EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Curriculum Vitae

Personal information

András Biro

Work experience

1. Employer: National Institute of Pharmacy and Nutrition
   - Start date: 042021
   - End date:
   - Position: Inspector
   - Activities: GMP, GLP, GDP inspection
   - Country: Hungary
2. Employer: Egis Pharmaceutical Ltd.
   - Start date: 042012
   - End date: 042021
   - Position: Head of Validation Department
   - Activities: Lead site validation team (18 members group) Develop validation qualification method on GMP, GLP, GDP area Coordinate and management of Process _ Cleaning, Computerized Sytstem validation and qualification tasks at Egis sites Develop and coordinate Computerize system validation (lead the serialization project validation) Participate and support of inspection and audits
   - Country: Hungary
3. Employer: Chionion (sanofi_aventis) Pharmaceutical Company
   - Start date: 2010
   - End date: 042012
   - Position: Head of Quality project support / Administration and resources group
   - Activities: Support continuous improvement of the site GMP, GLP Quality System. Integrate risk management principles into Quality Systems. Coordination of site Quality Document management system. Coordination of qualification and validation activities at the site. Coordination and participation in global IT system validation project as QA rep. Contribute to the continuous improvement of R&D Budapest site performance Lead site validation network team Lead and coordinate R&D third party audits Change Control Coordinator and/or Q&C approver of changes Support deviation investigations, and related CAPA activities.
   - Country: Hungary
4. Employer: Chionion (sanofi_aventis) Pharmaceutical Company
   - Start date: 2008
   - End date: 2010
   - Position: Head of validation domain in R&D Quality and Compliance of Chinoin
   - Activities: Support continuous improvement of the site GMP, GLP Quality Systems'. Integrate risk management principles into validation system. Coordination of qualification and validation activities at the site. Coordination and participation in global IT system validation projects as QA rep. Lead site validation network team (5 members group) Contribute to the continuous improvement of R&D Budapest site performance. Lead and coordinate third party audits. Change Control Coordinator and/or Q&C approver of changes Support deviation investigations, and related CAPA activities.
   - Country: Hungary
5. Employer: Chionion (sanofi_aventis) Pharmaceutical Company
   - Start date: 2006
   - End date: 2008
   - Position: Validation domain in R&D Quality and Compliance of Chinoin
   - Activities: Support continuous improvement of the site GMP, GLP Quality Systems'. Integrate risk management principles into validation system. Coordination of qualification and validation activities at the site.
   - Country: Hungary
6. Employer: Produkem Ltd.
   - Start date: 2005
   - End date: 2006
   - Position: Head of Quality Control Laboratory
   - Activities: Lead the quality control group Analytical methods development (HPLC, GC, electrochemical and classical analysis) Validation of analytical methods Process and in_process controls of intermediates and drug products Cleaning validation
   - Country: Hungary
7. Employer: CF Pharma Ltd.
   - Start date: 2003
   - End date: 2005
   - Position: Chemical engineer in the QA/QC group
   - Activities: Develop analytical methods Analytical methods development (HPLC, GC, electrochemical and classical analysis) Validation of analytical methods Process and in_process controls of intermediates and drug products
   - Country: Hungary

Education and training

1. Subject: BUDAPEST UNIVERSITY OF TECHNOLOGY AND ECONOMICS
   - Start date: 1998
   - End date: 2001
   - Qualification: M.Sc. on Chemical Engineering, BME

- Organisation: Mechanical Engineering for the Chemical Industry, Chemical Technology, Analytical Chemistry, Electro_analytical Chemistry, Liquid chromatography, Gas chromatography, Laser spectroscopy,
- Country: Hungary

2. Subject: ECA
   - Start date: 042008
   - End date: 042008
   - Qualification: Computer Validation
   - Organisation: The GAMP 4 Approach / Computer Validation Lifecycle Risk management ERES Supplier audits Validation process
   - Country: Germany
3. Subject: sanofi_aventis
   - Start date: 072008
   - End date: 072008
   - Qualification: IACS auditor trainng
   - Organisation: auditor training in sanofi_aventis
   - Country: Hungary
4. Subject: ECA
   - Start date: 042008
   - End date: 042008
   - Qualification: Computer validation expert
   - Organisation: Laws regulation Guidelines for Cumputer Validation The GAMP 5 Approach /computer validation lifecycle Risk management the GAMP way Supplier audits Validation documents
   - Country: Germany
5. Subject: SGS
   - Start date: 072009
   - End date: 072009
   - Qualification: ISO 9001:2008 training
   - Organisation: ISO system building and audit.
   - Country: Hungary

Additional information

Publications

_ A. Biró, É. Pergel, G. Árvai, I. Ilisz, G. Szepesi, A. Péter, F. Lukács High_Performance Liquid Chromatographic Study of Topiramate and Its Impurities, Chromatographia Supplement, Vol. 63, (2006), S137_S141 _ M. Kadar, A. Biro, K. Tóth, B. Vermes, P. Huszthy, Spectrophotometric determination of the dissociation constants on Benesi_ of crown ethers with grafted acridone unit in methanol based on Hildebrand evaluation, Spectrochimica Acta Part A, 62, (2005), 1032_1038 _ A. Biró., K. Tóth: Adaptional possibility of sol_gel based hydrogen ion selective optode as a planar waveguide is flow_injection analysis, XXV. Chemical Lectural Days in 28_30 Oct. 2002, Szeged, Hungary.

Projects

Memberships

Other Relevant Information