ April 2013 _ Member of the Quality Review of Documents Working Group, EMA

Other Relevant Information