Curriculum Vitae

Personal information

Javier Alonso Naveda

Work experience

1. Employer: AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS
   - Start date: 032014
   - End date:
   - Position: Pharmacist, Coordinator of EMA's procedures, QRD_vet member.
   - Activities: To coordinate EMA's procedures supporting the ES CVMP members. QRD_Veterinay member.
   - Country: Spain
2. Employer: AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS
   - Start date: 092010
   - End date: 032014
   - Position: QUALITY ASSESSOR OF NON_IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCTS
   - Activities: Vet_Medicinal Product Information, physicochemical, biological or microbiological of non_immunological veterinary medicinal products in National and European applications for marketing authorisations applications.
   - Country: Spain
3. Employer: AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS
   - Start date: 012008
   - End date: 012010
   - Position: QUALITY, SAFETY AND EFFICACY ASSESSOR
   - Activities: Supporting assessment of design, development and production of medical devices. Supporting assessment of the quality management dossier of medical devices companies. Support for the clinical assessment of medical devices. Support for the assessment of analytical techniques, test methodologies and procedures for inspection of medical devices. Application of the regulation of medical devices.
   - Country: Spain
4. Employer: PRIM, S.A. Suministros Médicos
   - Start date: 092000
   - End date: 012008
   - Position: March 2005_January 2008 Qualified Person (substitute).June 2003_March 2005 Regulatory Affairs and Quality Assurance Manager on behalf of Qualified Person. September 2000_June 2003 Regulatory Affairs and Quality Assurance Technician.
   - Activities: Disseminate quality concepts to the Organization in accordance with the requirements of EN ISO 9001 and EN ISO 13485, participate in the development, review and management of all documentation concerning the quality management system with participation of all Organization departments, conducting internal audits on the company and release its reports, ensure the withdrawal obsolescence of any procedure and / or instruction, replace and disseminate them appropriate. Treatment of non_conformities and Corrective Actions. Request manufacturer declarations of conformity and regulatory certificates. Evaluate certificates and work with manufacturers to obtain regulatory documentation. Monitoring and control of the technical and regulatory requirements for contract manufacturing aspects. Management of the technical/administrative documentation with AEMPS and Department of Pharmacy of the local areas of Spain (CCAA). Adopt the official rules for sealing coupon and packaging material of the medical devices included on the reimbursement of effects and accessories. To advise the organization on aspects like expiration date, non_conformity products, labeling and traceability of medical devices. To advise and provide the organization with diverse technical documentation such as instructions for use, latex content, composition, etc. Monitoring surveillance system. Communications to the Competent Authority. Responsible for tracking customer complaints and non_conformities, data analysis of product returns and recalls, assist in the evaluation of suppliers and resolve discrepancies in quality. Monitoring and control subcontractor for pest control. Performing as Authorized Representative in the EU.
   - Country: Spain
5. Employer: OTRI_SCHOOL OF PHARMACY. DEPARMENT OF PHARMACY AND PHARMACEUTICAL TECHNOLOGY I. COMPLUTENSE UNIVERSITY OF MADRID (UCM)
   - Start date: 061999
   - End date: 032000
   - Position: LABORATORY TECHNICIAN
   - Activities: "Studies of piroxicam and trimetazidine hydrochloride generic solution". JMT PHARMA, S.A. and Department of Pharmacy and Pharmaceutical Technology I. "In vitro release rate of topical preparations of analgesics (NSAIDs)". Farmalíder, S.A. and Department of Pharmacy and Pharmaceutical Technology I. "Release rate of in vitro Acyclovir Topical Preparations. Analysis by HPLC". Laboratories Synthelabo, S.A. and Department of Pharmacy and Pharmaceutical Technology I.
   - Country: Spain
6. Employer: PHARMACY GAYOSO
   - Start date: 061998
   - End date: 091998
   - Position: PHARMACIST
   - Activities: PHARMACIST
   - Country: Spain

Education and training

1. Subject: School of Pharmacy. Department of Pharmacy and Pharmaceutical Technology I. Complutense University of Madrid.
    - Start date: 011999
    - End date: 122001
    - Qualification: MASTERS DEGREE
    - Organisation: III Master in Industrial Pharmacy and Galenic (600 hours). Professional Practice (6 months) Instituto Berna de España, S.A. Madrid. Spain. ▪ Collaborate and receive training in the various activities of manufacturing medicines from receipt and storage, quality assurance and to the production of different dosage forms (solutions for injection, tablets, coated tablets, oral solutions, suppositories).
    - Country: Spain
2. Subject: School of Pharmacy. Department of Pharmacy and Pharmaceutical Technology I. Complutense University of Madrid
    - Start date: 011997
    - End date: 091999
    - Qualification: Certificate of Advanced Studies (Recognition Research Aptitude)
    - Organisation: Advanced Course of Pharmacy and Pharmaceutical Technology (320 hours). Preparation and Quality Control of Pharmaceutical Solid Forms (Tablets and Pellets) Cosmetology and Dermopharmacy; Percutaneous Administration Forms, Bioavailability and Bioequivalence, Drug Stability, Industrial Pharmacy.
    - Country: Spain
3. Subject: SCHOOL OF PHARMACY. COMPLUTENSE UNIVERSITY OF MADRID
    - Start date: 091990
    - End date: 021997
    - Qualification: PHARMACIST
    - Organisation: BACHELOR OF PHARMACY
    - Country: Spain

Additional information

Publications

▪ POSTER PRESENTATION IN CONGRESS: February 1999, IV National Congress organized by the Spanish Association of Lectures of Galenic Pharmacy. Santiago de Compostela. J. Alonso Naveda and A. M. ª Rodríguez Bayón. Development of Ketoprofen Transdermal Systems. Preparation and in vitro studies Transfer. Department of Pharmacy and Pharmaceutical Technology I. School of Pharmacy. UCM. September 2000, Congress Sustained Release in Vitoria. Santiago Torrado, C. Carrascosa, J. Alonso, P. de la Torre, Susana Torrado. The Influence of EGG Albumin as filler for direct compressed tablets prolonged release of S_(+) Ibuprofen. Department of Pharmacy and Pharmaceutical Technology I. School of Pharmacy. UCM.

Projects

▪ RESEARCH EXPERIENCE. Preparation of Solid Dispersions by lyophilization with Benzimidazole Carbamates in different polymeric excipients. Dissolution Rate Studies and Analysis by UV_Vis spectrophotometry. Stability of Physical Mixtures and HPLC analysis. Department of Pharmacy and Pharmaceutical Technology I, School of Pharmacy, UCM. Internal Student in the Department of Pharmacy and Pharmaceutical Technology I, School of Pharmacy, UCM. (March 1996_December 1998): Developing of NSAID formulations in Transdermal Patches. Oily gels, hydrophilic synthetic and natural polymers were prepared. In vitro release studies in modified Franz cells and cellulose membranes. UV_Vis Spectrophotometric Analysis.

Memberships

QRD member, veterinary medicinal products, EMA.

Other Relevant Information

February 2024 ▪ Biotechnology and Veterinay biological products. Novemver 2023 ▪ Pharmacovigilance and Quality defects (VMP). AEMPS. October 2023 ▪ Lean Management. October 2022 ▪ ONE HEALTH: CORONAVIRUS (ANIMALS & HUMANS). AEMPS. October 2022 ▪ Management of procedures for marketing authorisations according to Regulation (EU) 2019/6 on veterinary medicinal products. AEMPS. October 2022 ▪ National Planning against Antimicrobial Resistances. AEMPS. May 2022 ▪ Limited markets: Approach to determining eligibility for authorisation under Article 23. EU NTC EMA. March 2021 ▪ Environmental Risk VMP. AEMPS. November 2020 ▪ Civil servant training. AEMPS. June 2019 20 hours ▪ Residues of VMP. Food safety. Withdrawal periods. AEMPS. June 2018 15 hours ▪ Quality management system in the Veterinary Medicinal Department at AEMPS. June 2018 _ Seminar ▪ Veterinary Clinical Field Trials. Universidad Europea de Madrid. March 2018 _ Lecturer ▪ QRD vet application. News. Veterindustria. September 2017 _ 16 hours ▪ National Programme Antimicrobial Resistance (PRAN) and its involvement on the assessment of VMP. AEMPS February 2017 _ Lecturer ▪ Management of Veterinary centralised procedures in AEMPS. Veterindustria. November 2016 _ 20 hours ▪ Assessment of Veterinary Clinical field trials. AEMPS_EU NTC. June 2016 _ 20 hours ▪ Production models BEEKEEPING. AEMPS_EU NTC. November 2015 _ 25 hours ▪ Residues of Veterinary Medicinal Products in Foods. AEMPS. October 2015 _ 20 hours ▪ Immunology. Applications to Veterinary Medicinal Products. AEMPS. December 2014 _ 20 hours ▪ Advanced Therapies in Veterinary. AEMPS. March 2014_May 2014 ▪ Management of CP, Referrals, QRD. AEMPS. October 2013 _ 15 hours ▪ Manufacture and Control of Sterile Pharmaceutical Forms. AEMPS. October 2012 _ 18 hours ▪ Bioequivalence studies in veterinary medicinal products. AEMPS. October 2011 _ 20 hours ▪ Training of variations. AEMPS. November 2011 _ 20 hours ▪ Instrumental techniques and test methods applied to the control of drugs. AEMPS. October 2011 _ 15 hours ▪ QWP Junior Assessors' Training. AEMPS. February 2011 _ 15 hours ▪ Validation and transfer of analytical procedures. Application in quality assessment. AEMPS. June 2010 _ 7 hours ▪ Review of obligations of importers and distributors of medical devices. FENIN/AEFI/AEMPS. November 2009 _ 15 hours ▪ Legislative update of medical devices and cosmetics. AEMPS. July 2009 _ 20 hours ▪ ACCESS intermediate. AEMPS. December 2008 _ 15 hours ▪ Legislative update of medical devices and cosmetics. AEMPS. September 2008 _ 8 hours ▪ Licenses for manufacturing activities, import and distribution of medical devices. FENIN/AEFI/AEMPS. July 2008 _ 18 hours ▪ META_ANALYSIS. AEMPS. October 2007 ▪ Applications of EDI and electronic invoicing for suppliers of SAS. AECOC. February 2006 _ 25 hours ▪ Quality Management Systems applied to Medical Devices. ENS/AEMPS. June 2006, June 2004 _ 1 hour ▪ As a lecturer at the Master of Industrial Pharmacy and Galenic to provide 1 hour lecture with the theme: "Quality Management Systems for Suppliers of Medical Devices". PRIM_School of Pharmacy. Department of Pharmacy and Pharmaceutical Technology I. UCM . December 2005 ▪ Exporting Healthcare Technology: Certificates and Certifications. PROMOMADRID/FENIN. June 2005 _ 10 hours ▪ Application of Risk Management to Medical Devices. UNE EN ISO 14971. ISO 22442_1. AEFI/AEMPS. March 2005 _ 12 hours ▪ Electrical safety applied to medical devices. PRIM/European Social Fund. May 2004 _ 24 hours ▪ Operation, use and programming of wash cycles on washer machines type HAMO Steris model T21. PRIM/STERIS Iberia, S.A. September 2004 _ 10 hours ▪ Basic course of regulation of medical devices. AEFI/SNS/AEMPS. September 2004 _ 24 hours ▪ Operation, use and programming of wash cycles on washer machines type HAMO Steris model LS950. PRIM/STERIS Iberia, S.A. April 2004 _ 6 hours ▪ Course of Ellman medical devices (ORL). PRIM. January 2004 _ 12 hours ▪ Treatment of non_conformities and corrective actions ISO 9000. Spanish Association for Quality (AEC). November 2003 _ 8 hours ▪ Advanced Excel Course. PRIM/CETICSA. June 2003 ▪ Technical Seminar on Certification and Quality. Imadex/FENIN. July 2002 _ 8 hours ▪ ISO 13485:2000 Quality Management Systems for Medical Devices. Tecno_Med Engineers. July 2001 _ Day ▪ Day of work on the new ISO 9000:2000 and its implications in the field of Medical Devices. FENIN September 2000 _ 16 hours ▪ Internal Auditing of Quality Management Systems ISO 9000. Spanish Association for Quality (AEC) February 1999 ▪ Pharmaceutical Technology Days. San Pablo CEU/AEFI. November 1998 _ 20 hours ▪ Basics and Practical Application of Good Laboratory Practice. AEFI. October 1998 ▪ INFORFARMA'98. CGCOF/SEIS. October 1998 ▪ New regulation of Excipients. AEFI. May 1998 ▪ Certificate of Compliance of starting materials and its monograph of the European Pharmacopoeia. AEFI/AFAQUIM/Farmaindustria/Royal Spanish Pharmacopoeia. November 1997 _ Jannuary 1998 ▪ As a lecturer of Galenic Pharmacy providing training in Pharmacy to students of Galenic Pharmacy belong to the 4th year of the Bachelor of Pharmacy. CEF Apotheca, S.L. Madrid. April 1997 ▪ Near Infrared

Spectroscopy. Kontron Instruments, S.A. March 1997 ▪ Characterization of Materials and Polymers using Instrumental Techniques. Waters Chromatography S.A. January 1997 ▪ Dissolution Testing. Gomensoro, S.A.