

Curriculum Vitae

Personal information Peter Zsolt Fekete

Work experience

- Employer: Icelandic Medicines Agency
 Start date: 052016

 - End date:
 - Position: quality expert
 - Activities: quality assessment
 - Country: Iceland
- 2. Employer: National Food Chain Safety Office, Directorate of Veterinary Medicinal Products, Pharmaceutical Department
 - Start date: 022014 End date: 042016
 - Position: quality expert

 - Activities: quality assessment of marketing authorization applications, renewals and
 - variations of veterinary medicinal products
 Country: Hungary
- 3. Employer: AccepTher Ltd.

 Start date: 102013
 - End date: 122014

 - Position: scientific writer, microbiology expert
 Activities: regulatory, and scientific writing tasks on the compilation and control of CTD
 - Module 3 sections of human medicinal products (bacterial and viral vaccines)
 - Country: Hungary
- 4. Employer: Charles River Laboratories Preclinical Services

 Start date: 012013
 - End date: 112013

 - Position: R&D microbiologist Activities: microbiology R&D activities during bacteriological test method transfers
- Country: Ireland
 Employer: Gedeon Richter Plc.
 - Start date: 122010

 - End date: 122012 Position: Regulatory Affairs officer
 - Activities: regulatory affairs support of biotechnology and nanomedicinal drug development
- Country: Hungary
 Employer: South Dakota State University
 - Start date: 082008 End date: 062010
 - Position: research fellow, microbiologist
 - Activities: research on the adhesion of enterotoxic E. coli (ETEC), vaccine development against porcine ETEC
- Country: United States
 7. Employer: Veterinary Medical Research Institute of the Hungarian Academy of Sciences
 - Start date: 041996
 - End date: 122010
 - Position: research fellow, microbiologist
 - Activities: research on the virulence and antibiotic resistance genes of animal intestinal E. coli pathotypes, vaccine development against porcine postweaning diarrhoea
- Country: Hungary
 Employer: Department of Clinical Immunology, National Institute of Oncology
 - Start date: 051993
 - End date: 041996
 - Position: assistant research fellow
 - $\label{lem:activities: research on the antibody dependent cell_mediated citotoxicity (ADCC) and$ complement dependent cytotoxicity (CDC) of oncological patients

Education and training

- 1. Subject: Eötvös Lóránd University, Faculty of Science

 - Start date: 1997 End date: 2005 Qualification: PhD
 - Organisation: microbiology thesis: Analysis of virulence plasmids of enterotoxic Escherichia coli (ETEC) strain isolated from porcine postweaning diarrhoea
- Country: Hungary
 Subject: Eötvös Lóránd University, Faculty of Science
 Start date: 1994

 - End date: 1997 Qualification: MSc
 - Organisation: microbiology
- Country: Hungary
 Subject: University of Horticulture and Food Industry

- Start date: 1988
- End date: 1992Qualification: BSc
- Organisation: graduate engineer of food technology
- Country: Hungary

Additional information

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

- 2024 BWP-CAT training on AAV based gene therapy (EMA, Amsterdam, Netherlands)
- 2021 Fermentation products training (online MEB, Netherlands)
- 2020 Drug Product manufacturing theory training (Biotech Training Facility, Leiden, Netherlands)
- 2019 Upstream and downstream processing training (Biotech Training Facility, Leiden, Netherlands)
- 2019 Biological medicinal products Q assessor training (MEB, Utrecht, Netherlands)
- 2018 Quality assessment training for Clinical trials (BfArM, Bonn, Germany)
- 2017 Clinical Trials Regulation: Quality Assessment (IMPD) (SÚKL, Prague, Czechia)
- 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 enterotoxic 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 " $T\acute{E}T$ " 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 Liége, 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

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

Other Relevant Information

- $\hbox{- pharmaceutical assessment of MAAs of medicines containing small chemical entities as active substances}\\$
- scientific advice on biological and biosimilar medicinal products, ATMPs, and medical device related issues