Curriculum Vitae

Personal information

Mihaela Buda

Work experience

01/01/2025 - Present

Head of Section Biological Standardisation Programme (BSP)

European Pharmacopoeia Department - European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe, Strasbourg (France)

- Management and coordination of the BSP and its individual projects related to the establishment of reference standards for biologicals, standardisation of analytical procedures and validation of alternative methods (3Rs)
- Technical Secretariat to the BSP Steering Committee

01/06/2013 - 31/12/2024

Scientific Programme Manager

European Pharmacopoeia Department, Division B Biologicals - European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe, Strasbourg (France)

- Scientific Secretary to expert groups and working parties: P4Bio (single source biotherapeutics), Monoclonal Antibodies (MAB), mRNA Vaccines for human use (mRNAVAC), Group 6B (Human Plasma and Plasma Products), AQbD; WAT (Water) and DIA (Dialysis)
- Elaboration of Ph. Eur. documentary standards in the field of biotherapeutics, blood products and mRNA vaccines
- Design and coordination of collaborative studies on development, validation and verification of analytical procedures

01/03/2013 - 31/05/2013

Principal scientific assistant

European Pharmacopoeia Department, Division B Biologicals - European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe, Strasbourg (France)

- Scientific secretary to the P4Bio Working Party (single source biotherapeutics)

01/03/2009 - 29/02/2012

Scientific Technical Officer

Institute for Reference Materials and Measurements, Joint Research Centre, European Commission, Geel (Belgium)

- Development, production and certification of DNA-based reference materials for quality control and calibration in bioanalysis, in line with ISO Guide 34
- Analytical laboratory practice under ISO/IEC 17025 accreditation
- Coordination of certification campaigns, method validations/evaluations and international collaborative studies

01/12/2007 - 28/02/2009

Post-doctoral fellow

Institute for Pharmacy and Molecular Biotechnology, Ruprecht-Karls University, Heidelberg (Germany)

- Research focus: DNA/RNA-based hybrid catalysts, novel approaches to asymmetric catalysis in water
- Domains of competence: bioorganic chemistry, analytics, oligonucleotide solid phase synthesis, bioconjugation, molecular biology, organic synthesis, mass spectrometry
- Reported to "Deutsche Forschungsgemeinschaft" (SFB 623 Molecular Catalysts, Collaborative Research Centre, Heidelberg)

01/04/2003 - 30/11/2007

PhD student

Institute for Pharmacy and Molecular Biotechnology, Ruprecht-Karls University, Heidelberg (Germany)

- Research focus: DNA/RNA-based hybrid catalysts, novel approaches to asymmetric catalysis in water
- Domains of competence: synthesis and structure analysis of DNA/RNA conjugates, derivatization and biolabeling, homogeneous catalysis, solid phase synthesis; MS functionalized oligonucleotides, peptides and PNAs

01/11/2001 - 31/03/2003

Scientific assistant

Faculty of Chemistry and Chemical Engineering, Babes-Bolyai University, Cluj-Napoca (Romania)

- Domains of competence: computational chemistry, molecular modelling, QSAR, statistics

Education and training

01/04/2003 - 30/11/2007

PhD in Pharmaceutical Chemistry – Dr.rer.nat.

Institute for Pharmacy and Molecular Biotechnology, Ruprecht-Karls University, Heidelberg (Germany)

- Title of thesis: "DNA-Based Ligands for Use in Asymmetric Catalysis and Development of Metallo-(deoxy)Ribozymes"

01/10/2000 - 30/06/2001

M.Sc. degree in Chemistry (specialisation: Catalysis and Biocatalysis)

Faculty of Chemistry and Chemical Engineering, Babes-Bolyai University, Cluj-Napoca (Romania)

01/10/1995 - 30/06/2000

Diplomed Engineer in Chemistry (specialisation: Biochemistry and Biotechnology

Faculty of Chemistry and Chemical Engineering, Babes-Bolyai University, Cluj-Napoca (Romania)

Additional information

Publications

Selected publications

A. Ascione, M. Belfiore, J. Vesterinen, M. Buda, W. Holtkamp, F. Luciani, *Charge heterogeneity of therapeutic monoclonal antibodies by different cIEF systems: views on the current situation*, MABS, 2024, 16(1)

M. Buda, *Development of Ph. Eur. standards for therapeutic monoclonal antibodies: infliximab case study*, Generics and Biosimilars Initiative (GaBi), 2022, 11(3), 104-111

M. Buda, O. Kolaj-Robin, E. Charton, *Biotherapeutic products in the European Pharmacopoeia: have all challenges been tackled?* Generics and Biosimilars Initiative (GaBi), 2022, 11(1), 7-12

C. Lang, O. Kolaj-Robin, G. Cirefice, L. Taconet, E. Pel, S. Jouette, M. Buda, C. Milne, E. Charton, *Replacement, Reduction, Refinement. Animal welfare progress in European Pharmacopoeia monographs: activities of the European Pharmacopoeia Commission from 2007 to 2017*, Pharmeur Bio Sci Notes, 2018, 12-36

M. Buda, S. Wicks, E. Charton, *Elaborating European Pharmacopoeia monographs for biotherapeutic proteins using substances from a single source*, Pharmeur Bio Sci Notes, 2016, 129-134

W. Meyer, M. Caprioara-Buda, B. Jeynov, P. Corbisier, S. Trapmann, H. Emons, *The impact of analytical quality criteria and data evaluation on the quantification of genetically modified organisms*, European Food Research and Technology, 2012, Vol. 235, 597-610

M. Caprioara-Buda, W. Meyer, B. Jeynov, P. Corbisier, S. Trapmann, H. Emons, *Evaluation of plasmid and genomic DNA calibrants used for the quantification of genetically modified organisms*, Analytcial and Bioanalytical Chemistry, 2012, Vol. 404, 29-42

M. Caprioara, R. Fiammengo, M. Engeser, A. Jäschke, *DNA - based phosphane ligands*, Chemistry–A European Journal, 2007, 13 (7), 2089-2095

Projects

Elaboration of Ph. Eur. monographs and general chapters for recombinant DNA products (including monoclonal antibodies), mRNA vaccines and plasma-derived products

Development, validation and verification of pharmacopoeial analytical procedures

Design, coordination and evaluation of collaborative studies for analytical standardisation (physicochemical tests and potency assays)

Analytical Quality by Design

Establishment and lifecycle management of Ph. Eur. biological reference materials

Certification of reference materials for calibration in bioanalysis; metrology

Studies of DNA/RNA chemistry and structural analysis, including mass spectrometry of synthetic oligonucleotides

EDQM representative/Observer member in ICHQ2(R2)/Q14 EWG and IWG

Participation in the Drafting group for revision of 'WHO Recommendations for the preparation, characterization, establishment and use of WHO international biological reference preparations' Annex 2, TRS No 932

Memberships

Other Relevant Information