

PERSONAL INFORMATION

Peter Zsolt Fekete

WORK EXPERIENCE

May 2016–Present

quality expert

Icelandic Medicines Agency (Iceland)

quality assessment

February 2014–April 2016

quality expert

National Food Chain Safety Office, Directorate of Veterinary Medicinal Products, Pharmaceutical Department (Hungary)

quality assessment of marketing authorization applications, renewals and variations of veterinary medicinal products

October 2013–December 2014

scientific writer, microbiology expert

AccepTher Ltd. (Hungary)

regulatory, and scientific writing tasks on the compilation and control of CTD Module 3 sections of human medicinal products (bacterial and viral vaccines)

January 2013–November 2013

R&D microbiologist

Charles River Laboratories Preclinical Services (Ireland)

microbiology R&D activities during bacteriological test method transfers

December 2010–December 2012

Regulatory Affairs officer

Gedeon Richter Plc. (Hungary)

regulatory affairs support of biotechnology and nanomedicinal drug development

August 2008–June 2010

research fellow, microbiologist

South Dakota State University (United States)

research on the adhesion of enterotoxigenic E. coli (ETEC), vaccine development against porcine ETEC

April 1996–December 2010

research fellow, microbiologist

Veterinary Medical Research Institute of the Hungarian Academy of Sciences (Hungary)

research on the virulence and antibiotic resistance genes of animal intestinal E. coli pathotypes, vaccine development against porcine postweaning diarrhoea

May 1993–April 1996

assistant research fellow

Department of Clinical Immunology, National Institute of Oncology (Hungary)

research on the antibody dependent cell-mediated cytotoxicity (ADCC) and complement dependent cytotoxicity (CDC) of oncological patients

EDUCATION AND TRAINING

1997–2005

PhD

Eötvös Lóránd University, Faculty of Science (Hungary)

microbiology

thesis: Analysis of virulence plasmids of enterotoxigenic Escherichia coli (ETEC) strain isolated from

porcine postweaning diarrhoea

1994–1997 **MSc**

Eötvös Lóránd University, Faculty of Science (Hungary)

microbiology

1988–1992 **BSc**

University of Horticulture and Food Industry (Hungary)

graduate engineer of food technology

ADDITIONAL INFORMATION

Expertise

replicon typing of F18 adhesin producing enterotoxigenic and verotoxigenic *E. coli* strains isolated from porcine postweaning diarrhoea and oedema disease cases

cloning and sequencing the toxin specific locus (TSL) as a plasmid-encoded pathogenicity island like structure from a F18+ enterotoxigenic and verotoxigenic *E. coli*

sequencing of the conjugative virulence plasmid pTC of a porcine post weaning F18 adhesin producing enterotoxigenic *E. coli* strain

detection and classification of tetracycline resistance genes from different *E. coli* and *Salmonella* serotypes

detection and phylogenetic characterisation of *Salmonella* Genomic Island 1 (SGI1) in animal and food isolates of *Salmonella* Typhimurium

determination of heat-labile (LT) enterotoxin expression of wild-type and mutagenised ETEC strains

molecular cloning of ETEC enterotoxin genes to generate vaccine candidate strains

determination of the adhesion promoting ability of the heat-labile enterotoxin produced by enterotoxigenic *E. coli* strain to intestinal epithelial cells

microbiology R&D activities during bacteriological test method transfers

providing CMC regulatory support to biotechnology and nanomedicinal drug development

preparation of regulatory submissions in compliance with the applicable national and EMA regulations

coordination of scientific advice procedures and pre-CTA consultations with national competent authorities and with the EMA

compilation of IMPDs and substantial amendments for ongoing clinical trials

communication with regulatory contract research organizations on the quality, non-clinical and clinical requirements of biotechnology and nanomedicinal drug development

quality assessment of marketing authorization applications, renewals and variations of veterinary medicinal products

quality assessment of marketing authorization applications, renewals and variations of human medicinal products

Publications

Szmolka, A., Lestár, B., Pászti, J., Fekete, P., Nagy, B. 2015. Conjugative IncF and IncI1 plasmids with tet(A) and class 1 integron conferring multidrug resistance in F18(+) porcine enterotoxigenic *E. coli*. *Acta Vet Hung.* 63(4) 425-443.

Fekete, P.Z., Mateo, K. S., Zhang, W., Moxley, R. A., Kaushik, R. S., Francis, D. H. 2013. Both enzymatic and non-enzymatic properties of heat-labile enterotoxin are responsible for LT-enhanced adherence of enterotoxigenic *Escherichia coli* to porcine IPEC-J2 cells. *Vet. Microbiol.* 164. 330-335

Fekete, P. Z., Brzuszkiewicz, E., Blum-Oehler, G., Olasz, F., Szabó, M., Gottschalk, G., Hacker, J., Nagy, B. 2012. DNA sequence analysis of the composite plasmid pTC conferring virulence and antimicrobial resistance for porcine enterotoxigenic *Escherichia coli*. *Int. J. Med. Microbiol.* 302. 4-9

Fekete, P. Z., Nagy, B. 2008. *Salmonella* Genomic Island 1 (SGI1) and genetic characteristics of animal and food isolates of *Salmonella* Typhimurium DT104 in Hungary. *Acta Vet. Hung.* 56. 5–11

Tóth, A., Nógrády, N., Fekete, P. Z., Pászti, J., Füzi, M. 2007. Extended-spectrum-beta-lactamase-producing *Salmonella enterica* strains isolated from humans in Hungary, 2000 to 2004. *J. Antimicrob. Chemother.* 59. 579-582.

Nogrady, N., Gado, I., Fekete, P. Z., Paszti, J. 2005. Chloramphenicol resistance genes in *Salmonella enterica* subsp. *enterica* serovar Typhimurium isolated from human and animal sources in Hungary. *Vet. Med. Czech*, 50. 164–170.

Nagy, B., Fekete, P. Z. 2005. Enterotoxigenic *Escherichia coli* in veterinary medicine. *Int. J. Med. Microbiol.* 295. 443–454

Olasz, F., Fekete, P. Z., Blum-Oehler, G., Boldogkoi, Z., Nagy, B. 2005. Characterization of an F18+ enterotoxigenic *Escherichia coli* strain from post weaning diarrhoea of swine, and of its conjugative virulence plasmid pTC. *FEMS Microbiol. Lett.* 244. 281-289.

Fekete, P. Z., Schneider, G., Olasz, F., Blum-Oehler, G., Hacker, J. H., Nagy, B. 2003. Detection of a plasmid-encoded pathogenicity island in F18+ enterotoxigenic and verotoxigenic *Escherichia coli* from weaned pigs. *Int. J. Med. Microbiol.* 293. 287-298..

Fekete, P. Z., Gerardin, J., Jacquemin, E., Mainil, J. G., Nagy, B. 2002. Replicon typing of F18 fimbriae encoding plasmids of enterotoxigenic and verotoxigenic *Escherichia coli* strains from porcine postweaning diarrhoea and oedema disease. *Vet. Microbiol.* 85. 275-284.

Nagy, B., Fekete, P. Z. 1999. Enterotoxigenic *Escherichia coli* (ETEC) in farm animals. *Vet. Res.* 30. 259-284

Projects

2016

EU and international assessor training on biosimilars (EU-NTC)

2015

EU Assessors Training on Quality Assessment of Drug Substances (EMA QWP & Ravimiamet - Estonian State Agency of Medicines)

2015

Senior Quality Assessor Training (EMA QWP)

2014

Assessing the Fate of Veterinary Medicinal Products in the Environment - Training of Assessors - FOCUS modelling (EMA ERAWP)

2014

Residues of veterinary medicinal products in food of animal origin (BTSF - Better Training for Safer Food)

2012

Advanced regulatory affairs training, organized by the MAGYOTT (Hungarian Regulatory Affairs Society)

2011

Beginners regulatory affairs training, organized by the MAGYOTT (Hungarian Regulatory Affairs Society)

2008-2010

research fellow (exchange visitor) Veterinary Science Dept. of South Dakota State University, Brookings, U.S.A. research field: studies on the adhesion of enterotoxigenic *E. coli* (ETEC), vaccine development against porcine ETEC

2006

Health Protection Agency (HPA), London; 2 weeks PFGE practical course, supported by the MedVetNet)

2005

1 month study trip at the Institut für Molekulare Infektionsbiologie, Universität Würzburg (supported by the „TÉT” German-Hungarian Fellowship Grant)

2004

1 week proteomics practical training organized by the Institut für Molekulare Infektionsbiologie, Universität Würzburg (supported by the „TÉT” German-Hungarian Fellowship Grant)

2004

2 weeks study trip at the Institut für Molekulare Infektionsbiologie, Universität Würzburg (supported by the „TÉT” German-Hungarian Fellowship Grant)

2000

Institut für Molekulare Infektionsbiologie, Universität Würzburg (1 month, supported by the FEMS Young Scientists Fellowship Grant)

1999

University of Liège, Veterinary Faculty, Department of Bacteriology (1 month, supported by the Vallonian-Hungarian Intergovernmental Cooperation)

1998

Institut für Molekulare Infektionsbiologie, Universität Würzburg (1 month, supported by the Bayerische Forschungstiftung)

Memberships

HURAS - Hungarian Regulatory Affairs Society

Public Board of the Hungarian Academy of Sciences (id#: 16821)

Other Relevant Information