

Curriculum Vitae

Personal information

Viola Bardoczy

Work experience

02/2018 - 11/2023 Senior Comparability Specialist (Gedeon Richter Plc.)

- Biosimilarity and CMC planning for biosimilars
- Organizing and writing of analytical similarity assessment studies for biological products
- Collaboration with analytical and regulatory departments for managing regulatory submissions
- Data analysis of stability and biosimilarity studies
- Initiation of process changes considering regulatory requirements
- Scientific justification and limit determination for drug substance and drug product specifications

01/2008-01/2018 R&D application scientist (Gedeon Richter Plc. - Department of Bio-analytics)

- Design and application of bio-analytical methods for the qualification of biosimilar intermediates and drug products (proteins), concerning the requirements of ICH quality guidelines
- Data analysis, writing and review of the Common Technical Document (CTD) Module 3 part of biosimilar products
- Transfer and validation of specification methods. Design, application and evaluation of experiments, coordination of the work of technicians.
- The applied and supervised bio-analytical methods include:
DNA analysis methods: PCR, Real-time PCR, gel and chip electrophoresis
Protein analysis methods: SDS-PAGE, Western blot, HPLC

09/2004-12/2007 Research fellowship at BME, Department of Biochemistry and Food Technology

- Research area: wheat germ based in-vitro translation systems and protein specific aptamer selection by SELEX. (Recombinant DNA technology and protein production.)

Title of PhD thesis: Design and application of in-vitro translation vectors for wheat-germ extract based protein expression

09/2003- 06/2004 Professional Practice at the Hungarian Institute of Enzymology as Undergraduate student,

Education and training

2017; 2020 CMC Technical writing course /Gedeon Richter Plc.

2014 CMC Analytical comparability masterclass for biosimilars and biobetters /Fleming

2012 Quality assurance and validation in the laboratory /University of Veszprém

2008 Chromatography methods training course / Budapest University of Technology and Economics (BME)

05/ 2010 PhD with Summa cum Laude results at Budapest University of Technology and Economics

09/2004- 12/2007 PhD student at Budapest University of Technology and Economics

09/1999-07/2004 Budapest University of Technology and Economics (BME), Msc. in Bioengineering
Faculty of Chemical Engineering, specialized on Bioengineering
Date of graduation: July 2004

Additional information

Publications

Maureen, McKeague ; Ranganathan, Velu ; Kayla, Hill ; Viola, Bardóczy ; Tamás, Mészáros ; Maria, C DeRosa

Selection and Characterization

TOXINS 6 : 8 pp. 2435-2452. , 18 p. (2014)

	Boglárika, Sonkoly ; Viola, Bardóczy ; Tamás, Mészáros In: Dissmeyer, N; Schnittger, A (szerk.) Plant Kinases : Methods and Protocols New York, Amerikai Egyesült Államok : Humana Press (2011) pp. 55-63. , 9 p.
3	Balogh, Z ; Lautner, G ; Bardoczy, V ; Komorowska, B ; Gyurcsanyi, RE ; Meszaros, T FASEB JOURNAL 24 : 11 pp. 4187-4195. , 9 p. (2010)
4	Lautner, G ; Balogh, Z ; Bardoczy, V ; Meszaros, T ; Gyurcsanyi, RE ANALYST 135 : 5 pp. 918-926. , 9 p. (2010) Aptamer-b
5	Bardóczy, G ; Gécz, V ; Sawasaki, V ; Endo, Y ; Mészáros, T BMC BIOTECHNOLOGY 8 Paper: 32 , 7 p. (2008) A set of
6	Meszaros, T ; Helfer, A[*] ; Hatzimasoura, E ; Magyar, Z ; Serazetdinova, L ; Rios, G ; Bardoczy, V ; Teige, M ; The Arabidopsis MAP kina PLANT JOURNAL 48 : 4 pp. 485-498. , 14 p. (2006)
7	Aranyi, T ; Ratajewski, M ; Bardoczy, V ; Pulaski, L ; Bors, A ; Tordai, A ; Varadi, A Identification of a DNA methylati JOURNAL OF BIOLOGICAL CHEMISTRY 280 : 19 pp. 18643-18650. , 8 p. (2005)

Projects

Design and validation of bio-analytical methods (gel-electrophoresis, real-time PCR, RP_HPLC methods)

Design and development of in-vitro translation vectors for wheat-germ based protein expression

Protein specific aptamer selection

Study of methylated-DNA regions

Memberships

Member of the Hungarian Academy of Sciences Public Body

Member of the Hungarian Academy of Sciences, Bio-Analytical Working Committee

Other Relevant Information