

2012 PDA/FDA Virus and TSE Safety Conference
Speaker Biography Summary

Howard Anderson, PhD

FDA

Dr. Anderson has been with the FDA for seven years in the Division of Therapeutic Proteins, responsible for the primary review of the product quality for NDA, BLA, and IND applications for enzyme replacement therapies. Prior to his current position he was a Regulatory Affairs Scientist with the U.S. Military HIV Research Program for five years. His responsibilities included management of GMP production, testing, and GLP pharmacology/toxicology evaluation of HIV vaccines. This work led to the approval of two IND applications by the FDA and the products are being evaluated in clinical trials. He holds a PhD degree from the University of Massachusetts, Amherst in Molecular and Cellular Biology and was a postdoctoral fellow in the Experimental Immunology Branch at the National Institutes of Health.



David Asher, MD

CBER/FDA

David M. Asher, MD, is a graduate of Harvard College and the Harvard Medical School. He is a diplomate of the American Board of Pediatrics and a member of the American Society for Virology, the Infectious Diseases Society of America and the Society for Pediatric Research. Dr. Asher joined the Food and Drug Administration in 1995 after working for more than 25 years in the Laboratory of Central Nervous System Studies at the National Institutes of Health, where he conducted research on transmissible spongiform encephalopathies (TSEs) and other infectious diseases. He is now the Chief and Supervisory Medical Officer in the Laboratory of Bacterial and Transmissible Spongiform Encephalopathy Agents within FDA's Division of Emerging and Transfusion-Transmitted Diseases, Office of Blood Research and Review, Center for Biologics Evaluation and Research (CBER). He participates in regulatory activities, serving on FDA-wide committees dealing with policy issues related to the transmissible spongiform encephalopathies and on similar committees in CBER and other FDA Centers. He has also participated in activities of the US Department of Defense, Environmental Protection Agency, International Standards Organization, World Health Organization and Pan American Health Organization concerning TSEs. His recent regulatory research has involved evaluation of stability and safety of cell substrates bearing mutations associated with familial TSEs, resistance of vaccine cell substrates to infection with TSE agents, development of new methods to evaluate decontamination procedures for TSE agents dried on instruments and work surfaces, and other issues related to TSE safety of blood, blood components and derivatives, and other medical products.



Johannes Blümel, PhD

Paul-Ehrlich-Institut

Dr. Johannes Blümel is leading the virus safety section at the Paul-Ehrlich-Institut, Langen. He is dealing with assessment of virus safety and TSE safety of blood products and recombinant DNA products such as monoclonal antibodies for clinical trials and marketing authorization. He participates as expert in EMA-Biologics Working Party (BWP) and EDQM TSE-certification procedure. Further, he is working in several research projects on virus inactivation and virus removal.

Prior to joining the Paul-Ehrlich-Institut in 1998, Dr. Blümel worked at the University Hospital, University of Bonn (1993-1998) He performed basic research on virus replication and received a five years training in medical virology and virus diagnostics.

Dr. Blümel completed his Diploma Study in Biology (molecular genetics, microbiology, biophysics and physical chemistry) in 1991 at the University of Freiburg, Germany. He received his Ph. D. degree at the Department of Virology, University of Freiburg, Germany (1993). In 2010 he received teaching graduation (Habilitation) in Medical Virology from the University Frankfurt.



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Kurt Brorson, PhD

CDER, FDA

Kurt Brorson, PhD is a staff scientist in CDER's Division of Monoclonal Antibodies, Office of Biotech Products. Kurt Brorson received a B.A. in biology from the University of Chicago (Chicago IL) in 1984 and Ph.D. in molecular biology from the California Institute of Technology (Pasadena CA) in 1990. After a 2-year postdoctoral fellowship at the NIH, he joined FDA in 1992 as a staff fellow and was promoted to a staff scientist in 1999. In addition to review, inspection, training and policy activities, he conducts research on viral safety issues associated with biotechnology products. He has won numerous internal awards from FDA, CBER and CDER and is the author of more than 40 scientific journal articles and book chapters. He is a member of PDA, the American Chemical Society, the American Association for the Advancement of Science and the American Society for Microbiology.



Dayue Chen, PhD

Eli Lilly & Company

Dr. Dayue Chen received his Ph.D. in Virology from Baylor College of Medicine in Houston, Texas. He has extensive experience in bioprocess development and viral safety throughout all stages of clinical development. For the past twenty five years, his career in the field of virology has covered both academic/discovery research and industrial R&D, resulting 30 + publications in peer reviewed journals. He is currently a research advisor in Bioprocess Research and Development Division at Eli Lilly and Company. In his current position, he oversees viral safety throughout the production chain from bank testing to viral clearance studies for all biologicals produced in mammalian cell cultures at Eli Lilly and Company.



Lisa Connell Crowley

Amgen, Inc.

Dr. Connell-Crowley has been with Amgen for 8 years as a scientist in the Purification Process Development group. She has developed purification processes for clinical and commercial manufacturing and more recently has served as process team leader for early clinical phase products. She is a subject matter expert in viral clearance and leads a technology working group on this topic. Dr. Connell-Crowley holds a PhD in Biochemistry from Baylor College of Medicine in Houston, Texas.

Houman Dehghani, PhD

Amgen, Inc.

Dr. Dehghani is a Director at Amgen. His area of expertise is viral and microbial safety evaluation of mammalian cell culture processes. Following his post-doctoral training at the National Institute of Allergy and Infectious Diseases, he joined BioReliance as a study director. Subsequently, he joined Amgen, Inc. in 2003 as a member of the Biosafety Development Laboratory. Currently he leads the Cellular Resources department, with groups involved in cell banking, managing critical reagents and development and assessment of new technologies for detection and identification of adventitious contaminants of mammalian cell culture processes as well as viral clearance assessment studies in both cGMP and development settings. He holds a Ph.D. degree from Michigan State University in Cell and Molecular Biology.



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Gerald Feldman, PhD

CDER, FDA

Dr. Feldman is a Senior Investigator in the Division of Monoclonal Antibodies, at the Center for Drugs (CDER), FDA. He received his doctorate in Immunology and Infectious Diseases from the Johns Hopkins University in Baltimore, MD. After a post-doctoral fellowship at the NIH where he studied the immunological facets of arthritis and other chronic diseases, Dr. Feldman joined the staff of the Division of Cytokine Biology in the Office of Therapeutics Research and Review at CBER in 1989, receiving tenure in 1996. He has been involved in all phases of the regulatory process, from pre-IND product development through licensing and post-licensure inspections. Dr. Feldman has also been involved in guidance document development, and has represented the Agency on a wide range of issues ranging from Assay Validation to TSEs. His active research interests involve mechanisms of receptor signaling, with a current emphasis on prion protein-mediated activation of inflammatory cells.



Olga Galperina

Human Genome Sciences, Inc.

Olga Galperina is an Associate Director in Purification Sciences (Biopharmaceutical Development) at Human Genome Sciences, Inc. She has a Masters degree in Chemical Engineering and a Ph.D. degree in Biochemistry.

Olga has been with HGS for almost 16 years. During this time she has led process development and validation activities for multiple HGS projects. Since 2004, in addition to process development, Olga leads viral safety-related activities at HGS. She has designed and supervised execution of more than 30 viral clearance studies, including several studies for marketing authorization. She has created and currently maintains an internal viral clearance database, handles all viral safety-related documentation, writes adventitious agents sections in regulatory submissions and handles viral safety questions raised during inspections and submissions review.



Judy Glynn

Pfizer, Inc.

Judy K. Glynn is currently a Senior Principal Scientist in the BioTherapeutics Pharm Sci unit at Pfizer Inc, and has been employed in the biotechnology area for 22 years. At Pfizer, her responsibilities include downstream process development and technical transfer of both microbial and mammalian based products (with a focus on antibodies) from early development through to commercialization. Prior to Pfizer, Judy worked for Centocor and Chiron Corp., performing downstream development, technical transfer, and early clinical manufacturing. Judy received her Masters degree in Biology from Washington University in St. Louis.

Martin Groschup, PhD

Friedrich-Loeffler-Institut

Martin H. Groschup is director of the Institute of Novel and Emerging Infectious Diseases (INEID) at the Friedrich-Loeffler-Institut (FLI). FLI is the Federal Research Institut for Animal Health in Germany and includes eleven institutes (Dept.). MHG has been working on prion diseases and agents for the last 20 years. He is heading the German national BSE/scrapie reference laboratory. INEID-FLI is devoted to prion disease research and acting as national BSE and scrapie reference laboratory. When the BSE epidemic in the United Kingdom and elsewhere became under control, MHG's research interests have extended to developing diagnostic assays and to experimental studies on the pathogenesis of other emerging zoonotic diseases such as bunya- (CCHF, RVF), hepe-, alpha-, flavi- and henipahviruses. The laboratory and animal facility at FLI allows handling infectious



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Martin Groschup, continued

agents and animal infection studies under conditions up to BioSafetyLevel 3. A BSL4 laboratory and large animal unit is currently under commissioning.

Roger Hart, PhD

Amgen, Inc.

Dr. Hart has served as a scientific director for late-stage process commercialization at Amgen Inc. since 2006. In this capacity he develops forward-looking strategies and technologies to support process design, understanding, licensure, and modernization. Previously, he served in early-stage process development at Amgen Inc., beginning in 1996, having held a similar role in industrial research at Genentech, commencing in 1991. He received a Ph.D. degree in Biochemical Engineering from California Institute of Technology under the late James E. Bailey. In his many career capacities, Dr. Hart developed product pipeline candidates and processes, supported GMP manufacturing implementation, and invented technologies to enable efficient and robust manufacturing of protein therapeutics. Among his contemporary research activities, he has applied his technical experience and innovative skills to devise and realize methods to treat process fluids to inactivate adventitious agents and thereby enhance product safety and reduce business risk. In the latter, he has placed special emphasis on developing technologies to support use of ultraviolet light for manufacturing-scale virucidal treatment of biopharmaceutical process fluids.



Yashurio Kishioka, PhD

PMDA

Dr. Kishioka has worked for Pharmaceutical and Medical Devices Agency (PMDA) since 2008. He is responsible for reviewing the applications of biopharmaceuticals including biosimilar products for approval of marketing and investigational new drug in the Office of Biologics 1. Through his experience in PMDA, he is familiar with the safety of biopharmaceuticals, especially virus and TSE safety. He holds a PhD from the Hokkaido University in Meat Science with emphasis in Molecular Biology.



Lilly Kong, DVM

PrimeradX

Lilly Kong joined PrimeradX in early 2009 as CSO. PrimeradX is dedicated to the emerging field of molecular diagnostics. Lilly directs scientific and technical affairs to support the development and commercialization of the novel molecular quantitative multiplex multi-modal diagnostic platform. Prior to joining PrimeradX, Lilly served as the Vice President of Research and Development at Focus Diagnostics, a wholly owned subsidiary of Quest Diagnostics, managing both molecular and immunological diagnostic products and laboratory services. Lilly is a veterinarian, virologist and molecular biologist by training. She received a D.V.M. from National Taiwan University, an M.S. in Veterinary Microbiology from Auburn University, and had her postdoctoral fellowship training in Hematology at the University of Alabama, Birmingham.



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Herbert Lutz

Millipore Corporation

Herbert Lutz has degrees in chemistry and chemical engineering from UCSB and attended graduate school in Business and Chemical Engineering at MIT. He has worked in the area of separations and purification for 30 years. Herb currently focuses on the development, validation, scale-up and trouble-shooting of new downstream purification applications such as virus clearance, sterile filtration, clarification, tangential flow filtration, chromatographic purification, and membrane absorbers. He has also worked in product management, and strategic marketing.



As a thought leader in the field, Herb is a frequent conference presenter, chair and has assisted in organizing several conferences. He has published several book chapters including the Membrane Separation Section of Perry's Chemical Engineer's Handbook, holds a filtration patent, is on the scientific advisory board for Biopharm International, and has published in the areas of scaling, ultrafiltration, membrane adsorption, integrity testing and virus clearance. Mr. Lutz has taught membrane applications for Millipore, for the ASME Bioprocess course, and for the Society for Bioprocessing Professionals.

Marc Martin, PhD

ANSM

Dr. Martin has been working for AFSSAPS for 10 years. Dr. Marc Martin gained a Ph.D. in the Service of Neurovirology of Pr. D. Dormont at CEA in Fontenay-Aux-Roses France. He has been involved in the screening and understanding of mechanism of action of immunomodulatory and non-inflammatory molecules for their capacity to inhibit HIV replication in cell cultures. Dr. Martin was also involved in the evaluation of the inactivation capacity of some chemicals toward HIV. In 2001, he joined the viral safety Unit at AFSSAPS where he is in charge of the evaluation of marketing authorization dossiers for plasma-derived products, Biotech products, and vaccines, and other biological products of human and animal origin used for the preparation of medicinal products. Dr. Martin is also involved in different Working Groups at AFSSAPS and EMEA dealing with Prion and Viral safety for Plasma and Urine-derived products, Epidemiology of blood donors.



Raymond Nims, PhD

RMC Pharmaceutical Solutions, Inc.

Raymond Nims brings over 37 years of experience in the biomedical sciences. He currently provides consulting services as an employee of RMC Pharmaceutical Solutions. From 2006 to 2009, Ray served in Amgen's corporate Quality Control group, providing subject matter expertise in viral and mycoplasma testing of raw materials and products, and serving as business process owner for Amgen's global contract analytical testing lab outsourcing program. From 1994 to 2006, Ray directed laboratories at BioReliance performing viral safety, endotoxin, and cell line identity studies for biologics cell line characterization, raw material testing, and product lot release testing. From 1985 to 1994, Ray served as a chemist at the National Cancer Institutes' Laboratory of Chemical Carcinogenesis.



Raymond obtained a PhD in chemistry (chemical toxicology) at The American University, Washington, DC, in 1993. He currently serves on the editorial boards for the International Journal of Toxicology and the BioProcessing Journal, and has served on the ad hoc advisory boards for USP chapters 1237, 1050, and 1050.1. He is a generalist in the biomedical sciences, with a publication list spanning a wide range of areas in chemistry, carcinogenesis, biochemistry, pharmacology, toxicology, and virology.

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Wendy Osheroff, PhD

Grifols Therapeutics Inc.

Dr. Osheroff joined the Pathogen Safety Research group in the Biological Products division of Bayer Health Care in 1999, where she was involved in developing, validating, and implementing assays used to test human plasma for infectious viruses. In 2003, she assumed a position that performed risk assessments in support of the pathogen safety of both plasma and recombinant products. Today Dr. Osheroff is the Section Head of the Pathogen Safety Support and Compliance group at Grifols Therapeutics Inc. where she oversees many aspects of pathogen safety for Grifols' plasma and recombinant derived therapeutic products, including the evaluation and assessment of commercial and clinical manufacturing, development and monitoring of virus safety testing for clinical studies, and preparation of regulatory documents, marketing materials, and responses to regulatory and medical inquiries concerning the pathogen safety of the company's products.



Suzette A. Priola, PhD

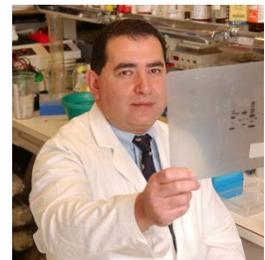
NIAID, NIH

Dr. Priola has been with the National Institutes of Health's National Institute of Allergy and Infectious Diseases since she arrived at the Rocky Mountain Laboratories in 1991 as a post-doctoral fellow in the Laboratory of Persistent Viral Diseases. She is now a Senior Investigator and Chief of the TSE/Prion Molecular Biology section. Her laboratory studies various aspects of prion disease in order to understand the basic mechanisms underlying prion pathogenesis and to identify new targets for diagnostics and therapeutics. She has studied the molecular mechanisms underlying prion species barriers and prion strains as well as the mechanisms by which mutations in the prion gene can lead to heritable forms of prion disease. Her most recent work has focused on the early steps involved in prion infection of a cell and on using proteomics to understand the molecular basis of different prion disease phenotypes. She holds a B.S. in Biology from the University of New Mexico and a PhD in Microbiology and Immunology from UCLA.

Jack Ragheb, MD, PhD

CDER/FDA

Jack A. Ragheb, M.D. Ph.D. is a Senior Regulatory Research Officer and Principal Investigator in the Division of Therapeutic Proteins/OBP/OPS/CDER/FDA and an Attending Physician on the Allergy Immunology Service, NIAID, National Institutes of Health in Bethesda, MD. A graduate of the Johns Hopkins University and School of Medicine, he performed his clinical training at the Johns Hopkins Hospital and National Institutes of Health. A recipient of numerous research awards, his work and publications has spanned the fields of retrovirology, gene therapy, immune activation, and clinical trials in immune tolerance. His lab is presently evaluating the risk of zoonotic human infection from porcine parvovirus contaminated therapeutic proteins.



CAPT Rebecca Sheets, PhD

NIH

CAPT Rebecca Sheets serves as the Vaccine Scientific and Regulatory Specialist in the National Institute of Allergy and Infectious Diseases at the National Institutes of Health. In this role, she formulates regulatory strategy for the Division of AIDS and the Vaccine Research Center on pre-clinical development translating research concepts into HIV and other vaccine candidates suitable for human clinical trials. She also serves as a subject matter expert on vaccine cell substrates and vaccine pre-clinical safety assessment, including toxicology.

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Rebecca Sheets, continued

Rebecca Sheets obtained her B.S. degree in Biology from the California Institute of Technology; M.S. degree in Cellular, Viral, and Molecular Biology from the University of Utah School of Medicine, and Ph.D. in Pathology from the University of Southern California, School of Medicine.

Dr. Sheets served for 9 years (1993-2002) as a Scientific Reviewer in the Viral Vaccines Branch of the Division of Vaccines and Related Products Applications, Office of Vaccines Research and Review, CBER/FDA. In 1994, to foster her commitment to public health, she became a Commissioned Officer in the U.S. Public Health Service (Scientist Category), in which she has been promoted to the rank of Captain (CAPT). She transferred to NIH in 2002.

Both at FDA and at NIH, she has striven to advance policy regarding vaccine cell substrates. Because of her virology background, a strong focus of this effort has been in regard to the adventitious agent tests. Since 2006, she has served as the Co-chair of the World Health Organization's Study Group on Cell Substrates, as the Chair of the Adventitious Agents Sub-committee, and on the Drafting Group, a sub-set of the Study Group consisting of the Chairs, Rapporteur, and WHO Secretariat. This Study Group was tasked with providing technical advice to revise the WHO's guidance on the subject, which was adopted by their Expert Committee on Biological Standardization in Oct. 2010.

Further, NIH policy mandates that researchers reduce, refine, or replace animals used for product safety testing. In this spirit, CAPT Sheets has ongoing research projects to determine how to achieve this goal with animals used in adventitious agent testing. In addition, she has considered means to streamline or more rationally assure preclinical safety of vaccine candidates than the standard toxicology ("drug-screening") studies currently required.

Jeffrey Skene

Health Canada

Jeffrey Skene has been with Health Canada since 2003. He began his career at Health Canada in Regulatory Affairs and later joined the group responsible for the review of monoclonal antibodies as a CMC reviewer. Today, Mr. Skene is a Senior Biologist/Evaluator in the Monoclonal Antibodies Division and performs the CMC review of mAb submissions, On-Site Evaluations (OSE) and oversees laboratory testing. He holds a M.Sc. in Biochemistry with a specialization in Molecular Biology.

Rachel Specht, PhD

Genentech, Inc.

Dr. Specht has been with Genentech since 2006 in Purification Development and the Process Virology Group. Dr. Specht holds a PhD in Chemical Engineering, Colorado State University, 2007. Dissertation: *Aedes* densovirus analysis and examinations in bioprocessing. Dr. Specht joined the Process Virology group as an associate scientist in 2007. Currently she is a Scientist and Group Leader in the Process Virology group. Current areas of focus at Genentech are virus clearance validation, modular virus validation, virus filtration and Q-PCR (publications in Biotechnology and Bioengineering, Biotechnology Progress, Biologicals, PDA Journal, Journal of Chromatography A, AIChE Journal)



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Tara Tagmyer, PhD

Merck & Company

Dr. Tagmyer has been with Merck & Co. since 2007 supporting live virus vaccine manufacturing. In her role, Dr. Tagmyer is responsible for managing complex root cause investigations and process optimization efforts. Most recently, Dr. Tagmyer's focus has shifted to adventitious agent risk assessments and remediation efforts for legacy live virus vaccines. She holds a B.S in Biochemistry from the Pennsylvania State University and a Ph.D. in Molecular Virology from the University of Pittsburgh, School of Medicine.



Glenn C. Telling, PhD

Colorado State University

Dr. Telling's involvement in prion disease research began as a trainee with Nobel Laureate Stanley Prusiner. He subsequently worked as an independent investigator at the UK Medical Research Council Prion Unit, and at the Sanders Brown Center on Aging at the University of Kentucky. Since late 2011, Dr. Telling has directed the Prion Research Program (PRP) at Colorado State University where he is also a Professor in the Department of Microbiology, Immunology and Pathology. While the Telling lab is particularly recognized for transgenic mouse modeling of prion diseases, it is one of only a handful of research groups with the resources and expertise for studying prion diseases using whole animal, transgenic, cell biological, biochemical, and molecular genetic approaches. The overarching goal of Dr. Telling's research program is to study the mechanism of prion replication, prion species barriers and strain diversity, and the molecular basis of inherited human prion diseases.



Jeffrey Ucran

Accelaron Pharma

Mr. Ucran has been with Accelaron Pharma since 2005 and currently leads the Purification Process Development Group. He is responsible for the design, scale-up, and tech transfer of all downstream processes performed in support of each of Accelaron's clinical stage protein therapeutics. Mr. Ucran holds B.S. degrees from the University of Massachusetts at Amherst in Biology and Kinesiology.



Dominick Vacante, PhD

Johnson & Johnson Pharmaceutical R&D

Dominick A. Vacante, Ph.D. has been with Janssen Research & Development since 2009 and is a subject matter expert in virology, mycoplasma and TSEs providing support for pharmaceutical development and marketed products. Prior to that, he was at Ceregene, Inc. developing gene therapy products for neurological diseases leading process development, the contract manufacture of viral vectors, DNA plasmids and delivery devices; in-house quality control, assay and vector development. Prior to that, he was at BioReliance developing new assay technologies, starting up a viral contract manufacturing facility and process development. Earlier in his career at BioReliance, he was study director for virus detection assays, clearance studies and virus production. Prior to that, he was at the National Institute of Neurological Diseases and Stroke in the Infectious Diseases Branch researching the molecular neurovirology of human polyomaviruses (JCV, BKV) and HIV. He earned his Ph.D. degree in biochemistry from the University of Illinois in Chicago and his B.A. degree in biochemistry and molecular biology from Northwestern University.



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Rosemary Versteegen, PhD

International Serum Industry Association

Dr. Versteegen received her B.Sc. and Ph.D. degrees in Biochemistry from Glasgow University, Scotland. She held Postdoctoral scholarships at Cambridge University, England and the National Institutes of Health working in areas of disease research. Following several years in NIH sponsored cancer research programs, she joined Life Technologies and held various key roles, both technical and business oriented, including Vice President of the GIBCO Manufacturing Facility, Vice President of Regulatory Affairs, Vice President of New Business Development and Vice President of Strategic Planning. In 2000, Dr. Versteegen became a founding partner of the Lifa Group, a consulting organization focused on helping life science and biotechnology companies grow through clearly enunciated, actionable strategic plans. Since its inception in 2006, Dr. Versteegen has been the CEO of the International Serum industry Association, a global life science not-for-profit association

Didier Vilette, PhD

National Veterinary School of Toulouse

Dr. Vilette joined as a scientist the Institut National de la Recherche Agronomique (INRA) in 1990 to study the mechanisms of illegitimate recombination and how DNA transcription affects the stability of genetic information.

Fifteen years ago, he shifted to the prion field and get involved in a new INRA lab that has generated the first cell culture models enabling the propagation of ovine prions in cultured cells and also produced ovine PrP transgenic mice now used to characterize field isolates of sheep scrapie. He has focused his interests on developing cell culture models to study various aspects of prion multiplication, including the genetic susceptibility to prion disease, the mechanisms by which prions invade the cells and the mechanisms used by prions to spread from cell to cell. More recently, he developed cell-based assays for the detection of prion infectivity as tools to study the infectious properties of the abnormal PrP protein. He holds a PhD thesis in Biological Sciences with emphasis in virology and cell biology.



Hannelore Willkommen, PhD

Regulatory Affairs & Biological Safety Consulting

Dr. Hannelore Willkommen works as Consultant for Regulatory Affairs and Biological Safety (RBS). In this capacity, she supports firms in the development of virus and TSE safety strategies for biotech products, plasma derivatives, tissues or advanced therapy medicinal products such as gene or cell based products as well as medical devices. Dr. Willkommen is a member of an USP Expert Panel; she is furthermore very active in the non-profit organization Parental Drug Association (PDA); Dr. Willkommen leads at present the PDA Biotech Interest Group Europe and has been a member of the PDA Biotechnology Advisory Board since 2007.



Dr. Willkommen joined the Paul-Ehrlich-Institute, the German Agency for Vaccines and Biological Medicinal Products, in 1990. She worked before at the Official Control Agency for Immunobiological Medicinal Products in Berlin finally as Head of the Department of Virology. From 1992 to 1994, she was Head of the Section of Viral Diagnostics at the Paul-Ehrlich-Institut. Dr. Willkommen chaired the Virus Safety Section at the Paul-Ehrlich-Institut from its founding in 1994 until her retirement in 2002. From 1990 to 2002, she was responsible for the viral and TSE safety assessment of the products in the responsibility of the Paul-Ehrlich-Institut in national or European license procedures. Dr. Willkommen played a leading role in drafting national and European guidelines on viral and TSE safety of biotech and blood products and contributed as well to the development of ICH guidelines. Dr. Willkommen worked from 2002 to 2005 as Vice President Regulatory Affairs at Clearant Inc., Maryland, USA. She founded her consultancy business in 2005.

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Bruno You, PhD

French Fractionation and Biotechnology Laboratory

Dr. You has worked for more than 10 years in virology research programs for different institutes and universities. From 2001 to 2003 he worked with a contract testing company dedicated to the performance of viral clearance studies. Since 2003, he has been working at LFB, as manager of an internal lab dedicated to the optimization of analytical tools for the validation of manufacturing processes in respect to TSE risk (design of new TSE spikes, TSE titration assays, TCIA). Since 2009, Dr. You has been in charge of the Viral Clearance Studies team of LFB.



Mikihiro Yunoki, PhD

Benesis Corporation

Mikihiro Yunoki has worked in Benesis Corporation, the former company name of which was The Green Cross Corporation, since 1987 in the plant and research laboratory. In the past 10 years, he has managed a research project of Parvovirus B19, HAV and HEV inactivation/removal and prion removal. Currently, he is managing safety measures of plasma products in Benesis Corporation.

Min Zhang

Genentech, Inc.

Ms. Min Zhang has been with Genentech since 1997 and has been in Process Virology since 2004. Her areas of focus are viral clearance for CHO (Chinese Hamster Ovary)-derived products, and QbD (Quality by Design) approaches for virus removal (publication in Biotechnology and Bioengineering). She is responsible for developing and implementing QPCR assay for CHO retrovirus-like particles and using this assay to evaluate new approaches for retroviral clearance of purification process. Before that, she worked as a Staff Research Associate at University of California San Francisco. She started undergraduate training in Plant Biology at Nanjing University in P.R. China, continued and received her B.S. in Biology at Lock Haven University in Pennsylvania, and her M.S. degree in Biology at Pennsylvania State University.

