

Accelerating Global Deletion of the Abnormal Toxicity Test. *Planning common next steps.*

A workshop organized by
Animal Free Safety Assessment Collaboration (AFSA),
Humane Society International (HSI),
the European Federation of Pharmaceutical Industry and Associations
(EFPIA),
in collaboration with the International Alliance for Biologicals
Standardisation (IABS).
October 14th, 2021
12:30 – 16:45 CEST



**HUMANE SOCIETY
INTERNATIONAL**



Keynote Speakers

Thierry Gastineau

Global Quality Head of Innovation, Culture and Engagement at Sanofi Pasteur, France



Thierry has 34 years of experience in the pharmaceutical industry and has been with SANOFI PASTEUR (Vaccines) for 19 years. He has been the first IFPMA representative at IPAC (Immunization Practices Advisory Committee) at WHO (2010 – 2012). Until he joined Sanofi Pasteur Global Quality department in April 2019, most of his career has been with World Wide Regulatory Affairs activities (where his last position was Global Head of Regulatory CMC for 5 years). He is a member of multiple associations and working groups: Vaccines Europe; Co-leader of CMC/Quality Core Team, ICH Q12 Task Force leader, IFPMA: Leader of Vaccines Head of Quality group, Vaccines Europe / IFPMA: Leader of the CMC/GMDP Covid-19 Task Force, Member of the US PDA (Parenteral Drug Association), Member of the One-Voice-of-Quality group.

By education, he is Pharmacist (Lyon – France) and he holds a post graduate in molecular biology (Grenoble – France).

Catherine Milne

Head of section for Biological Standardisation, International Standards for Antibiotics (ISA) and Official Control Authority Batch Release (OCABR), France



Catherine received her doctoral degree from the University of Toronto, Department of Molecular and Medical Genetics and was a post-doctoral fellow at the Medical Research Council, Laboratory of Molecular Biology in Cambridge, England in the field of molecular genetics and developmental biology. She joined the Council of Europe, European Directorate for the Quality of Medicines & HealthCare (EDQM) in 1999. In her current role as EDQM Biological Standardisation Programme (BSP) administrator, she coordinated a number of projects for the standardisation of methods and reference materials for the evaluation of human and veterinary vaccines and medicinal products derived from human blood and plasma with a focus on the 3Rs. She represents EDQM as an observer at the EMA BWP, CAT and the J3Rs working party and is on the IABS VBC.

Roundtable: Global perspectives on ATT deletion

Chair: Shahjahan Shaid

Program Manager and Head of 3R, GSK, Germany



Shahjahan has a PhD in Biology with a focus on immunology and host pathogen interaction. Before he joined GSK Vaccines, he worked on diagnostics of zoonoses at the German Federal Health Robert Koch Institute. In his current role in global quality, he is leading the company strategy to reduce animal by substituting them with state-of-the-art technologies.

Mark van Ooij

*Scientific Director, Drug Substance Development
Vaccines and Process Development Department,
Janssen Vaccine Technology, The Netherlands*



Mark obtained his PhD in Molecular Virology from the University of Nijmegen and he started as independent Scientist @ Crucell in 2005 in the Molecular Virology Department. In 2008 he founded the Molecular & BioAssay (MBA) group at the Analytical Development Department; focus on molecular biological and cell based potency content, identity and purity test including assay automation. He initiated in 2013 the Virus Safety group as part of the MBA group focussing on product and process virus safety evaluations from raw materials to end product including development of analytical strategies for detection of contamination viruses.

He was responsible for in vivo testing for adventitious safety testing and potency testing for viral vectored vaccines and worked to expand the Virus Safety Group tasks to include Microbial Safety evaluation as of 2014. He was US Pharmacopeia Viral Vaccine expert panel member 2016-2020, and now is a US Pharmacopeia Expert committee member. In 2018 he became Head of Platform Innovation and Implementation to prepare strategic topics for discussion with Health Agencies Scientific Advice meetings.



Leena Madhuri

Quality Control Lead, Indian Immunologicals, India

Leena has 16 years of experience in quality control, the last 10 in Indian Immunologicals. She is responsible for compliance of QC testing and release of vaccines and recombinant therapeutic proteins. She is leading QC functions with thorough knowledge on cGMP, cGLP, Compliance and regulations. She has experience in QC analytical methods with respect to Bacterial vaccines (*In-vitro*; *In-vivo*), Viral vaccines (*In-vitro*; *In-vivo*), Stability studies, Analytical Method validations, and Quality Management Systems and Computer System Validations.



Dianliang Lei

Technical Specifications and Standards unit of Health Product Policy and Standards; Switzerland

Dianliang obtained a PhD in medical science at the Medical School of Osaka University Japan in 1996. He joined the World Health Organization in 2003 as a scientist working in Technical Specifications and Standards unit of Health Product Policy and Standards department, responsible for development of WHO international standards including measurement standards and written standards for vaccines and biological products. He has been in charge of development of WHO Guidelines for lot release of vaccines, GMP for biological products, Guidelines for post-approval changes to vaccines, Recommendations for acellular pertussis vaccines, DT-based combined vaccines, Hepatitis E vaccines, Enterovirus vaccines, yellow fever vaccines and Manual for establishment of national standards. Dr Lei, before joining WHO, was deputy director of National Institute for the Control of Pharmaceutical and Biological Products responsible for regulation, quality control and biological standardization of vaccines in China. He contributed to the strengthen the regulation system for vaccines in China, especially on the national requirements (pharmacopeia), standards, specification for vaccines and lot release system.

Dean Smith

Associate Director in the Center for Biologics Evaluation (CBE) at Health Canada



Dean has over 20-years experience in regulatory science in support of innovation in vaccine development, manufacturing and quality control. He has a wide range of biologics-based scientific and regulatory experience from his Senior Scientific Evaluator and management roles in CBE Divisions, including Bacterial and Viral Vaccines, as well Hemostatic Agents and Blood Substitutes. Representing Health Canada, he contributes to WHO's vaccine and vaccine stability guidance development initiatives. He is Health Canada's representative to the European Directorate of Quality of Medicines (EDQM), Group 15 (Vaccines), with the European Pharmacopeia, and serves on the Science and Ethics Advisory Committee for IMI project VAC2VAC under the European Vaccines Initiative. He obtained his Ph.D. in Immunology from the University of Alberta, Alberta, Canada, where his research dealt with vaccine antigen discovery, autoimmunity and viral vector-based gene therapy.

Robin Levis

Deputy Director, Division of Viral Products OVR/CBER/FDA, USA



Robin has worked at the US Food and Drug Administration since 1995. She is currently the Deputy Director of the Division of Viral Products in the Office of Vaccines Research and Review at CBER/FDA; a position she has held since 2006. Prior to this position, she served as the Regulatory Coordinator for the Division of Viral Products (2002-2006) and served as a Senior Staff Fellow in the Laboratory of Vector Borne Viral Diseases (1995-2002). Her initial research work at the FDA related to flavivirus replication and the role of the NS1 protein. She then transitioned to be the lead CMC reviewer for licensed rabies virus vaccine products and rabies vaccine and related products under development. Her work with rabies virus vaccines was related to the development of an alternative, in vitro potency assay as an alternative to the NIH potency test. In addition to her work in the Office of Vaccines at CBER, she serves as the CBER representative to ICCVAM, and as an observer to EDQM Group 15 for vaccines that develop vaccine specific quality monographs for the European

Pharmacopeia, is on the Scientific and Ethics Advisory Committee for the Innovative Medicines Initiative (IMI) funded VAC2VAC consortium, and serves on several vaccine working groups for the Coalition for Pandemic Preparedness Innovations. Her role on these International working groups is to provide regulatory support to CMC development and product quality. Prior to coming to the FDA, Robin received her PhD from Washington University in St. Louis, Missouri. She conducted two post-doctoral fellowships. One at the NIH working on polyoma- and papillomavirus replication and the second at The Uniformed Services University of Health Sciences on species specificity of viral replication of human coronaviruses.



Philippe-Alexandre Gilbert

Senior Program Officer CMC, Bill & Melinda Gates Foundation, USA

Philippe-Alexandre is a Biochemistry graduate of the University of Ottawa. He subsequently received his Master's degree in Molecular Biology and his Ph.D. in Chemical Engineering at Laval University. For more than 20 years, Philippe has built a solid expertise in bioprocess development for the production of vaccines, gene therapy vectors and oncolytic viruses for cancer therapy. He had the privilege of working for both Academia (Robarts-Schulich in Canada and the Emerging Pathogen Institute at the University of Florida) and the private sector with Sanofi-Pasteur, MedImmune Vaccines, Novartis Vaccines and GSK Vaccines. In both North America and Europe, Philippe led task forces on the development of vaccines for HIV, RSV, CMV, SARS, Influenza and COVID. Philippe, just recently, was responsible for the Flu Technology Group at Sanofi Pasteur for the development of the Next Generation Flu vaccine. He joined the Vaccine Development and Surveillance (VDS) group at the Bill and Melinda Gates Foundation as Senior Program Officer CMC.

Session: Many countries many approaches, how far are we for a global alignment

Chair: Joris Vandeputte

President of IABS (International Alliance for Biological Standardization), Belgium



Joris has 45 years science, industry and international organisation's experience. With global experience in the complete value chain of vaccines, his main activities are in one health, global access to vaccines and the impact of innovation on vaccine strategies at European and global level. Platform technologies and replacing animal testing for batch release of vaccines are main topics actually. Joris got his Doctors degree in Veterinary Medicine in 1976 at Gent University, Faculty of Veterinary Medicine, Belgium. As a virologist at this University (1976-1980), Joris discovered H1N1 flu as a pathogen for swine, leading to a better understanding of the role of swine and avian in H1N1 as a zoonosis. Subsequently, at the Belgian Ministry of Agriculture, he worked on animal disease control in Belgium and the European Union before joining Institut Mérieux, Rhône Mérieux, which became Merial. He occupied leading positions in global vaccine development, strategy, regulatory affairs, marketing and production, in the fields of animal vaccines and flu vaccines (both human and animal). At GAVI, 2001 to 2005, he was vice president advocacy and resource mobilisation in the EU resulting major and sustained financial contributions to GAVI. Since 2005, support and consulting on global vaccine projects has become his main activity (TVBI, ZAPI, VAC2VAC, DRIVE, MANCO). Joris is co-founder of Magnetrap a company specialised in the development of game changing point of care detection methods for infectious diseases, including malaria and poverty related diseases. In 2005, he founded Trivarop, consulting company in the field of vaccines, biotechnology, zoonoses and neglected diseases.



Takuo Mizukami

Laboratory Director, National Institute of Infectious Diseases (NIID), Japan

Takuo is Laboratory Director in the Department of Safety Research on Blood and Biologicals of NIID and he is Lecturer at The University of Tokyo, Dept of Veterinary Medicine since 2011. He obtained his Post-doctoral research fellowship, at the Weatherall Institute of Molecular Medicine, John Radcliffe Hospital, the University of Oxford from 2009 to 2011, while he was principal investigator at NIID. He holds his current role at NIID and since 2014 he is part-time lecturer at the University of Tokyo, Dept of Veterinary Medicine. He has received various awards in the field of vaccinology, toxicology and veterinary sciences. He is a member of many Japanese professional organizations and reviewer and editorial board member of many peer reviewed journals.



Yoshihisa Shirasaki

Manager, CMC RA department, Regulatory affairs, GlaxoSmithKline K.K., Japan

Yoshihisa works in his current role since 2019, and he is a member of EFPIA Japan vaccine division and Japan vaccine industry consortium (EFPIA Japan/PhRMA/ Japan Pharmaceutical Manufacturers Association (JPMA)/ Japanese Association of Vaccine Industries (JAVI). He graduated from Kanazawa Univ. School of Pharmaceutical Sciences in 1999 and worked as research scientist from 1999 to 2008 in Senju Pharmaceutical Co. Ltd., from 2008 to 2013 in Taisho Pharmaceutical Co. Ltd., and he worked in the CMC Regulatory affairs, Japan Vaccine Co. Ltd. (Joint venture between GSK K.K. and DaiichiSankyo) from 2013 to 2019.



Jack Xie

Head of Nonclinical Safety (NCS) China at Janssen China

Jack is responsible for overall NCS operations and oversees multiple functions including Toxicology, Pathology, DMPK, Clinical Bioanalysis, and Occupational Safety. He is a member of Senior Leadership Team of Janssen China R&D and Scientific Affairs and a member of global NCS Leadership Team. Before joining Janssen in 2019, he was the Site Head

of Pharmaceutical Sciences in Roche Innovation Center Shanghai. He was a member of Roche China R&D Leadership Team and a member of Roche Global Translational Safety Committee. He is a certified toxicologist by the American Board of Toxicology (DABT) and a council member of Chinese Society of Toxicology (CSOT). He is currently the Chair of Nonclinical Expert Working Group of RDPAC (R&D-based Pharmaceutical Association Committee) in China. Jack obtained his PhD in Pharmacology and Toxicology from University of Rhode Island.

Xiantang Li*

Senior Director, DSRD Asia Lead Pfizer, USA



Xiantang is a toxicology pathologist. He received his bachelor's degree in veterinary medicine (BVM) from China Agricultural University and veterinary pathology training (DACVP) from Cornell University. Xiantang joined Pfizer Drug Safety Research and Development (DSRD) as a toxicology pathologist. He has provided toxicology pathology assessment of numerous drug candidates of various therapeutic areas and drug modalities. He had also conducted several general toxicity studies as a study director and participated in the management of drug research programs of both small and large molecules on behalf of nonclinical drug safety. Currently, he is the DSRD Asia Lead, coordinating the implementation of DSRD drug safety R&D strategies and initiatives in Asia/China.

James Ooi

Pre-clinical safety representative in Novartis, China



James has more than 15 years of biopharmaceutical industry experience. He currently serves as the pre-clinical safety representative in Novartis, China. He received his Veterinary Medicine degree From National Taiwan University, and his PhD in Pharmacology from New York University. He completed his post-doctoral residency training in Comparative Pathology from NEPRC/HMS Harvard. Prior to joining Novartis, he was the principal scientist, providing leadership and support in the discovery and early safety evaluation in the research effort in Novo Nordisk China. Before that, he was with Vertex pharmaceuticals serving as pre-clinical safety functional area expert for various projects.



Ying-Ying Zhou

Senior Principal Scientist in the Safety Assessment & Laboratory Animal Research Department at Merck Research Laboratories, US

Ying-Ying's areas of interest include safety pharmacology, general toxicology, electrophysiology, and signal transduction. She has been working in big pharmaceutical companies for almost 20 years. In her early industry career, she established the GLP hERG laboratory with emerging ICH S7B guideline, and led the safety pharmacology groups to develop various regulatory-required as well as investigative CV and CNS assays to support from the pre-clinical candidate selection up to safety assessment for late drug development. She has also served as a nonclinical safety representative and overseen multiple compounds from Target ID, candidate selection, through preclinical and clinical development to post-marketing. More recently, she became the China liaison and has been heavily involved in developing China strategy, building the partnership with China functional groups and driving increased communication with China regulatory bodies. For external activities, Ying-Ying served in Safety Pharmacology Society Academic Outreach Committee and ILSI HESI CV Safety Pro-Arrhythmia Models Project Committee. She is a member of China RDPAC (R&D-based Pharmaceutical Association Committee) nonclinical working group too.



Yue Yang*

Research prof. of school of pharmaceutical science, Tsinghua University, China

Yue obtained her PhD degree from Shenyang Pharmaceutical University. She is the first Ph.D graduated in Pharmacy Administration in China. Her research interests are pharmacy administration law and policies. She is the head of Regulation Science Center of Tsinghua University. She was the Vice Dean of School of Business Administration, Shenyang Pharmaceutical University, in charge of education and research from 2009 to 2014. Dr. Yang is a Member of the Expert Committee on the Pharmacy Administration Law from 2013 to present. She leads a program about vaccine injury compensation to support the Articles in the Vaccine Law making. She has participated in important policy-making and policy-evaluation of the government agencies, including

NMPA(CFDA), as well as National Health Commission of P.R. China and Ministry of Industry and Information Technology, etc.

Alla Trapkova

Deputy General Director of the Federal State Budgetary Institution 'Scientific Centre for Expert Evaluation of Medicinal Products' of the Ministry of Health of the Russian Federation



Alla is an expert in the area of medicinal product regulation and quality control with over 20 years of experience at senior positions in Russian regulatory agencies, such as the Federal Service for Surveillance in Healthcare (Roszdravnadzor). In her present position, she is in charge of a variety of activities, including, but not limited to pre-marketing evaluation of medicinal products, elaboration of the Russian Pharmacopoeia, implementation of the quality assurance system, and development of international cooperation. Prior to working at top positions at the Russian expert and regulatory authorities, Alla worked as a GMP inspector. She has a PhD in pharmacology, her scientific research has focused mainly on immunopharmacology, which resulted in over 40 scientific papers in Russian and foreign scientific periodicals and other publications. Alla is a holder of an 'Excellence in Healthcare' award badge, a medal of the Order of Merit for Country of the II Degree, and a Presidential Certificate of Acknowledgement.

Viktor Aleksandrovich Dmitriev*

General Director of the Association of Russian Pharmaceutical Manufacturers (ARFP), Russia.



Viktor graduated from the Moscow "Sechenov" Medical University in 1988. He worked as a sanitary doctor at the Sanitary and Epidemiological Station of the Fourth Main Directorate under the USSR Ministry of Health. In 1991 at the "Sechenov" University, he was Assistant Rector in the department of international cooperation as assistant rector, and then Deputy Dean for work with foreign students. In 1996, he worked in the assessment of medicines for the Ministry of Health of the Russian Federation and RosZdravNadzor. Researcher, raising to position of Deputy Director General of the Federal State Institution of Science and Technology of the Ministry of Health of the Russian Federation and RosZdravNadzor.

In 2002, he was one of the founders of the Association of Russian Pharmaceutical Manufacturers (ARFP) and was the first executive director of ARFP. From 2004 to 2008, he headed the Interstate Commission for Standardization, Registration and Quality Control of Medicines, Medical Products and Medical Equipment of the CIS Member States. He was Elected General Director ARFP in 2007. Currently he is a member of the Board of the Russian Union of Industrialists and Entrepreneurs; the Subcommittee on the Circulation of Medicines of the Government Commission on Public Health, the Council of the Chamber of Commerce and Industry of the Russian Federation; the Coordination Council of the Presidium of the General Council of the United Russia Party on the innovative development of the medical and pharmaceutical industry. He is candidate of Medical Sciences and sits in the editorial boards of four journals, and has authored over 50 scientific papers.



Elena Sakanyan*

Scientific Director, Microgen, Russia

Before this latest assignment, Elena was the head of the Department of Pharmaceutical Chemistry and Vice-Rector for Research at the St. Petersburg State Chemical and Pharmaceutical Academy (SPbCPA); a member of the specialized commission of the Pharmacopoeial State Committee, the deputy Chairman of the Technical Committee of Medicines of the Federal Agency for Metrology of the Russian Federation. She was Director of the Center for Pharmacopoeia and International Cooperation of the Federal State Budgetary Institution "Scientific Centre for Expert Evaluation of Medicinal Products" of the Ministry of Health of Russia; the Deputy Chairman of the Council of the Ministry of Health of Russia for State Pharmacopoeia; the President of the EurAsian Pharmacopoeial Committee and a member of working group on the creation of the WHO Guidelines for Good Pharmacopoeial Practice (CPP). She has been the official representative of the Pharmacopoeia of the Russian Federation in the WHO Commission on Specifications for Medicines, as well as an observer from the Pharmacopoeia of the Russian Federation in the European Pharmacopoeia.



Jai Prakash

Senior Principal Scientific Officer, Indian Pharmacopoeia Committee, India

Jai has done B. Pharm. and M. Pharm. (Pharmacology) from Delhi Institute of Pharmaceutical Sciences and Research, and Doctorate from the Department of Pharmacology, All India Institute of Medical Sciences (AIIMS). At present, he is Senior Principal Scientific Officer and Officer-in-Charge, National Coordination Centre for Pharmacovigilance Programme of India at Indian Pharmacopoeia Commission (IPC), Ministry of Health & Family Welfare, Govt. of India, Ghaziabad. He also held the Charge of the Secretary-cum-Scientific Director, IPC. He has overall more than 20 years of experience in the areas of teaching, research, administration, pharmacovigilance, pharmacopoeia and formulary science. He has been temporary advisor /expert for WHO's Expert Committees, Geneva, Switzerland. He has been the member of National Expert Committee for Allergens, member of Institutional Human Ethics Committee, National Institute of Biologicals, Noida, Multidisciplinary Expert Committee of National Pharmaceutical Pricing Authority, New Delhi, Scientific Body of Pharmacopoeia Commission for Indian Medicine and Homeopathy etc. Also served as the member of Core group for Revision of National List of Essential Medicines, 2011, India and member of CDSCO Expert Committee on Draize Test.



Sunil Kumar Goel

Additional Director QC, Serum Institute of India

Sunil is a microbiologist by training and is related to the field of Human Vaccines for the last 33 Years. He is a Ph D in Microbiology. After having served Government of India at National Control Lab (CDL)/Central Research Institute, Kasauli for 27 years he got voluntary retired from Government service and joined in Quality Control Department of Serum Institute of India at Pune in 2015 and is working there as an Additional Director. He is a WHO Approved and certified trainer and had been the course director of WHO GTN Course on Lot Release of Vaccines in English Language. He had been closely associated with WHO as a Temporary Advisor in various activities related to vaccines and was also a member for WHO-NRA Assessment Team for Lot Release and Lab Access Functions. He was also

nominated as NODAL OFFICER for preparation of First WHO Regional working Reference Standard of Pertussis vaccine meant for South East Asia. He is a member of Institutional Animal Ethics committee, 3Rs Working Group of DCVMN, Member of Humane Society International and is actively involved in implementation of 3Rs. Sunil has 12 Publications in National and International Journals and 4 Patents to his credit.

Eniek Suwarni

NQCLDF (National Quality Control Laboratory Drug and Food) departement, Indonesia FDA



Eniek works for Indonesian FDA (Indonesian Food and Drug Authority). She is a veterinarian and a laboratory analyst. My responsibilities are performing toxicology testing, such as abnormal toxicity, specific vaccine toxicity, etc as well as animal laboratory breeding.

Amrullah Aninditio Subagio

Quality Control Division, Biofarma Indonesia



Amrullah is a veterinarian and a laboratory analyst. His responsibilities are performing viral vaccine quality testing, such as neurovirulence test, abnormal toxicity, test for extraneous agent, in vivo potency test and health monitoring for animal laboratory.

Kyung Jin Jung

Toxicologist, Korea Institute of Toxicology



Kyung is a trained in toxicology and pharmacology, She joins Korea Institute of Toxicology as a principal research scientist in the Department of toxicity evaluation since 2009. Her research is rooted within biochemistry, pharmacology, and toxicology. Her experiences about underlying molecular mechanisms of cancer and aging involved roles at exploration of molecular interaction for understanding a variety of drug targets. Her research focuses on immunotoxicology and immunoanalytical method development for detection of biopharmaceuticals and targeted biomarkers. The development of immunoanalytical methods, from new uses of large molecule biopharmaceuticals in non-clinical and

clinical phases, is central to recent studies. Additionally, she has considerable teaching experience and is the author of more than 50 published papers.

Collaborative session: defining next steps



Chair: Vaughn Kubiak
IABS-EU/Consultant, France

Vaughn has over 40 years of experience in global animal health, with a primary focus on development, licensure, and maintenance of global veterinary biologicals. He has helped develop and improve conventional and innovative immunological veterinary medicinal products for all major species during his career. Vaughn has worked for a number of global animal health companies, with positions in R&D, QA/QC, regulatory affairs, product management, and commercial operations. Prior to his retirement from full-time activities in 2019, Vaughn spent the last 17 years with Zoetis Inc., where he held management positions in Regulatory Affairs, Biologicals Process Development, and Biological Analytical Development. During his last role in Zoetis (2009 – 2019), he was responsible for the European, Middle East, and African Biological Regulatory Affairs team in Sandwich, England and then Zaventem, Belgium. Vaughn remains connected to the Animal Health Industry through limited consulting. He holds Bachelor of Science and Master of Science degrees in Microbiology from the Ohio State University and Emory University, respectively.

Closing remarks: Importance of regulatory alignment

Rajinder Suri

CEO, DCVMN International



Rajinder is responsible for leadership, governance, strategic orientation and operational excellence of DCVMN Secretariat. To meet un-precedented challenge posed by COVID-19, Rajinder worked shoulder to shoulder with industry associations like IFPMA and BIO along with COVAX partners. He is member of several advisory expert groups including COVAX Manufacturing & Supply Task Force Leadership Team, MI4A (Market Information for Access to Vaccines) Advisory Group to WHO on Malaria, Global TB Vaccines R&D Roadmap by EDCTP, Expert Group on Seasonal Influenza Vaccine and Market Design and Demand Intelligence pillar of the Partnerships for African Vaccine Manufacturing (PAVM). He brings with him over 43 years of experience and deep insights of the industry including Pharmaceuticals and Biological products as well as Organizational Development in India and International markets. He has invested over 24 years at the top management level including four years on the Board of Directors of the Indian subsidiary of Sanofi Pasteur and remaining in Pharma. He has been Member-Gavi-Policy & Planning Committee (PPC) as well as Vice-President, DCVMN Executive Committee (2014-16).

Philippe-Alexandre Gilbert

Senior Program Officer CMC, Bill & Melinda Gates Foundation, US



Philippe-Alexandre is a Biochemistry graduate of the University of Ottawa. He subsequently received his Master's degree in Molecular Biology and his Ph.D. in Chemical Engineering at Laval University. For more than 20 years, Philippe has built a solid expertise in bioprocess development for the production of vaccines, gene therapy vectors and oncolytic viruses for cancer therapy. He had the privilege of working for both Academia (Robarts-Schulich in Canada and the Emerging Pathogen Institute at the University of Florida) and the private sector with Sanofi-Pasteur, MedImmune Vaccines, Novartis Vaccines and GSK Vaccines. In both North America and Europe, Philippe led task forces on the development of vaccines for HIV, RSV, CMV, SARS, Influenza and COVID. Philippe,

just recently, was responsible for the Flu Technology Group at Sanofi Pasteur for the development of the Next Generation Flu vaccine. He joined the Vaccine Development and Surveillance (VDS) group at the Bill and Melinda Gates Foundation as Senior Program Officer CMC.

Organizing Group

Laura Viviani

*Director of Biologicals, 3Rs Senior Project manager
DCVMN, Switzerland*



Laura has been working in the field of 3Rs since 2011, first in Novartis International, then in Novartis Vaccines and Diagnostics, later GSK Biologicals. She is a consultant for Humane Society International, an animal protection global organization, since 2017 where she supported the dialogue on 3Rs with industry and regulatory and international organizations stakeholders. She joined DCVMN in 2019 where she works with developing countries vaccines manufacturers to implementing 3Rs.

Kirsty Reid

Director for Science Policy at EFPIA, Belgium



Kirsty is the Director for Science Policy at EFPIA – the European Federation of pharmaceutical industry and associations. She is team leader and Science Policy topic lead where her focus includes Innovation policy implementation with particular focus on science and research matters including licence to operate and supporting the health Public Private partnership – Innovative medicines initiative (IMI)-related work. She has over 16 years experience in EU public and regulatory affairs covering various EU legislation and policy areas, working specifically on animal experimentation; alternatives to animal testing, and environment, health and safety issues. She obtained her PhD in Biology in South Africa in 2003 and came to Belgium where she lives now.

Emmanuelle Coppens

*Quality Control of vaccines, 3Rs and animal welfare,
Sanofi Pasteur, France*



Veterinarian, 23 years of experience in the Pharmaceutical Industry. She graduated from French National Veterinary school with a specialty diploma in laboratory animal science and with a thesis in Molecular Virology. After a first experience in Pierre Fabre (human medicine company) research center Animal Resources department (Castres, France), she joined Sanofi Pasteur (Human vaccines and sera company) Quality Control (QC) department in the vicinity of Lyon, France. She was head of an *in vivo* laboratory unit dedicated to analytical testing

and animal derived reagents production and then moved to transversal activities. In parallel to being expert in neurovirulence and tumorigenicity (histopathology), she was in charge of analytical lifecycle management projects as well as compendial monitoring for *in vivo* analytical testing and AAALAC accreditation of animal facilities. Since 2019, she is a global analytical expert in 3Rs and Immunology with the mission to coordinate removal of *in vivo* analytical testing within Sanofi Pasteur company. Her fields of expertise are *in vivo* & *in vitro* bioassays, neurovirulence and safety *in vivo* testing, applicable to human vaccines and biologicals and has always been involved in promoting 3Rs.

Shahjahan Shaid

Program Manager and Head of 3R, GSK, Germany



Shahjahan has a PhD in Biology with a focus on immunology and host pathogen interaction. Before he joined GSK Vaccines, he worked on diagnostics of zoonoses at the German Federal Health Robert Koch Institute. In his current role in global Quality, he is leading the company strategy to reduce animal by substituting them with state-of-the-art technologies.

Jack Xie

Head of Nonclinical Safety (NCS) China at Janssen China



Jack is responsible for overall NCS operations and oversees multiple functions including Toxicology, Pathology, DMPK, Clinical Bioanalysis, and Occupational Safety. He is a member of Senior Leadership Team of Janssen China R&D and Scientific Affairs and a member of global NCS Leadership Team. Before joining Janssen in 2019, he was the Site Head of Pharmaceutical Sciences in Roche Innovation Center Shanghai. He was a member of Roche China R&D Leadership Team and a member of Roche Global Translational Safety Committee. He is a certified toxicologist by the American Board of Toxicology (DABT) and a council member of Chinese Society of Toxicology (CSOT). He is currently the Chair of Nonclinical Expert Working Group of RDPAC (R&D-based Pharmaceutical Association Committee) in China. Jack obtained his PhD in Pharmacology and Toxicology from University of Rhode Island.



David Wright

Nonclinical Toxicologist, Pfizer, US

He is a nonclinical toxicologist with over 20 years of industry experience. He has expertise in developmental and reproductive toxicology, general toxicology, and safety pharmacology. In his current role at Pfizer, he is a project team representative and nonclinical regulatory strategy lead for projects in oncology and rare diseases as well as a nonclinical lead for numerous products in Pfizer's Established Health portfolio across many therapeutic areas. David is a strong proponent of the 3Rs and is grateful to be part of the effort to accelerate global deletion of the ATT.



Zhechu Peng

Project Toxicologist, Boehringer Ingelheim, US

Zhechu received her PhD in Molecular Pharmacology and Toxicology from University of Southern California, in Los Angeles, United States. Currently, she is a project toxicologist at Boehringer Ingelheim in Ridgefield, United States. At her current role Zhechu practices regulatory toxicology and is responsible for the toxicology programs of various novel therapies. Prior to her position at Boehringer Ingelheim, Zhechu had experience in working with laboratory animals through employed as Study Director for general toxicology studies at Labcorp. Zhechu devotes her spare time on volunteering for American College of Toxicology.



Helle Northeved

*Senior Vice President for Nonclinical Safety Research
Lundbeck, Copenhagen, Denmark*

Helle educational credentials include a DVM and a PhD in Toxicological Pathology from the University of Copenhagen. Helle has extensive experience in pharmaceutical industry of more than 30 years in preclinical development. Her professional background crosses a broad spectrum of activities, having worked in the areas of toxicology and preclinical development. Helle has been involved in the development and regulatory activities for pharmaceuticals targeting brain diseases including depression, schizophrenia, Parkinson's and Alzheimer's disease. Helle is currently responsible for the nonclinical safety evaluation of new innovative drugs for the treatment of diseases of the brain. Her area of

responsibility covers regulated and non-regulated studies and generation of regulatory documentation to support clinical trials and marketing applications worldwide within toxicology, pharmacokinetics and drug metabolism. Helle responsibilities also extend facilities for experimental animals. Helle teaches at regular intervals at the University of Copenhagen within the areas of Drug Development, Toxicology and Safety Assessment.

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