Juan Arciniega, D.Sc.

Center for Biologics Evaluation and Research, U.S. FDA

Dr. Arciniega is a Research Microbiologist at the Center for Biologics Evaluation and Research of the U.S. Food and Drug Administration. He received an undergraduate degree in chemistry, bacteriology, and parasitology in 1982; a Master of Science degree in clinical biology in 1985; and a Doctor of Science degree in the same specialty in 1987, all from the National School of Biological Sciences in Mexico City. Before joining the Laboratory of Pertussis at CBER in 1989 as a Visiting Fellow, he worked for nine years in different capacities at the Mexican National Public Health Laboratory, most recently as Underdirector for Biological Control, in charge of two departments with responsibility for sanitary testing of food and biologics. He was also a founding member of the Permanent Commission of the Mexican Pharmacopoeia (Biologics and Bioassay and Statistics Committees).

His research and regulatory activities have focused on pertussis, diphtheria, and anthrax vaccines. Currently Dr. Arciniega is a member of the Laboratory of Respiratory and Special Pathogens, Division of Bacterial, Parasitic, and Allergenic Products, where he works on the development and improvement of quality control methods for bacterial vaccines. Additionally, he participates in regulatory activities, such as vaccine licensing, batch release, and facility inspections (product expertise). He has published more than 15 papers in his field and cooperated with the World Health Organization and the Pan American Health Organization as a Temporary Advisor; with the European Center for the Validation of Alternative Methods (ECVAM); and with the European Directorate for the Quality of Medicines (EDQM). Dr. Arciniega has mentored several young Latin American vaccine regulators and other scientists.

Karen K. Brown, Ph.D.

Pair O'Docs Consultants

Dr. Brown received her Bachelor of Science degree from Washburn University, Topeka, Kansas, in Chemistry and Biology, and her Ph.D. degree from Oklahoma State University in Biochemical Microbiology. She is an active member of United States Animal Health Association (USAHA), American Association for the Advancement of Science (AAAS), Association of Veterinary Biologics Companies (AVBC), and the American Health Institute (AHI).

Dr. Brown has a background in biochemistry and molecular biology, as well as over 31 years of experience in industrial research for large traditional pharmaceutical/biological companies. Early in her career, Dr. Brown recognized that *in vitro* assays could be used to quantify the antigen in final product vaccines. She established one of the first laboratories in industry to develop *in vitro* tests to replace animal potency testing for release of veterinary biological products. The laboratory succeeded in developing *in vitro* tests for EHV-1, EHV-4, Tetanus Toxoid, Equine Influenza (A1 and A2), Streptococcus equi, Clostridium novyi, Clostridium sordelli, Clostridium septicum, Clostridium perfringins type C, and hyaluronic acid.

Dr. Brown retired from Bayer Healthcare in 2002 to do more consulting work in the area of *in vitro* assay development. Dr. Brown is the primary inventor on 25 issued U.S. patents and over 1000 issued foreign patents and has numerous publications and presentations. Among the latter are a 2002 presentation at the United States Animal Health Association Meeting, St. Louis, Missouri, entitled "Use of In Vitro Techniques to Reduce the Use of Animals in Veterinary Biologics Manufacture" and a 2007 presentation in Langen, Germany, on Autogenous Biologicals- Science and Regulation.

In 2007, Dr. Brown chaired the Independent Peer Review Panel "Five *In Vitro* Test Methods Proposed for Assessing Potential Pyrogenicity of Pharmaceuticals and Other Products" (ICCVAM [NIH]). In 2009, Dr. was selected to serve a three-year term on SACATM, where she has been actively working to highlight the need for additional acceptance of *in vitro* assay development and use in the animal health industry.

Warren Casey, Ph.D.

National Institute of Environmental Health Sciences, NIH

Dr. Casey received his undergraduate degree in biochemistry and his Ph.D. in microbiology from North Carolina State University (NCSU). He is currently the Deputy Director of the U.S. National Toxicology Program's Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), National Institutes of Environmental Health Sciences (NIEHS) and a Diplomate of the American Board of Toxicology (DABT). Dr. Casey also serves as an Adjunct Associate Professor in the Department of Microbiology at NCSU.

Prior to joining NICEATM, Dr. Casey was the Manager of Pharmaceutical Microbiology at Glaxo Inc. from 1994 to 1999; Head, Biomarker Development, at GlaxoWellcome, Inc., from 1999 to 2002; and a Senior Scientist, Discovery and Investigative Toxicology, at GlaxoSmithKline, Inc., from 2002 to 2009.

Dr. Casey is the author or co-author of about 28 publications in peer-reviewed journals, holds three patents, and has made presentations at several recent scientific meetings.

Ivo Claassen, Ph.D.

Central Veterinary Institute, The Netherlands

Since 2007, Dr. Claassen has been seconded by the Central Veterinary Institute (CVI), Lelystad, The Netherlands, on a posting in Indonesia to assist the Indonesian government in the control of Avian Influenza (H5N1). He is the coordinator of a partnership program between The Netherlands and Indonesia on capacity building of veterinary services and vaccine producers in Indonesia.

Dr. Claassen earned his undergraduate degree in medical biology in 1986 from the Free University, Amsterdam, The Netherlands, and his Ph.D. in 1998 from Erasmus University Rotterdam, The Netherlands. His research interests include vaccine production and quality control, immunology, virology, and bacteriology.

His previous positions include Manager of the Bacteriology and Transmissible Spongiform Encephalopathies (TSEs) Department, Head of State Quality Control and Standardisation Department, Institute of Animal Science and Health, Lelystad, The Netherlands from 1999 to 2006. He was Head of the Laboratory of Quality Control, Institute of Animal Science and Health, Lelystad, The Netherlands from 1997 to 1999. From 1986 until 1997, he held positions at the Dutch Institute for Health and Environment in Vaccine Quality Control.

Johan Descamps, Ph.D.

GlaxoSmithKline Biologicals, Belgium

Dr. Descamps is a Senior Scientist at Glaxo SmithKline Biologicals, Rixensart, Belgium ,where he is mainly involved in Research and Development and Quality Control of bacterial and viral vaccines as well as technical contacts with different National Control Authorities on bacterial and viral vaccines. He received his degree in bio-engineering with specialisation in industrial biology and microbiology from the University of Leuven, Belgium, and his MBA from the University of Brussels, Belgium.

Before joining GSK, he worked as a Research Assistant on antiviral compounds at the Rega Institute, University of Leuven, Belgium, and at Yale University, New Haven, Connecticut, USA. Dr. Descamps is also a member of the Biological Steering Group on Vaccines at ECVAM (European Centre for the Validation of Alternative Methods).

Hans Draayer, M.Sc.

Pfizer Animal Health

Hans Draayer is the Senior Director of Biological Regulatory Affairs for Veterinary Medicine Research and Development, Pfizer Animal Health, where he directs regulatory activities for veterinary biologicals. He started his industry career in 1979 as a Research Scientist with Beecham Laboratories. In addition to his vaccine development background, Mr. Draayer has over 20 years of experience in global Regulatory Affairs.

Mr. Draayer graduated from South Dakota State University in 1979 with a Master of Science Degree in microbiology, specializing in veterinary virology.

Theresa Finn, Ph.D.

Center for Biologics Evaluation and Research, U.S. FDA

Dr. Finn is the Associate Director for Regulatory Policy in the Office of Vaccines Research and Review (OVRR), Center for Biologics Evaluation and Research, FDA. She received her B.A. and her Ph.D from Trinity College, Dublin, Ireland. Dr. Finn joined CBER in 1990 and has over 18 years of vaccine regulatory experience. This experience includes serving as reviewer on numerous INDs and as chair and reviewer on a number of vaccine license applications and supplements. In addition, she has represented FDA and OVRR on several working groups and committees.

Jeffrey Galvin, Ph.D.

Pfizer Animal Health

Dr. Galvin received his undergraduate degree in microbiology from South Dakota State University in 1990 and a PhD in immunobiology from Iowa State University in 1995. Jeff was a Post-doctoral Research Fellow from 1996 to 1999 in the Department of Microbiology in the College of Medicine at the University of Oklahoma, Health Sciences Center. Dr. Galvin joined Pfizer Animal Health in 1999 as a Research Scientist in Biologicals Development as head of an analytical lab and is now Associate Director of Bacterial Vaccine Process Development.

Dr. Galvin has extensive experience in animal models of disease and in development of animal-based potency tests. He has developed rodent models of autoimmune diseases of the heart (myocarditis and strep induced rheumatic fever) and intestinal models of infectious disease. While at Pfizer, he has led a team of scientists to develop numerous *in vitro* and *in vivo*-based potency assays for veterinary bacterial-based vaccines including challenge and serologic based tests. Dr. Galvin has served on two Institutional Animal Care and Use Committees during his time at Pfizer.

Glen Gifford, D.V.M., M.Sc., DACVPM

Canadian Food Inspection Agency, Canada

Dr. Gifford is National Manager of the Canadian Centre for Veterinary Biologics (CCVB), Canadian Food Inspection Agency. The CCVB is responsible for regulating the manufacturing, importation, and distribution of Canadian veterinary biologics in Canada.

Dr. Gifford studied veterinary medicine at the Western College of Veterinary Medicine at the University of Saskatchewan in Saskatoon and graduated in 1980. He worked in mixed veterinary practice for three years before returning to the University of Saskatchewan for graduate studies in veterinary pathology. He worked on a project to study the pathogenesis of **pnemonic** pasteurellosis in cattle. After completing graduate studies, he joined a research institute in Saskatoon, working on research projects to develop and test vaccines and other animal health products for use in cattle. He joined the Veterinary Biologics Section in 1987 as a veterinary biologics evaluator. In 1996, he was appointed to his current position as National Manager of the Veterinary Biologics Section, which was recently renamed the Canadian Centre for Veterinary Biologics (CCVB).

Dr. Gifford and the CCVB staff work closely with individual manufacturers and importers, as well as with livestock industry representatives and other stakeholders, to develop and implement science-based regulatory controls for veterinary biologics with the objective of facilitating timely access to safe and effective animal health products.

The CCVB actively participates in international harmonization initiatives and encourages development and acceptance of alternative methods to reduce, refine, and replace the use of animals in veterinary biologics regulatory testing.

Marlies Halder, V.M.D.

Institute for Health & Consumer Products, ECVAM

Dr Halder studied Veterinary Medicine at the Veterinary Faculty of the University of Munich (Germany) and obtained a V.M.D. from the University of Munich in 1987 for research on crustaceans and fish diseases. She worked for several years as a research scientist at the University of Munich and the Akademie fuer Tierschutz, Neubiberg, Germany. Her working areas included the use of *in vitro* methods in ecotoxicology as well as the diagnosis of and epidemiological studies on viral and fungal diseases of fish and crustaceans.

Dr Halder joined the European Commission in October 1995 and currently holds a position as a senior scientist at the European Commission's Joint Research Centre, Institute for Health & Consumer Protection, European Centre for the Validation of Alternative Methods (ECVAM)/In Vitro Methods Unit in Ispra, Italy. She is responsible for 3R activities related to the quality control of biologicals and environmental toxicity.

Coenraad F.M. Hendriksen, D.V.M., Ph.D.

Netherlands Vaccine Institute, The Netherlands

Dr. Hendriksen studied veterinary medicine at Utrecht University, Utrecht, The Netherlands and received post-doctoral training in laboratory animal science. In 1989 he obtained his Ph.D. from Utrecht University on a thesis entitled “Alternatives to Animal Testing in Diphtheria and Tetanus Research. Replacement, Reduction and Refinement in Vaccine Potency Control and Serology.” He became the animal welfare officer at the National Institute of Public Health and the Environment (RIVM), Bilthoven, The Netherlands; coordinator of the RIVM’s institutional centre of alternatives; and research scientist with particular interest in development and validation of 3R alternatives in the area of vaccine quality control. Currently he holds the same positions at the Netherlands Vaccine Institute, Bilthoven (NL). He also has a part-time position at the Veterinary Faculty of Utrecht University, where he holds a chair on alternatives.

Dr. Hendricksen is the author or co-author of about 90 publications in peer-reviewed journals and editor of several volumes and publications on vaccine quality control and the opportunities for 3R alternatives. He is a member of several national and international committees in the area of animal testing and alternatives. He is chairman of the government’s advisory committee on animal experimentation (CCD), chairman of ECVAM’s task force on vaccine quality control, board member of the Alternatives Congress Trust, and member of the Mirror Group of the European Partnership on Alternative Approaches to animal testing (EPAA). His contributions have been recognised with the Russell & Burch award (U.S.), the Doerenkamp-Zbinden award (Switzerland), and the Felix Wankel award (Germany). Dr. Hendricksen is married and has two children.

Richard E. Hill, Jr., D.V.M., M.S., DACVPM

Center for Veterinary Biologics, USDA

Dr. Hill is currently the Director of the Center for Veterinary Biologics, United States Department of Agriculture (USDA). Dr. Hill received a D.V.M. degree from Michigan State University in 1983 and, following graduation, worked in private veterinary practice. In 1985, he joined the USDA and worked as a field Veterinary Medical Officer before joining the Biologics Program in 1986. Dr. Hill worked as an Inspector, Epidemiologist, and Team Leader for the Biologics Program, where he was involved in regulatory compliance and coordination of the pharmacovigilance program. In 1990, he received an M.S. degree in Veterinary Preventive Medicine at Iowa State University. He is a Diplomate in the American College of Veterinary Preventive Medicine. In 1995, Dr. Hill transferred to the position of Quality Assurance Manager, responsible for overseeing the Quality Assurance Program at the National Veterinary Services Laboratories and Center for Veterinary Biologics-Laboratory. In November 1998, he rejoined the Center for Veterinary Biologics as Director of Licensing and Policy Development. In May 2005, Dr. Hill was named Center Director.

Yoshinobu Horiuchi, Ph.D.

Pharmaceuticals and Medical Devices Agency, Japan

Dr. Horiuchi graduated from the Faculty of Sciences, Kyushu University in 1971. He obtained a Ph.D. degree from the School of Medicine, Showa University in 1992. While at the Chiba Serum Institute, he was involved in vaccine research and production and in the development of acellular pertussis vaccine during the late 1970s.

Dr. Horiuchi joined the Department of General Biologics Control of the National Institute of Health (NIH), Japan, in 1991. He took part in National Lot Release Testing for vaccines and was appointed to the position of Chief Researcher at the Laboratory of Biological Statistics of the NIH in 1993. Beginning in 2002, he also worked as the Chief Researcher at the Laboratory of Pertussis and Endotoxin Control of the National Institute of Infectious Diseases (NIID). During his time at the NIH, Dr. Horiuchi was appointed as a permanent board member to the committee for evaluating Pharmacopeia Reference Standard Endotoxin and was also involved in various World Health Organization (WHO) working group activities to develop WHO guidance documents. He joined the Office of Biologics II of the Pharmaceutical and Medical Devices Agency (PMDA), Japan, as a Technical Expert in 2008.

While at the NIID, Dr. Horiuchi developed *in vitro* pyrogen tests using rabbit peripheral blood and, in collaboration with his colleagues, a human monocytic cell line that has responsiveness to various pyrogens similar to that of human peripheral blood. In collaboration with colleagues at NIID and National Institute of Biological Standards and Control (NIBSC), he also developed an *in vitro* test method that uses a combination of assays, including an enzyme-linked immunosorbent assay and an enzyme-linked high-performance liquid chromatography (HPLC) assay, to assess residual pertussis toxin activity in acellular pertussis vaccines.

Richard Isbrucker, Ph.D.

Health Canada, Canada

Dr. Isbrucker received his undergraduate degree in microbiology and immunology in 1988 and a Ph.D. in pharmacology in 1996, both from Dalhousie University in Nova Scotia, Canada.

He joined the Center for Vaccine Evaluations (formerly Center for Biologics Research) of Health Canada as a Research Scientist in 2008. He conducts research in assay development and alternative toxicity testing methods, such as a current project evaluating the biological relevance of alternative *in vitro* assays for monitoring residual pertussis toxin in vaccine preparations.

Prior to joining Health Canada, Dr. Isbrucker worked in both industry and nonprofit sectors developing assays for high-throughput and secondary functional screening of potential anti-cancer and anti-inflammatory agents. He has also worked as a consultant in regulatory toxicology and was Assistant Director of Toxicology with Burdock Group consulting firm from 2004 to 2006.

James Keller, Ph.D.

Center for Biologics Evaluation and Research, U.S. FDA

Dr. Keller received his Ph.D. in 1996 from the University of California at Santa Barbara. He spent five years as a post-doctoral researcher with the U.S. Army and with the National Institutes of Health, National Institute of Child Health and Human Development (NICHD). Dr. Keller joined the Food and Drug Administration, Center for Biologics Evaluation and Research (FDA/CBER) as a principal investigator in 2001. His primary duties involve the review of adult and pediatric vaccines containing tetanus and diphtheria toxoids. Other review duties include the review of Investigational New Drug applications. Dr. Keller's research has examined Botulinum neurotoxin mechanisms and toxin antigenicity. His laboratory recently developed an antigen quantification assay for formalin-inactivated botulinum neurotoxin toxoids. Parallel research projects are examining tetanus toxin synthesis and toxoid antigenicity with the aim of developing antigen quantification assay(s) for tetanus content within currently licensed vaccine products.

Hajime Kojima, Ph.D.

JaCVAM, National Institute of Health Sciences, Japan

Dr. Kojima received his undergraduate degree in 1983 from Gifu University, Department of Agriculture, Faculty of Agricultural Chemistry and his Ph.D. in 1996 in information science from the University of Nagasaki. He currently is the Director of the Japanese Center for the Validation of Alternative Methods (JaCVAM) and a Visiting Lecturer at the Fujita Health University School of Medicine. Dr. Kojima is also a member of the International Cooperation on Alternative Test Methods (ICATM) and an observer on both the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) and the European Scientific Advisory Committee (ESAC).

Prior to joining JaCVAM in 2006, Dr. Kojima held several positions with increasing responsibility at the Nippon Menard Cosmetic Co., Ltd., including Researcher at the Biochemical Institute from 1986 to 1994, Chief of the Biochemical Institute from 1994 to 1995, Chief of the Research Laboratories from 1995 to 2001, and Assistant Manager of the Research Laboratories from 2001 to 2005.
Dr. Kojima has received several awards, including The Japanese Society for Alternatives to Animal Experiments (JSAAE) Paper Prize in 1998, 2000, and 2003. Dr. Kojima is also a member of several professional societies, including the Japanese Society for Dermatoallergology and Contact Dermatitis, the Japanese Society of Toxicology, The Society of Toxicology, the Japanese Environmental Mutagen Society, the Japanese Society for Alternatives to Animal Experiments, the Safety Evaluation Forum, and the Japanese Association for Animal Cell Technology.

Jodie Kulpa-Eddy, D.V.M.

Animal & Plant Inspection Service, USDA

Dr. Kulpa-Eddy is a Senior Staff Veterinarian with the U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Agricultural Select Agent Program, one of three agencies responsible for enforcement of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

She received her Doctor of Veterinary Medicine (D.V.M.) degree from the University of Minnesota in 1985. She spent four years in private practice and has been employed by the USDA since 1989. She has been assigned as a biologics specialist (inspecting facilities that produce animal vaccines and diagnostic test kits), veterinary medical officer (inspecting animal dealers, transporters, exhibitors, and research facilities), and staff veterinarian (developing policy and regulations under the Animal Welfare Act). She began her current position in December 2009. The Select Agent program oversees laboratories working with potential bioterrorism pathogens and toxins, and ensures that these entities maintain adequate biosafety and security measures.

She has served as the USDA representative to the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) since 2001. In January 2009, she was elected to a second two-year term as Vice-chair. Dr. Kulpa-Eddy is also currently the co-chair of ICCVAM's Biologics Working Group (BWG).

Richard McFarland, M.D., Ph.D.

Center for Biologics Evaluation and Research, U.S. FDA

Dr. McFarland received a B.S. in zoology, a Ph.D. in experimental pathology, and a M.D. from the University of North Carolina at Chapel Hill. He completed residency training in anatomic and clinical pathology and fellowship training in immunopathology at University of Texas Southwestern/Parkland Memorial Hospital, Dallas, Texas, USA.

Dr. McFarland is currently the Associate Director for Policy in the Office of Cellular, Tissue and Gene Therapies (OCTGT) in the Center for Biologics Evaluation and Research (CBER), at the U.S. Food and Drug Administration (FDA). In this capacity, Dr. McFarland serves as a primary contact for regulatory policy issues, guidance development, and product jurisdiction for the office.
Dr. McFarland has 10 years of experience in the FDA/CBER, 5 primarily as a pharmacology/toxicology reviewer in the former Office of Therapeutics, Research and Review (OTRR) and in OCTGT. He has been the Associate Director for Policy in OCTGT since the inception of the position. Prior to joining CBER, Dr. McFarland was a faculty member in the Department of Pathology at the University of Texas Southwestern Medical School (UT Southwestern) and an attending physician at Parkland Memorial Hospital.

Dr. McFarland has been a CBER representative to the Interagency Committee for the Validation of Alternative Methods (ICCVAM) since 2000. He is also the current co-chair of ICCVAM's Biologics Working Group (BWG) and, as a result, has given numerous presentations reporting on BWG validation projects and CBER's intramural research related to the 3Rs. In addition, he served on the Organizing Committee for the Biologics Sessions of the 6th World Congress held in Tokyo in August 2007.

Suman Mukhopadhyay, Ph.D.

National Institute of Allergy and Infectious Diseases, NIH

Dr. Mukhopadhyay is currently a Program Officer, Bacterial Zoonoses at the Bacteriology and Mycology Branch (BMB), Division of Microbiology and Infectious Disease (DMID) of the National Institutes of Health/National Institutes of Allergy and Infectious Disease (NIH/NIAID). He oversees basic research on pathogens mainly associated with the following diseases: plague (Yersinia), tularemia (Francisella), melioidosis (Burkholderia pseudomallei), glanders (Burkholderia mallei), Leptospira, Brucellosis, Coccida, Pasteurella, and any agents causing febrile illness in human.

He received his undergraduate degree in chemistry from the University of Calcutta, Calcutta, India in 1987; a Master of Science degree in biochemistry and molecular biology from the same university in 1989; and a Ph.D. in Molecular Microbiology from the McMaster University, Hamilton, Ontario, Canada in 1997.

Dr. Mukhopadhyay did a Postdoctoral Fellowship at the Laboratory of Biochemistry, National Cancer Institute, focusing on the study of mechanisms regulating initiation of DNA replication, an important aspect of understanding cancer. Dr. Mukhopadhyay then joined the University of Maryland as an Assistant Professor, where he set up the Laboratory of Microbial Pathogenesis. His lab research integrated the tools of genomics, proteomics, and bioinformatics with those of conventional molecular biology, biochemistry, genetics, and immunology, to study host–pathogen interactions. Dr. Mukhopadhyay has authored several journal articles, holds two patents, and has presented several invited lectures.

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James Roth, D.V.M., Ph.D.

College of Veterinary Medicine, Iowa State University

Dr. Roth is a Distinguished Professor in the Department of Veterinary Microbiology and Preventive Medicine in the College of Veterinary Medicine at Iowa State University. He is the Executive Director of the Institute for International Cooperation in Animal Biologics (IICAB), which is a World Organization for Animal Health (OIE) Collaborating Center for Diagnosis of Animal Disease and Vaccine Evaluation in the Americas. The IICAB was jointly formed by Iowa State University and the U.S. Department of Agriculture/Animal and Plant Health Inspection Service (USDA/APHIS) in 1995. Dr. Roth is also the Director of the Center for Food Security and Public Health (CFSPH). The CFSPH was established in 2002 with funding from the Centers for Disease Control and Prevention with the mission to enhance national preparedness for accidental or intentional introduction of disease agents that threaten food security or public health.

Dr. Roth received a D.V.M. and a Ph.D. in immunology from Iowa State University. He has served as the major or co-major professor for 49 M.S. and Ph.D. students. Dr. Roth teaches immunology to veterinary students and has an active research program related to the immunology of infectious diseases of food-producing animals. He has authored or co-authored over 150 publications in refereed journals. Dr. Roth has contributed 33 chapters to monographs and has edited 11 monographs and one textbook. He has received five teaching awards and was named Clarence Hartley Covault Distinguished Professor in 1995. Dr. Roth received the Distinguished Veterinary Immunologist Award from the American Association of Veterinary Immunologists in 1997 and the Distinguished Veterinary Microbiologist Award from the American College of Veterinary Microbiologists in 2009. Dr. Roth received the American Veterinary Medical Association's (AVMA) 12th International Veterinary Congress Prize in 2001 and the AVMA’s Public Service Award in 2006. Dr. Roth has served on the National Science Advisory Board for Biosecurity since 2005. He also served on the Interagency Weapons of Mass Destruction Counter Measures Working Group (2003-2004) and the White House Office of Science and Technology Policy Agroterrorism Counter Measures Blue Ribbon Panel (2003-2004).

Steven Rubin, Ph.D.

Center for Biologics Evaluation and Research, U.S. FDA

Dr. Rubin received his undergraduate degree from the University of Maryland in 1990; a Master of Science degree in molecular biology from the Johns Hopkins University in Baltimore, Maryland, in 1993; and a Ph.D. from the Queen's University in the United Kingdom in 2010. Dr. Rubin joined the Johns Hopkins University as a Research Associate and faculty member in the Department of Medicine in 1993. He studied neuropathological and neurodevelopmental abnormalities in rats following perinatal Borna disease virus infection. In 1996, Dr. Rubin joined the U.S. Food and Drug Administration, Center for Biologics Evaluation and Research (FDA/CBER), where he currently directs a research program of senior scientists and support staff focused on the development of preclinical neurotoxicity assays for evaluating the neurological safety of candidate live attenuated vaccine viruses.

Dr. Rubin has authored over 60 journal articles, reviews, and book chapters. As an internationally recognized scientist in the field of neuropathogenesis, he has been invited to speak at numerous national and international meetings and is the recipient of over $3.7 million in grant awards. Dr. Rubin serves on a number of scientific/administrative review boards, committees, and working groups. He serves as an Ad Hoc Scientific Reviewer for numerous scientific journals in the fields of neurobiology, immunology, and virology. Dr. Rubin also chairs the CBER's Institutional Animal Care and Use Committee, a position he has held since 1999.

In his capacity as a regulatory scientist at the FDA, Dr. Rubin is a primary reviewer for Investigational New Drug submissions and Product License Applications for pediatric vaccines. Dr. Rubin also serves as an agency expert on live attenuated vaccine manufacture and has contributed to the drafting and publication of several guidance documents for industry.

Michael Schmitt, Ph.D.

Center for Biologics Evaluation and Research, U.S. FDA

Dr. Schmitt received his undergraduate degree in biology from the University of Texas at Austin in 1981 and his Ph.D. in microbiology from the same university in 1989.

Dr. Schmitt is currently a Microbiologist in the Laboratory of Respiratory and Special Pathogens, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration (CBER) where he is the lead product review specialist for vaccines containing diphtheria and tetanus toxoids. Dr. Schmitt is also involved in the review of submissions associated with vaccines for botulism, *Staphylococcus aureus*, and for therapeutics for botulism and cancer treatment (*Clostridium novyi* spore therapy). Prior to joining the FDA in 1995, Dr. Schmitt was a Postdoctoral Fellow from 1989 to 1992 and a Research Assistant Professor/Research Associate from 1992 to 1995 in the Department of Microbiology and Immunology at the Uniformed Services University of the Health Sciences, Bethesda, Maryland.

Dr. Schmitt has been awarded several honors including FDA On-the-spot Award for contributions and presentation at the Vaccines and Related Biological Products Advisory Committee on October 30, 1996; the Award of Merit as a member of the Revision to spore-Former Regulations Working Group in May 2004; and the Award of Merit as a member of the Pertussis licensing group for exceptional review of manufacturing data for licensure of Adacel and Boostrix in June 2006. Dr. Schmitt is a member of the editorial board for *Infection and Immunity* journal through 2010 and an Ad Hoc peer reviewer for the following journals: *Molecular Microbiology*, *Journal of Biological Chemistry*, *Gene*, *Journal of Bacteriology*, *The Journal of Infectious Diseases*, and *Microbiology*. Dr. Schmitt is also the author or co-author of more than 30 publications in peer-reviewed journals and book chapters.

Anne Schuchat, M.D., RADM, USPHS

National Center for Immunization and Respiratory Diseases, CDC

Dr. Schuchat is the director of CDC's National Center for Immunization and Respiratory Diseases and has worked at CDC since 1988 on immunization, respiratory, and other infectious diseases. Prior to her current appointment, she served as the director of CDC's National Immunization Program (NIP); acting director of the National Center for Infectious Diseases (NCID); chief of the Respiratory Diseases Branch at NCID; and as the initial medical director of the Active Bacterial Core surveillance (ABCs)/Emerging Infections Program Network, a multistate collaboration between CDC, state health departments, and academic institutions that tracks invasive bacterial infections, informs vaccine and prevention policy, and monitors program impact. Dr. Schuchat was named an Assistant Surgeon General of the United States Public Health Service in 2006. She also served as CDC's Interim Deputy Director for Science and Program from February to June 2009.

Globally, she has worked in West Africa on meningitis vaccine studies; in South Africa on surveillance and prevention projects; and in China on SARS emergency response, where she headed the Beijing City epidemiology team for the World Health Organization's (WHO) China Office. She served as a visiting professor for the Beijing Centers for Disease Prevention and Control.
Dr. Schuchat has made critically important contributions to the prevention of infectious diseases in children, including her role in perinatal group B streptococcal disease prevention, where she spearheaded the development of CDC′s guidelines that have led to an 80% reduction in newborn infections and a 75% narrowing of racial disparities among sufferers of this infectious disease. She also has been instrumental in pre- and post-licensure evaluations of conjugate vaccines for bacterial meningitis and pneumonia and in accelerating availability of these new vaccines in resource-poor countries through WHO and the Global Alliance for Vaccines and Immunization.

Anne Schuchat graduated with highest honors from Swarthmore College and with honors from Dartmouth Medical School. She served as resident and chief resident in internal medicine at New York University's Manhattan VA Hospital before beginning her public health career at CDC as an Epidemic Intelligence Service (EIS) officer.

She has authored or co-authored more than 180 scientific articles, book chapters, and reviews. Her contributions have been recognized by receipt of the USPHS Meritorious Service Medal, the American Public Health Association's Maternal and Child Health Young Investigator Award, the USPHS Physician Research Officer of the Year, and an Honorary Doctorate in Science from Swarthmore College. In 2008, she was elected to the Institute of Medicine.

Dorothea (Thea) Sesardic, Ph.D.

National Institute for Biological Standards and Control, United Kingdom

Dr. Sesardic, B.Sc. (Hons), Ph.D., obtained a degree in biological sciences in 1975 and a Ph.D. in microbial biochemistry in 1980 from the University of London (U.K.). She was a Research Assistant at the Medical Research Council (MRC) TB Unit at the Royal Postgraduate Medical School. Between 1982 and 1990, she was a Senior Postdoctoral Scientist at Department of Clinical Pharmacology, Imperial College London. Dr Sesardic joined the Division of Bacteriology at the National Institute for Biological Standards and Control (NIBSC) in 1990 where she is now Principal Scientist and head of a group working on a diverse range of products derived from bacterial toxins.

Dr Sesardic has extensive scientific and regulatory experience regarding product preclinical evaluation, batch release testing under the Official Control Authority Batch Release (OCABR) process, and post marketing surveillance. She is an expert adviser to U.K. Department of Health (DoH), World Health Organization (WHO), and the European Directorate for the Quality of Medicines (EDQM), representing the U.K. at EDQM European Pharmacopoeia (Ph Eur) Group of Experts No 15 for vaccines and sera since 2000. She is also a member of several Botulinum toxin expert working groups in Europe and an appointed member of a panel of experts on Biological and Biotechnological products for British Pharmacopoeia. Dr Sesardic is actively involved in the development of alternatives to animal testing (3Rs) and has contributed to Ph Eur monographs, WHO guidelines, and more recently *United States Pharmacopeia* (USP) revisions on bioassays replacing animals. She has more than 160 peer-reviewed publications and several book chapters on a range of topics.

JinHo Shin, D.V.M., Ph.D.

World Health Organization, Switzerland

Dr. Shin graduated from the College of Veterinary Medicine of Seoul National University in 1989. He obtained a Master's degree in veterinary internal medicine from the same college in 1991 and a Ph.D. degree in veterinary pathobiology from the Graduate School of the University of Minnesota, USA, in 1999.

From 1990 to 2000, Dr. Shin was a staff scientist at the Virology Division of the National Veterinary Research and Quarantine Service (NVRQS) based in Anyang, the Republic of Korea.

In 2000, he took a senior scientist post offered by the Korea Food and Drug Administration (KFDA). From 2000 to 2003, he was involved in the official release of viral vaccines and the evaluation of national requirements for manufacturing and controlling viral vaccines.

In 2003, he was seconded for two years to the World Health Organization (WHO) in Geneva, Switzerland. On completing the secondment, he joined the WHO as a regular staff member. Since 2003, he has been working at the Quality, Safety and Standards Team of the Immunization, Vaccines and Biologicals Department at the WHO Headquarters.

Since 2003, he has coordinated the development of International Biological Reference Standards and technical documents for evaluating the quality, safety, and efficacy of viral vaccines. He published several reports of expert meetings on such topics as plant-derived vaccines, molecular methods, stability of reference standards, Japanese encephalitis vaccines, yellow fever vaccines, and candidate dengue vaccines.

Janet Skerry, B.S.

U.S. Army Medical Research Institute of Infectious Diseases, DOD

Ms. Skerry is currently a Laboratory Technician at the United State Army Medical Research Institute for Infectious Diseases (USAMRIID). Ms. Skerry received her Bachelor of Science degree in veterinary science in 2000 and her certification by the American Association of Laboratory Animal Science as an Assistant Laboratory Animal Technician (ALAT) in 2004. Prior to joining USAMRIID she worked as a veterinary technician in small animal, exotic animal, and emergency/trauma medicine. Ms. Skerry began her career in research in 2004 at Sobran Inc., located on the National Institutes of Health campus in Bethesda, Maryland. She joined USAMRIID in September 2006.

Geetha Srinivas, D.V.M., Ph.D.

Center for Veterinary Biologics, USDA

Dr. Srinivas received her D.V.M. degree from the College of Veterinary Medicine, Bangalore, India. Dr. Srinivas continued her graduate degree at the VA-Maryland regional college of Veterinary Medicine, University of Maryland, College Park, Maryland, and received her M.S. degree in virology and immunology. Her research work for her M.S. degree was on the development of and characterization of strain-specific monoclonal antibodies to Newcastle disease virus. Dr. Srinivas earned her Ph.D. in 1995 in veterinary microbiology and immunology. Her dissertation work was on the development of receptor-specific monoclonal antibodies and molecular characterization of enteric receptors in pigs. After working as post-doctoral research scientist in the South Dakota State University, Brookings, South Dakota, Dr. Srinivas joined a licensed biologics firm in 1996, as the Manager in the Department of Product Development, heading the Virology Section. She joined the Center for Veterinary Biologics in 2003 and is currently the Section Leader for the Bacteriology Section in the Policy, Evaluation, and Licensing Unit of the CVB.

Paul Stickings, Ph.D.

National Institute for Biological Standards and Control, United Kingdom

Dr Stickings received his undergraduate degree in Biomedical Sciences in 1997 and a Ph.D. in Biochemistry in 2001, both from the University of Brighton. He held a postdoctoral scientist position at University College London (Pharmacology) for 3 years from 2002 prior to joining the group of Dr. Dorothea Sesardic at the National Institute for Biological Standards and Control (NIBSC) in 2005. Dr Stickings holds the position of Senior Scientist at NIBSC and works on a diverse range of products derived from bacterial toxins. He is involved in the control of diphtheria- and tetanus-based vaccines for EU batch release under the Official Control Authority Batch Release (OCABR) process and as part of the World Health Organization (WHO) Prequalification Programme. He has extensive experience in *in vitro* and *in vivo* assays used for assay of diphtheria and tetanus vaccines and antitoxins. Dr Stickings is a member of the drafting group responsible for revision of the WHO recommendations for diphtheria-, tetanus- and pertussis-based combination vaccines.

William Stokes, D.V.M.

National Institute of Environmental Health Sciences, NIH

Dr. Stokes is Director of the U.S. National Toxicology Program's Interagency Center for the Evaluation of Alternative Toxicological Methods and Executive Director for the Interagency Coordinating Committee on the Validation of Alternative Methods. He oversees the interagency evaluation of new, revised, and alternative safety testing methods and coordination of validation, regulatory acceptance, and national and international harmonization issues across ICCVAM's 15 Federal agencies. Stokes is a career officer and Assistant Surgeon General in the U.S. Public Health Service Commissioned Corps with the rank of Rear Admiral and served as the 8th Chief Veterinary Officer for the USPHS from 2003-07. He received his B.S. at the University of Louisville and his D.V.M. from the Ohio State University and is board certified by the American College of Laboratory Animal Medicine. His career began in the U.S. Army Veterinary Corps with assignments at the U.S. Army Medical Research Institute of Infectious Diseases and as chief of Veterinary Services at Tripler Army Medical Center. Dr. Stokes transferred to the USPHS Commissioned Corps in 1986 as Animal Program Director for the National Institute of Child Health and Human Development. At NIEHS, he has served as the Animal Program Director, Chief of the Comparative Medicine Branch, and Associate Director for Animal and Alternative Resources. He has received numerous awards, including the Enhancement of Animal Welfare Award from the Society of Toxicology, two NIH Director's Awards, the Russell and Burch Award from the Humane Society of the United States, and the American Veterinary Medical Association's Charles River Prize for outstanding contributions to laboratory animal medicine.

Willie Vann, Ph.D.

Center for Biologics Evaluation and Research, U.S. FDA.

Dr. Vann received his B.S. degree in biology in 1968 from Morehouse College, Atlanta, Georgia and his Ph.D. in biochemistry from Perdue University, West Lafayette, Indiana in 1973. Dr. Vann is currently Chief of the Laboratory of Bacterial Polysaccharides (LBP) – Division of Bacterial, Parasitic, and Allergenic Products, Office of Vaccine Research and Review, Center for Biologics Evaluation and Research (CBER), U.S. Food and Drug Administration (FDA). Dr. Vann's research interests are in the glycobiology of bacterial pathogens. His laboratory is currently using polysialic acid capsule synthesis as a model to study how pathogenic bacteria assemble capsular polysaccharides. Dr. Vann is also using polysialic acids and the receptor-binding domain of tetanus toxin as a model to study the design of well-characterized polysaccharide–protein conjugate vaccines.

Prior to becoming Chief of the LBP in 2006, Dr. Vann was Chief of the Laboratory of Bacterial Toxins, CBER, from 1996 to 2005; a Supervisory Research Chemist in the LBP, CBER, from 1993 to 1996; and a Research Chemist in the LBP, CBE, from 1979 to 1993. Dr. Vann also did postdoctoral research in bacterial polysaccharides and polysaccharide chemistry from 1973 to 1979 at the National Institute of Child Health and Human Development, Bethesda, Maryland, and the Max Planck Institute for Immunobiology, Freiburg, Germany.

Daniela Verthelyi, M.D., Ph.D.

Center for Drug Evaluation and Research, U.S. FDA

Dr. Verthelyi obtained her M.D. from the University of Buenos Aires, Argentina in 1988 and her Ph.D. from the Virginia-Maryland Regional College of Veterinary Medicine Virginia Tech in 1996. Dr. Verthelyi is currently Chief of the Laboratory of Immunology, Division of Therapeutic Proteins in the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA). Dr. Verthelyi is currently involved in the review of investigational new drug applications (INDs) and biologics license applications (BLAs) targeting infectious agents, cancer, and autoimmune diseases. She serves as the office resource for infectious disease-related regulatory and scientific issues, as well as for products that have the potential for immunogenicity-associated adverse events. She is the Principal Investigator supervising a research program investigating critical biomarkers and downstream modulators of Toll-like receptor-mediated immune activation *in vitro* and *in vivo.*

Dr. Verthelyi has authored or co-authored more than 50 scientific articles, holds 7 patents, has made numerous presentations at national and international meetings, is active in many professional societies, and is an *ad hoc* scientific reviewer for the *PNAS*, *Journal of Immunology*, *Cellular Immunology*, *Journal of Leukocyte Biology*, *Life Sciences*, *Journal of Endotoxin Research*, *Endocrinology*, *Virology*, and *Clinica Chemica Acta*.

Ralph Woodland, Ph.D.

Ph.D., Veterinary Medicines Directorate, United Kingdom

Dr. Woodland received his undergraduate degree in biological sciences in 1970 and his Ph.D. in microbiology in 1979 from the University of Birmingham, United Kingdom. Dr. Woodland is currently the Head of Biologicals Assessment Team at the Veterinary Medicines Directorate (VMD), New Haw, Addlestone, Surrey, U.K. The team is responsible for the assessment of quality, safety, and efficacy data presented in support of applications for Marketing Authorisations for new vaccines and for variations to existing Marketing Authorisations. Dr. Woodland was recognized by the European Medicines Agency (EMEA) as a National Expert for advice to the Committee for Veterinary Medicinal Products (CVMP) and is a member of the Immunologicals Working Party of the CVMP since 2004.

Prior to his current position with the VMD, Dr. Woodland served as a Research Assistant from 1974 to 1979 and a Lecturer from 1979 to 1990 at the Section of Virology, Institute of Ophthalmology in London. His research was directed into causes, methods of treatment, and prevention of ocular and genital infections; development of animal models to study the pathogenesis and treatment of chlamydial and viral infections; development of new and improved methods for laboratory diagnosis of ocular and genital viral and chlamydial infections; epidemiology of ocular and genital infections; and clinical trials of new treatments for ocular infections. Dr. Woodland also served as Supervisor of the animal facility and Deputy manager of the diagnostic laboratory.

From 1990 to 1997, Dr. Woodland was a Lecturer at the Royal Veterinary College, Potters Bar, Hertfordshire, U.K., with research interests in the pathogenesis and prevention of infectious abortion in small ruminants, including the development of a vaccine for ovine enzootic abortion.
Dr. Woodland also served as Study Director for vaccine clinical trials carried out to Good Laboratory Practices (GLP) standards and was a course organizer for a M.Sc. degree in Animal Health.

Dr. Woodland has authored over 30 papers and articles published in scientific journals and books and is a member of the following societies: The Society for General Microbiology, The British Society for Immunology, The Association of Veterinary Teachers and Research Workers, and The Veterinary Research Club.