Curriculum Vitae

Personal information

Rocío Fernández Granda

Work experience

1. Employer: **Spanish Agency of Medicines and Medical Devices**.
   - Start date: 07/2005
   - End date:
   - Position: Chemical and Pharmaceutical Assesor
   - Activities:

Quality assesor in Human and Veterinary medicinal products(Jul 2005 to date):

- Evaluation of the quality part of the dossier of applications and variations (ASMF, NAS and Finished products) of Marketing Authorisation for medicinal products (national, decentralised, Mutual Recognition, Referrals and Centralised procedures).

-Evaluation of quality defects , Scientific advice, Involved in the development of CVMP/CHMP quality guidelines and training of personnel.

Supervisor of the Illegal Products Lab OMCL (official medicines control laboratory): ES_AEMPS_C (Sept 2010 to January 2016):

- Start up of the Illegal Products Unit.

-Development and validation of methods to identify (screening methods) and to quantify unknown substances with pharmacological activity.

-Elucidation of APIs/potencial pharmacologically active substances presents in dietary supplements (ESI QTOF LC_MS).

   - Country: Spain

2. Employer: **EDQM**
   - Start date: 01/07/2015
   - End date: 31/12/2015
   - Position: Technical Secretariat (EPD) _ expert Group P4
   - Activities: Applied to substances still under patent protection where there is potential for future production of generics: _ Preparation, evaluation of comments (from manufactures, EDQM lab, OMCLs and P4 experts), follow_up of draft monographs of Finish Products (tablets, Oral solution and Solutions for Infusion). _ Preparation, evaluation of comments (from manufactures, EDQM lab, OMCLs and P4 experts), follow_up, up_dating of draft monographs of Active Substances.
   - Country: France
3. Employer: **MERCK SHARP & DOHME DE ESPAÑA (Frosst Ibérica)**.
   - Start date: 01/1999
   - End date: 07/2001
   - Position: Validation/Stability Analyst
   - Activities: Process Validation co_ordination, Support to cleaning validation, Support to equipment Qualification, Stability Management
   - Country: Spain
4. Employer: **JONHSON & JONHSON MSD**
   - Start date: 05/1996
   - End date: 01/1999
   - Position: Quality Control Analyst
   - Activities: Product and Raw material quality control, process validation reports, documentation (certifications, analytical methods, analytical protocols …), training laboratory personnel in quality standard.
   - Country: Spain

Education and training

1. Subject: Universidad Complutense de Madrid
   - Start date: 01/1990
   - End date: 09/1994
   - Qualification: **Ph. D. (Organic Chemistry)**
   - Organisation: Design, multi_step synthesis, and structural identification (IR, UV, 13C_NMR and 1H_NMR) of polycationic species with antitumor activity. Antitumor evaluation of these systems. Study of the interactions with the DNA (NMR). Molecular modelling calculations and NMR correlation studies
   - Country: Spain
2. Subject: Universidad Complutense de Madrid
   - Start date: 09/1984
   - End date: 06/1989
   - Qualification: **Master Degree in Science**
   - Organisation: **Chemistry _ Organic Chemitry**
   - Country: Spain
3. Subject: Colegio Oficial de Psicologos. & CEREM
   - Start date: 10/2002

- End date: 05/2004
- Qualification: **Master Degree**
- Organisation: **Prevention of Occupational HEALTH AND SAFETY . Industrial Hygiene & Ergonomics**.
- Country: Spain

Additional information

Publications

Journal of Medicinal Chemistry 1997, 40, 668_676. "Synthesis and Antitumor Evaluation of New Thiazolo[5,4_b]quinoline Derivatives". C. Alvarez Ibarra, R. Fernández Granda*, Mª Luz Quiroga Feijoo, Angelica Carbonell, F. Cárdenas, E. Giralt

Tetrahedron, Vol.52, Nº36, pp 11929_11946, 1996 " Determination of the pKa Values for Polycationic Species Derived from 9_Hidroxy and 9_Aminothiazolo[5,4_b]quinolines. A Problem related to the Tautomerism of these Systems". C. Alvarez Ibarra, R. Fernández Granda*, Mª Luz Quiroga Feijoo, J. M. Pingarrón, M. Pedrero

Projects

Memberships

1. Scientific European Expert (EMA) (2006 to date)
2. External Assessor of the Certification of Suitability of Monograps to the European Pharmacopoeia (2009 to date)
3. Member of Counterfeit/Illegal Medicines Working Group (EDQM) (2011 to February 2016)
4. Expert of MG working Party (EDQM) (March 2015 to date)
5. Member CEP AdHoc committee (EDQM) (August 2017 to date)
6. Member of HMA WGroup for risk assessment for post_marketing market surveillance (CMDv) (January 2018 to date)
7. Member of US EU MRA_PAIs Working Group (February 2019 to date)

Other Relevant Information

EU Network Trainning Centre: Technical organizer/coordinator: "Training on Risk analysis tool for sampling and testing of Human and Veterinary Medicinal Products" (AEMPS feb 2020).

EU Network training Instructor:

_ "The point of view of a quality assessor _ Practical Implementation for veterinary medicines" (Feb 2020)

_ "Gentamicin _ Histamine case: Other fermentation products _ Risk analysis (Feb 2020);

_ Assessment of veterinary medicinal products intended for minor use or minor species (MUMS)). Guideline on Quality requirements for veterinary medicinal products intended for MUMS/limited market. (Dec 2017)