



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 intermediers 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 Insitute of Enzimology as Undergraduate student, Title of thesis: The regulation mechanism of ABCC6 gene expression

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

2009 Masterclass for Endotoxin detection methods (Lonza)

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 (Employee of Gedeon Richter Plc. from 01/2008).

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 of a Novel DNA Aptamer for Label-Free Fluorescence Biosensing of Ochratoxin A](#)

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

Boglárika, Sonkoly ; [Viola, Bardóczy](#) ; [Tamás, Mészáros](#)

[Expression and purification of active protein kinases from wheat Germ extracts](#)

In: Dissmeyer, N; Schnittger, A (szerk.) [Plant Kinases: Methods and Protocols](#)

New York, Amerikai Egyesült Államok: Humana Press (2011) pp. 55-63., 9 p.

[Balogh, Z; Lautner, G; Bardoczy, V](#); Komorowska, B; [Gyurcsanyi, RE](#); [Meszaros, T](#)

[Selection and versatile application of virus-specific aptamers](#)

FASEB JOURNAL 24: 11 pp. 4187-4195., 9 p. (2010)

[Lautner, G; Balogh, Z; Bardoczy, V; Meszaros, T; Gyurcsanyi, RE](#)

[Aptamer-based biochips for label-free detection of plant virus coat proteins by SPR imaging](#)

ANALYST 135: 5 pp. 918-926., 9 p. (2010)

[Bardóczy, G](#); Géczy, V; Sawasaki, V; Endo, Y; [Mészáros, T](#)

[A set of ligation-independent in vitro translation vectors for eukaryotic protein production](#)

BMC BIOTECHNOLOGY 8 Paper: 32, 7 p. (2008)

[Meszaros, T](#); Helfer, A*; Hatzimasoura, E; [Maqvar, Z](#) ; Serazetdinova, L; Rios, G; [Bardoczy, V](#) ; Teige, M ; [Koncz, C](#) ; Peck, S et al.

[The Arabidopsis MAP kinase kinase MKK1 participates in defence responses to the bacterial elicitor flagellin](#)

PLANT JOURNAL 48: 4 pp. 485-498., 14 p. (2006)

[Aranyi, T](#); Ratajewski, M; [Bardoczy, V](#); Pulaski, L; [Bors, A](#) ; [Tordai, A](#) ; [Varadi, A](#)

[Identification of a DNA methylation-dependent activator sequence in the pseudoxanthoma elasticum gene, ABCC6](#)

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