SCIENTIFIC Conference

e-Book

AFSA COLLABORATION

Humane World for Animals

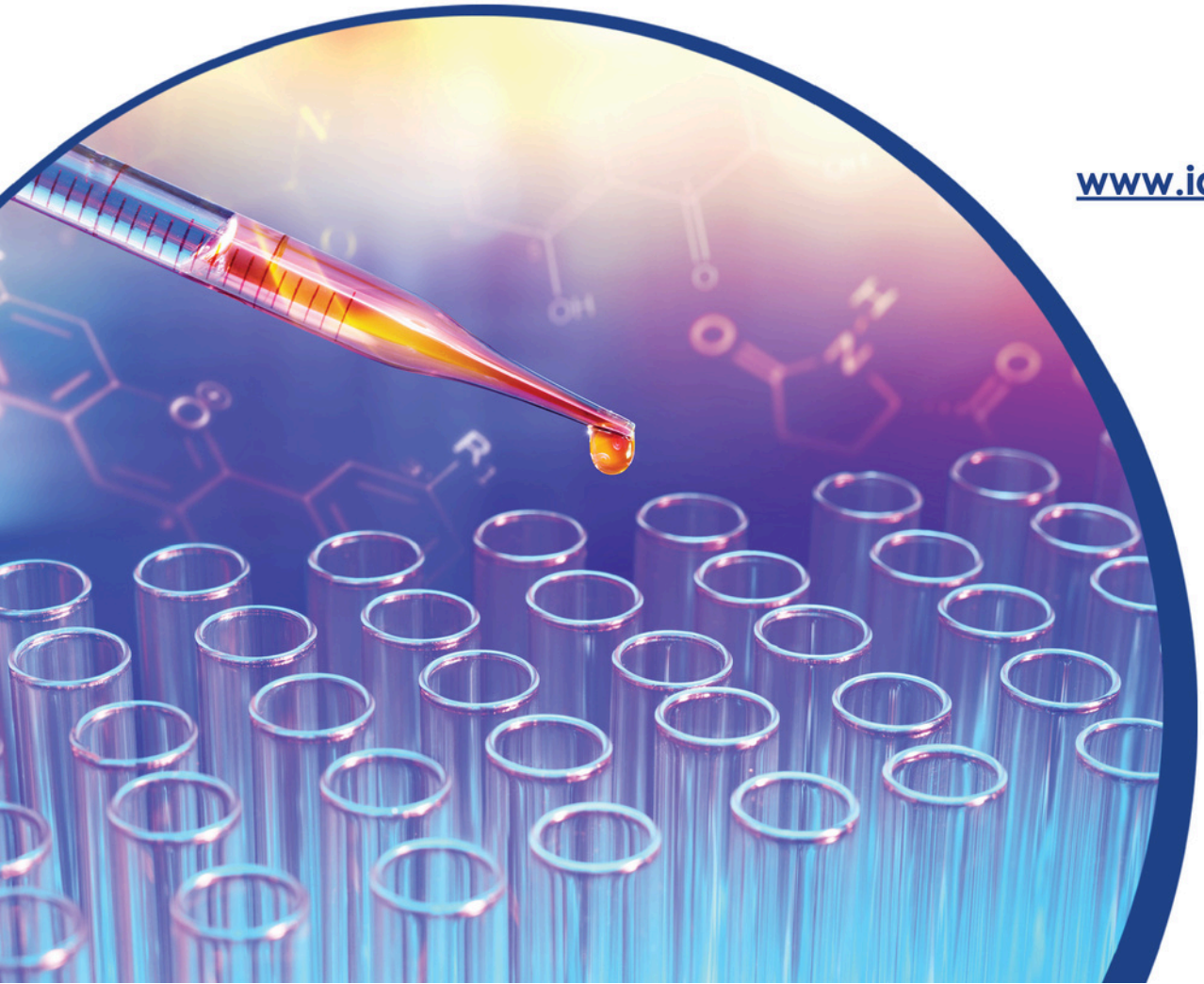
IABS

International Alliance for Biological Standardization

Animal testing replacement for vaccines. A One Health View: global outlook and future strategy

December 2-4 2025

BANGKOK, THAILAND



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Sponsors

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Humane World for Animals™

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About the Conference

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Humane World for Animals and the International Alliance for Biological Standardization have been collaborating together since the 2019 IABS conference “Animal Testing for Vaccines Implementing Replacement, Reduction and Refinement: Challenges and Priorities” (Akkermans et al.) and through the AFSA Collaboration since 2020. They successfully organized online and face to face meetings (AFSA Collaborations Events) to promote dialogue and joint actions on animal testing replacement for both human and veterinary vaccines. This conference brings together again all the stakeholders in the field with the scope to concretely discuss about future projects and policy changes that need to be implemented to successfully phase out the reliance on animal testing within the vaccines testing control strategy, including the importance of vaccines’ supply chain sustainability and continuity and the benefits of this in supporting the role of vaccines in One Health (ensuring animal health and food chain security, addressing zoonosis and emergency disease situations as well as the critical role of vaccines in reducing antimicrobial resistance (AMR)).

Scientific and Organizing Committees

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Scientific Committee

Elisabeth Balks - PEI
Emmanuelle Coppens - Sanofi
Pradip Das - Biological E
Debora Ferarrin - Butantan Foundation
Juliana Gutierrez - bioMerieux
Sunil Goel - Serum Institute of India
Carmen Jungbäck - IABS
Robin Levis - US FDA
Laurent Mallet - EDQM
Alexandrine Maes - WHO - NNB
Kutub Mahmood - PATH
Laure Martinez, Virbac - HealthforAnimals
Shawn Novick - IABS
Hendrik Jan Ormel - Chair of the Dutch Central Committee on Animal Testing
Ray Prasad - Bill & Melinda Gates Foundation
Shahjahan Shaid - GSK
Gautam Sanyal - Vaccine Analytics
Heidemarie Schindl - AGES
Dean Smith - IABS
Paul Stickings - MHRA
Catrina Stirling - Zoetis, HealthforAnimals
Joris Vandeputte - IABS
Geneviève Waeterloos - Sciensano
Wipawee Wongchana - Institute of Biologicals Products
Irma Riyanti - Bio Farma
Jack Xie - J&J

Organizing Committee

Laura Viviani - SciEthiQ for Humane Society International
Madinina Cox - IABS Secretariat Director
Marlène Martins - IABS Secretariat

Scientific Program

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8:30 AM

Opening remarks

- Joris VANDEPUTTE, IABS, Belgium
- Sarawut BOONSUK, Director General, Department of Medical Sciences, Ministry of Public Health, Thailand
- Phichet BANYATI, Director, Department of Medical Sciences, Ministry of Public Health, Thailand
- Laura VIVIANI, SciEthiQ for Humane World for Animals and AFSA, Italy

9:00 AM

Opening Lecture: Importance of investments in Asia and Thailand for vaccine R&D, state of the art quality testing and regulatory harmonization. Ongoing initiatives and opportunities to consider.

- Nakorn PREMSRI, National Vaccine Institute of Thailand, Thailand

SESSION 1

OneHealth approach to advance vaccine control strategies

Moderator: Catherine Milne, EDQM, France

The session aims to present and discuss how the OneHealth vision could place a further emphasis in the transformation of vaccines' control strategies. The focus on the final batch release testing is switching toward the control of the product's life cycle based on the knowledge of the critical quality attributes and transitioning away from non-validated animal-based testing.

9:30 AM

Presentation

- Catrina STIRLING, Zoetis (remote), UK

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9:50 AM

Panel Discussion

- Pradip DAS, Biological E, India
- Lorenzo TESOLIN, Sciensano, Belgium
- Corinne PHILIPPE, Boehringer Ingelheim, France
- Dean SMITH, IABS, Canada

10:30 AM

Coffee-break

SESSION 2

Industry perspective on phasing in non-animal testing and efforts to promote global alignment

Moderator: Laura Viviani, SciEthiQ, Italy

Speakers from both human and veterinary vaccines manufacturers present their ongoing efforts to promote regulatory acceptance and alignment of non-animal testing strategies for the release of their products, with an emphasis on how coordinated efforts and updated guidelines might benefit the overall products' value chain and public health.

10:45 AM

Animal Testing Replacement: Global Human Vaccine Manufacturer Perspectives

- Emmanuelle COPPENS, Sanofi, France

Implementation of non-animal testing and efforts to promote global alignment - An Industry Perspective

- Sunil GOEL, Serum Institute of India, India

Implementing non-animal testing

- Corinne PHILIPPE, Boehringer Ingelheim/HealthforAnimals, France

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11:30 AM

Panel discussion

- Emmanuelle COPPENS, Sanofi, France
- Sunil GOEL, Serum Institute of India, India
- Corinne PHILIPPE, Boehringer Ingelheim/HealthforAnimals, France

SESSION 3

Regulatory perspective - Ongoing progress in methods acceptance

Moderator: Henk-Jan Ormel, Dutch Competent Authority for Animal Procedures, The Netherlands

Panelists representing National Regulatory Agencies, Pharmacopoeias and international organizations share their current work on accepting non animal testing for the release of human and veterinary vaccines and discuss about their future plans and outstanding issues.

11:45 AM

Brief Introduction of WHO Guidelines on the replacement or removal of animal tests for the quality control of biological products
Dianlang LEI, WHO, Switzerland

EDQM's support for the 3Rs – status update and insights into Ph. Eur. General Chapter 5.2.14
Mihaela BUDA, EDQM, France

VICH concept paper on principles for technical guidance for the transition to in-vitro methods for batch potency tests in veterinary immunologicals
Kota SATO, National Veterinary Assay Laboratory, Japan

Indian Pharmacopoeia perspectives on alternatives to animal methods in testing of vaccines for human and animal use
Muthusamy KALAIVANI, Indian Pharmacopeia Commission, India

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Implementation of 3Rs to quality control of biologicals and lot release tests in Japan
Masaaki IWAKI, JIHS, Japan

ANVISA's regulatory perspectives on progress in alternative method acceptance
Evelin BALBINO, ANVISA, Brazil

Korea's Strategy for NAMs Adoption: Harmonizing Regulatory Science and Innovation
In-Sook PARK, Korea Regulatory Science Centre, South Korea

Advancing Vaccine Quality Control through Non-Animal Testing at National Control Laboratory, Badan POM
Fitra DELVIONA, BADAN POM, Indonesia

1:15 PM **Lunch Break**

WORKSHOP

How to build competence in new testing strategies in National Control Laboratories?

Moderator: Dean Smith, IABS, Canada, & Janette Turner, Humane World for Animals, UK

The workshop allows the audience to discuss in groups about the possible approaches to build competence and confidence in non-animal testing strategies after key stakeholders from international organizations and manufacturers share their experience.

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2:30 PM

How to build competence in new testing strategies in National Control Laboratories? - A WHO perspective
Alexandrine MAES (remotely) & Alain FAUCONNIER, WHO, Switzerland

Building competence in new testing strategies in National Control Laboratories
Sunil GOEL, Serum Institute of India, India

EU OMCL network experience contributes to method implementation and reduced animal use
Catherine MILNE, EDQM, France

How to Build NCL Competences? A Case Study from the Belgian National Control Laboratory
Lorenzo TESOLIN, Sciensano, Belgium

Building Competence in Non-Animal Testing Strategies for Vaccine Quality Control
Luca PORFIRI, FAO, Thailand

3:00 PM

Discussion groups (40') and reporting (20')

- Difficulties in implementation of new technologies (for NCL: expectations from companies)
- Successful cases of implementations
- Which mechanisms have been used or can be used to support competence's building, like the use of reliance for example? What are the barriers to use reliance (or similar mechanism)?

4:00 PM

Coffee-Break

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SESSION 4

A new pyrogenicity strategy

How MAT and recombinant BET are changing the approach to pyrogenicity

Moderator: Juliana Gutierrez, bioMérieux, Japan

Speakers present how the use of the Monocyte Activation Test and the recombinant Bacterial Endotoxin Test are changing pyrogenicity testing, providing examples of their implementation and regulatory acceptance.

4:15 PM

An EDQM update on pyrogenicity in European Pharmacopoeia
Mihaela BUDA, EDQM, France

Bacterial Endotoxin Testing: Progressive Science and Sustainability
Jay BOLDEN, Eli Lilly & Company, USA

Transition from LAL test for endotoxin to rFC methods
Corinne PHILIPPE, Boehringer Ingelheim/HealthforAnimals, France

Navigating the Transition: Regulatory and Practical Perspectives on Implementing the Monocyte Activation Test
Bernhard ILLES, Microcoat, Germany

Advancing 3Rs in Quality Control of Immunobiologicals: Butantan's Strategy for Implementing MAT and Recombinant Endotoxin Testing
Juliana GALVÃO DA SILVA, Fundação Butantan, Brazil

How Industry is Implementing in vitro Alternatives for Pyrogenicity testing
Emmanuelle COPPENS, Sanofi, France

Waive and Replace the Rabbit Pyrogen Test in Lifecycle Vaccine Release
Shahjahan SHAID, GSK (remote), Germany

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Panel Discussion

- Mihaela BUDA, EDQM, France
- Jay BOLDEN, Eli Lilly & Company, USA
- Corinne PHILIPPE, Boehringer Ingelheim/HealthforAnimals, France
- Bernhard ILLES, Microcoat, Germany
- Juliana GALVÃO DA SILVA, Fundação Butantan, Brazil
- Emmanuelle COPPENS, Sanofi, France
- Shahjahan SHAID, GSK (remote), Germany

6:15 PM

Closing of Day 1

Laura VIVIANI, SciEthiQ & Joris VANDEPUTTE, IABS, Belgium

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PATH WORKSHOP
Sustainable endotoxin testing: Developing a roadmap for LMIC
Part 1 – Cost Modelling Session

Moderator: Joe Little PATH & Sampa PAL

This session focuses on identifying and discussing the cost drivers associated with transitioning from limulus amebocyte lysate (LAL) to recombinant Factor C (rFC) for endotoxin testing, specifically within the context of low and middle-income countries (LMICs).

7:30 AM — **Introduction**
Sampa PAL and Joe LITTLE, PATH, Scientific Program Officer

7:40 AM — **Implementation of rFC: cost considerations**
Juliana GUTIERREZ, BioMerieux, Japan

7:50 AM — **Recombinant methods for endotoxin testing in India - Cost and market analysis**
Surat PARVATAM, Humane World for Animals India,
& K. V. S. Narayana RAJU, Consultant for DLR, India

8:00 AM — **The Cost of Innovation: Comparative Analysis of LAL vs. rFC/rCR in Butantan's Flu Vaccine Production**
Juliana GALVAO DA SILVA & Debora FERRARIN, Fundação Butantan, Brazil

8:10 AM — Discussion in working groups and reporting

9:30 AM — **Coffee-break**

Scientific Program

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PRESENTATION

In vitro Analytical Characterization based Quality and Potency Assessment of mRNA Vaccines

Moderator: Paul Stickings, MHRA, UK

The speaker presents how robust in vitro assays (especially potency) have been developed for different classes of vaccines, especially protein and mRNA, and gained widespread regulatory approvals.

9:45 AM

In vitro Analytical Characterization based Quality and Potency Assessment of mRNA Vaccines

Gautam SANYAL, Vaccine Analytics, USA

SESSION 5

Safety Testing: from development to implementation and regulatory acceptance

Moderator: Sarah Sheridan, Merck, UK

Speakers present concrete examples on how the review of the traditional animal-based assays allowed deletion of obsolete or redundant testing and pushed forward the implementation and acceptance of in vitro approaches.

10:15 AM

Safety tests for vaccines; Strategies to remove and replace animal tests in the European Pharmacopoeia (Ph. Eur.)

Catherine MILNE, EDQM, France

Next Generation Sequencing (NGS)- An alternative to animal based neurovirulence testing (NVT) for polio vaccines

Kutub MAHMOOD, PATH, USA

Next generation sequencing as an alternative to neurovirulence tests in animals for the quality control of live-attenuated viral vaccines)

Javier MARTIN, MHRA, UK

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A cell-based assay for tetanus toxin as an alternative to animal models used in safety testing of tetanus toxoid
Paul STICKINGS, MHRA, UK & Ciara DORAN, Sheffield University

Waiving of TABST/LABST (and more) in veterinary vaccines
Laure MARTINEZ, Virbac, France

How industry is Phasing Out in vivo Safety Testing
Emmanuelle COPPENS, Sanofi, France

Path To Remove and Replace Safety Testing In India
Pradip DAS, Biological E, India

SESSION 6
Roles of global health stakeholders in funding, cost sharing for capital investment, training and shaping global agendas

Moderator: Joris Vandeputte, IABS, Belgium

Transitioning from in vivo to in vitro testing strategies is a major transformation requiring investment in innovation, training, and alignment of regulations. The panelists discuss the role that global health stakeholders might have to support the change.

12:15 PM

Panel Discussion

- Dianliang LEI, WHO, Switzerland
- Meenu BATOLAR, CEPI Singapore
- Ole OLESEN, Independent Expert, Belgium
- Naree KETUSING, WOAH, Thailand

1:00 PM

Lunch

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SESSION 7

Potency Testing: Achievements and next steps for implementa□on

Moderator: Heidemarie Schindl, AGES, Austria

Speakers present the successful transition from in vivo to in vitro potency testing in both new and legacy vaccines, highlighting how different approaches to method development and validation have been worked and what are the remining challenges to overcome.

2:00 PM

Potency Testing for Adjuvanted Vaccines: Progress, Roadblocks and a Vision for Non-Animal testing
Badiaa BOUZYA, GSK, Belgium (remote)

Potency testing of aluminium adjuvanted tick borne encephalitis virus vaccines
Dieter PULLIRSCH, AGES, Austria

Gyrolab-Based In Vitro Immunoassay for Potency and Quality Control of Chikungunya VLP Vaccine: A Sensitive Alternative to Animal Models
Katarzyna OSETEK-MÜLLER, Bavarian Nordic, Germany

Replacing the in vivo potency test for human rabies vaccines: a global collaborative initiative
Jean-Michel CHAPSAL, Consultant & Project Manager BSP149, France

From in vivo to in vitro Testing for DTaP (Diphtheria, Tetanus, acellular Pertussis) Potency Testing (
Emmanuelle COPPENS, Sanofi, France

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Application of VP2 & VP4 mAb-based Indirect ELISA for Potency and Stability Assessment of Indian Trivalent Vaccine Formulations
Rabindra PRASAD SINGH, ICAR-National Institute on Foot and Mouth Disease, India (remote)

The next challenge – a fully in vitro approach to ensure quality and consistency of whole-cell pertussis vaccines
Paul STICKINGS, MHRA, UK

3:20 PM

Panel Discussion

- Badiaa BOUZYA, GSK, Belgium (remote)
- Dieter PULLIRSCH, AGES, Austria
- Katarzyna OSETEK-MÜLLER, Bavarian Nordic, Germany
- Jean-Michel CHAPSAL, Consultant & Project Manager BSP149, France
- Emmanuelle COPPENS, Sanofi, France
- Rabindra PRASAD SINGH, ICAR-National Institute on Foot and Mouth Disease, India (remote)
- Paul STICKINGS, MHRA, UK

4:00 PM

Coffee-Break

SESSION 8

Availability of critical reagents and use of reference standards

Lesson learnt and open challenges

Moderator: Dean Smith, IABS, Canada

The development of new products and testing strategies based on different and product specific assays and tests might require a revision on the concept and use of reference standards. Panelists share their view on the current and future scenarios.

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4:15 PM

Introduction: Setting the scene on critical reagents
Kutub MAHMOOD, PATH, USA & Paul STICKINGS, MHRA, UK

4:30 PM

Panel Discussion on Critical Reagents

- Paul STICKINGS, MHRA, UK
- Javier MARTIN, MHRA, UK
- Kutub MAHMOOD, PATH, USA
- Dianliang LEI, WHO, Switzerland
- Mihaela BUDA, EDQM, France

4:45 PM

Introduction: Setting the scene on use of reference standards
Dean SMITH, IABS, Canada

4:55 PM

Panel Discussion on Use of Reference Standards

- Paul STICKINGS, MHRA, UK
- Javier MARTIN, MHRA, UK
- Kutub MAHMOOD, PATH, USA
- Dianliang LEI, WHO, Switzerland
- Mihaela BUDA, EDQM, France

5:45 PM

Closing of Day 2

- Laura VIVIANI, SciEthiQ, Italy & Joris VANDEPUTTE, IABS, Belgium

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PATH WORKSHOP
Sustainable endotoxin testing: Developing a roadmap for LMIC
Part 2 – Regulatory session

Moderators: Joe Little PATH & Sampa PAL

This session focuses on identifying and discussing the regulatory challenges associated with transitioning from limulus amebocyte lysate (LAL) to recombinant Factor C (rFC) for endotoxin testing, specifically within the context of low and middle-income countries (LMICs).

7:30 AM — **Introduction**
Sampa PAL, PATH, Scientific Program Officer

7:40 AM — **Presentation - Title to be confirmed**
Jay BOLDEN, Eli Lilly, USA

7:50 AM — **Bacterial Endotoxin Test-Indian Pharmacopeia perspectives**
Muthusamy KALAIVANI, Indian Pharmacopeia Commission, India

8:00 AM — Discussion in working groups and reporting

9:30 AM — **Coffee-break**

SESSION 9
How future proof regulations could support vaccines' release paradigm's change

Moderator: Corinne Philippe, Boehringer Ingelheim, France

Panelists present their experience and vision on how future proof regulations could be conducive to the change in vaccines' release testing, highlighting their approaches to global alignment and reliance, and discussion on the challenges to overcome.

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9:45 AM

Panel Discussion

- Dianliang LEI & Alain FAUCONNIER, WHO, Switzerland
- Laure MARTINEZ, Virbac, France
- Charles SANDY, AUDA-NEPAD, South Africa
- Meenu BATOLAR, CEPI, Singapore
- Dean SMITH, IABS, Canada

SESSION 10
Future outlook on vaccines development, manufacturing and release strategies. How NAMs are going to change the field

Moderator: Colleen Pike, Humane World for Animals, USA

10:45 AM

The Pre-clinical (and Clinical) Utilities of Microphysiological Systems as In Vitro NAMs in Drug and Vaccine Development

- Danilo TAGLE, NIH (remote), USA

EU initiatives to advance NAMs in research and regulatory testing

- Ole OLESEN, Independent Expert, Belgium

11:45 AM

Panel Discussion

- Danilo TAGLE, NIH (remote), USA
- Ole OLESEN, Independent Expert, Belgium
- Gautam SANYAL, Vaccine Analytics, USA
- Dean SMITH, IABS, Canada
- Lorenzo TESOLIN, Sciensano, Belgium

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12:15 PM

Closing remarks

- Joris VANDEPUTTE, IABS, Belgium
- Sarawut BOONSUK, Director General, Department of Medical Sciences, Ministry of Public Health, Thailand
- Phichet BANYATI, Director, Department of Medical Sciences, Ministry of Public Health, Thailand
- Laura VIVIANI, SciEthiQ for Humane World for Animals and AFSA, Italy

Upcoming IABS Events

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2nd IABS Real World Evidence Workshop : The Role of Alternative Approaches to Phase 3 Clinical Trials for Vaccine Efficacy and Licensure

Montreal, Canada
December 10-11, 2025

Advances in Analytical Technologies for Biopharmaceutical Products

Virtual Meeting
June 3-5, 2026

ON THE HORIZON

Preterm Birth as a Sentinel Outcome in Maternal Immunization with focus on fetal outcomes – Methods and Context

Eastern Europe
May/June, 2026

Bovine Serum: challenges and opportunities in the research and development and manufacture of vaccines and other biological products

Budapest, Hungary
September, 2026

Products

Rabies virus series

- Rabies Virus N Protein Quantitation Kit
- Rabies Virus (PV/AG strains) G Protein Quantitation Kit
- Rabies Virus (PM/CTN strains) G Protein Quantitation Kit
- Recombinant Rabies virus (CTN strain) Glycoprotein (6His Tag)
- Recombinant Rabies virus Glycoprotein (6His Tag)
- Mouse anti-Rabies (CTN/PV/AG strains) G-protein antibody detection kit (ELISA)
- Human Rabies virus (PV/AG/CTN strains) G-protein antibody detection kit (ELISA)
- Mouse anti-Rabies (PM/CVS11 strains) G-protein antibody detection kit (ELISA)
- Human Rabies virus (PM/CVS11) G-protein antibody detection kit (ELISA)

HPV series

- 9-valent Human Papillomavirus HPV in vitro Potency Assays(6\11\16\18\31\33\45\52\58)

Pneumonia series

- 14 serotypes Immunoturbidimetric Mouse anti-Pneumococcal polysaccharide mAbs
- 21 serotypes Mouse anti-Pneumococcal polysaccharide mAbs
- 14 serotypes Pneumococcal polysaccharide(19F) detection kit (ELISA)

Meningitis series

- Meningococcal polysaccharide (A\C\W135\Y) polysaccharide conjugate quantitation kit (ELISA)
- Total Meningococcal polysaccharide (A\C\W135\Y) polysaccharides quantitation kit (ELISA)
- Meningococcal polysaccharide(A\C\W135\Y) monoclonal antibody agarose gel
- Immunoturbidimetric Mouse anti-Meningococcalpolysaccharide(A\C\W135\Y) mAbs
- Mouse anti-Meningococcal Meningitis(B) mAbs
- Mouse anti-Meningococcalpolysaccharide(A C\W135\Y) mAbs

We are at the conference，please contact us to set a face to face meeting by email us at **wangcy@antibodychina.com**

Biosketch

Dr Evelin Elfriede Balbino

Pharmaceutical-Biochemistry
State University of Londrina/Brazil
Health regulation and surveillance
specialist/Anvisa/Brazil since 2005

Evelin Elfriede Balbino is a Health Regulation and Surveillance Specialist at the Brazilian Health Regulatory Agency (Anvisa), where she has served since 2005. She holds a degree in Pharmaceutical-Biochemistry from the Universidade Estadual de Londrina, Brazil and brings extensive expertise in public health, pharmaceutical research, and product quality control.

She has pursued advanced training through several specialized programs, including Purification of Plant Extracts at INRA/Université de Tours (Université François Rabelais), France, Health Surveillance at Fundação Oswaldo Cruz (FIOCRUZ), Brazil, and Pharmaceutical Technology at the Universidade Federal Fluminense, Brazil. Additionally, she completed an international program in Principles and Practice of Clinical Research at the Harvard T.H. Chan School of Public Health through Executive and Continuing Professional Education.

With a multidisciplinary background combining scientific expertise and regulatory experience, Ms. Balbino plays a key role in ensuring the safety, quality, and efficacy of health products in Brazil.

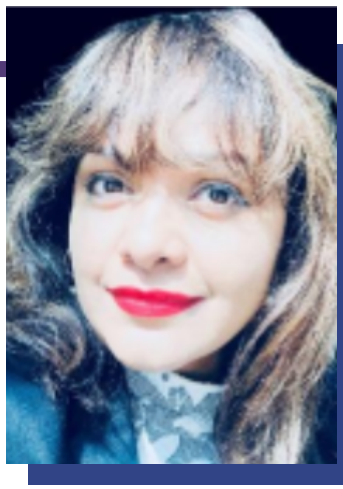
Abstract

Dr Evelin Elfriede Balbino

ANVISA's regulatory perspectives on progress in alternative method acceptance

The National Health Surveillance Agency (ANVISA) is the Brazilian regulatory agency that is responsible for regulating the quality control of vaccines. This presentation will provide an overview of the regulatory changes introduced by ANVISA and by the Brazilian Pharmacopoeia, which are working on the introduction of alternative methods to the use of animals. This implementation is aligned with the advances in alternative methods promoted by other regulatory agencies and organizations as World Health Organization (WHO), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and recognized Pharmacopoeias, and also aligned with the agenda of the National Council for the Control of Animal Experimentation (CONCEA). This presentation will also highlight the challenges that ANVISA, official laboratories and drug manufacturers needed to overcome to secure the introduction of those changes in the regulations and manufacture and how international collaboration has been key element to promote such changes. It is worth noting the complete deletion of the Abnormal Toxicity Test and the creation of a chapter dedicated to the Monocyte Activation Test to detect pyrogens in the 7th edition of the Brazilian Pharmacopoeia. Currently the revision of vaccine monographs is in progress and other changes are being considered, such as the introduction of the Recombinant Factor C (rFC) method for detection of bacterial endotoxins.

Biosketch



Meenu Batolar

CEPI

Meenu Batolar is a transformative leader in the pharmaceutical and vaccine development industry, currently serving as the Asia Pacific Lead for Global Regulatory Affairs at the Coalition for Epidemic Preparedness Innovations (CEPI). At CEPI, a global not-for-profit vaccine R&D funding organization, Meenu spearheads regulatory networks focused on epidemic and pandemic preparedness, driving forward-thinking dialogue and action for future outbreak readiness.

With a career spanning leading biopharmaceutical companies - including Takeda Vaccines, Sanofi Pasteur, Biogen Idec, Baxter, and UCB - Meenu has held pivotal roles across Regulatory Affairs, Pharmacovigilance, Compliance, Affiliate Leadership, and Government Affairs. Her expertise spans vaccines, neurology, renal, and hematology/oncology, reflecting a deep commitment to advancing public health through science and policy.

Among her landmark achievements:

- Led dengue vaccine registration in Vietnam & Thailand for individuals aged 4+ regardless of serostatus.
- Secured the first licensure of IPV in India, enabling combination vaccine pathways.
- Initiated the Flu Surveillance Network (FSN) with national institutes (NIV, Pune and ICMR, Delhi).

Biosketch

- Partnered with governments Hajj immunization programs with timely Meningitis and Influenza Vaccines.
- Expanded treatment algorithms from only injectables to Oral therapeutic options for Multiple Sclerosis.
- Played a key role in the development of India's first National Biosimilars Guidelines, receiving formal acknowledgment for contributions that helped shape regulatory best practices.

She has championed numerous regulatory innovations and best practices, building trusted relationships with health authorities, patient organizations, and industry platforms globally. Her leadership is defined by her Clifton Strengths - Adaptability, Positivity, Empathy, Connectedness, and Communication - which she channels into strategic thinking, influence, relationship building, and execution.

- Meenu holds a Master's in Pharmacology from AIIMS, New Delhi, and a Bachelor's in Pharmacy from DIPSAR. She is also a passionate storyteller, traveler, and wellness advocate, living in Singapore with her husband, twins, and their Shih Tzu, Pepper.

Biosketch

Jay Bolden

Lilly

Mr. Jay Bolden is a Senior Director in the Eli Lilly and Company global Analytical Sciences and Quality Control Organization. He is a bacterial endotoxins subject matter expert and leads a team with global QC oversight for endotoxins, microbiology, and virology test methods. Jay holds a B.S. in Biology and an Environmental Studies certificate from Indiana University and has over 25 years of industry experience in development, process and laboratory microbiology, and microbiology laboratory leadership. Jay is a member of the United States Pharmacopoeia Microbiology Expert Committee and has authored a book chapter and multiple peer-reviewed articles on endotoxins.

Abstract

Jay Bolden

Bacterial Endotoxin Testing: Progressive Science and Sustainability

This presentation encompasses the history of the recombinant bacterial endotoxins test, conservation connections to the test, our implementation efforts at Lilly and the opportunities and challenges ahead. I will also discuss the current state of global pharmacopoeias and share preliminary data and experience using recombinant cascade reagents. Participants will have the opportunity to discuss any aspect of the recombinant endotoxin test method implementation.

Biosketch

Sarawut Boonsuk

Work experience

- Deputy Director-General of the Department of Health
- Inspector-General, Ministry of Public Health
- Director-General of the Department of Medical Sciences, Ministry of Public Health (Current Position)

Advanced executive training programs

-Executive Certificate inAdvanced Certificate in Politics and Administration in a Democratic System
- Certificate in National Defense Course
- Certificate in Public-Private Partnership for Social Order and Peacekeeping

Education History

- Doctor of Public Health (Dr.P.H.) (International Program), Khon Kaen University
-Doctor of Philosophy (Ph.D.) in Clinical Tropical Medicine (International Program), Mahidol University
- Senior Executive Fellows in Harvard Kennedy School Executive Education

Awards

- Golden Garuda Medal for Outstanding Civil Servant
-Outstanding Alumni Award for Professional Achievement and Contribution to the Reputation of the Faculty of Medicine, Rangsit University
-Distinguished Alumni Award in Administration, Faculty of Public Health, Khon Kaen University

Biosketch

Significant achievement

- Pioneered and Implemented the Lung Cancer Screening System Using Low-Dose CT Scan in Health Region 1, the first of its kind in Thailand.
- Chair of the Emergency Response and Public Health Crisis Team for Floods and Landslides in Health Region 1.
- Championed and Chaired the One Region One Surveillance System for Health Impact Monitoring in Health Region 1, which received an Outstanding Agency Award from the Public Sector Development Commission.

National academic

- Feasibility Study on Introducing Three-Antiretroviral Combinations as Standard Regimens for Prevention of Mother-to-Child HIV Transmission in Thailand

Co-Authored Publication

- Manual for Enhancing Safety, Confidence, and Hygiene to Prevent New Waves of COVID-19 in Educational Institutions.
- Surveillance, Monitoring, and Response Plan Manual for COVID-19 Outbreaks in Educational Institutions.
- Operational Manual for Sandbox Safety Zone in Schools: Ensuring Safe and COVID-Free Learning Environments

International academic

- Mother to Child Transmission Rate of Hepatitis B after Tenofovir Disoproxil Fumarate Implementation. Current Pediatric Research.2023
- Boonsuk, S., Hattasingh, W., Limkittikul, K., Charunwatthana, P., & Boonsuya, C. (2023). The result of delivery mode on MTCT of hepatitis B virus by TDF implementation Thailand. Procedia of Multidisciplinary Research, 1(1), 3-3.
- Health Literacy Problems and its associated factors among elderly in Thailand. Resmilitaris, 13(1), 179-190. 2023

Biosketch

Badiaa Bouzya

Cell-Based and Biophysical Innovation Lead,
GlaxoSmithKline (GSK)

I am the Cell-Based and Biophysical Innovation Lead at GSK, with over 27 years of experience in the pharmaceutical industry since joining GSK in 1998. In my current role, I lead the innovation and implementation of cell-based assays and biophysical methods across GSK's Global Supply Chain manufacturing sites. My focus is on advancing analytical performance, efficiency, and compliance by transitioning from in vivo to scientifically robust in vitro approaches, adopting advanced analytical techniques, and enhancing biophysical assay capabilities to align with industry best practices and regulatory standards.

As a global technical lead in analytical science, I oversee the development, validation, and deployement of cutting-edge methods for biological products, establish global standards, and drive harmonization across the GSK network. I collaborate with internal teams and external regulatory bodies to ensure compliance with evolving regulatory requirements, strengthen innovation, and position GSK as a leader in analytical science.

Throughout my career, I have held various leadership positions, including Product & Process Analytics Head, Project Manager and Scientist. My expertise spans preclinical models, vaccinology, virology, molecular biology, in vitro and in vivo assay development, flow cytometry, and bioinformatics tools.

Biosketch

I have contributed to preclinical immunology for viral vaccines, including immunogenicity and efficacy studies, toxicity assessments, and regulatory submissions. My work has supported Phase I/II clinical trials for the vaccines targeting pediatrics and older adults.

I'm author and co-author on several peer-reviewed articles in high-impact journals (Nature Communications, Science Translational Medicine, The Lancet Infectious Diseases, npj Vaccines, ImmunoHorizons) :

- Bouzya B et al. Immunogenicity of an AS01-adjuvanted RSVPreF3 vaccine in animal models. npj Vaccines (2023). doi:10.1038/s41541-023-00729-4.
- Stokes A H et al. Repeated dose toxicity and DART studies of an RSV candidate vaccine in rabbits and rats. International Journal of Toxicology (2021). doi:10.1177/1091581820985782.
- Folschweiller N et al. Reactogenicity, safety, and immunogenicity of chimeric HA influenza split-virion vaccines (AS01, AS03, or non-adjuvanted): Phase 1–2 RCT. Lancet Infectious Diseases (2022). doi:10.1016/S1473-3099(22)00024-X.
- Sacconnay L et al. RSVPreF3-AS01 vaccine elicits broad neutralization of contemporary and antigenically divergent RSV strains. Science Translational Medicine (2023). doi:10.1126/scitranslmed.adg6050.

I'm graduated in Medical Biology from the Catholic University of Louvain.

My passion lies in merging scientific expertise with strategic innovation to drive impactful advancements in healthcare and ensure GSK remains at the forefront of analytical science and manufacturing excellence.

Abstract

Badiaa Bouzya

Potency Testing for Adjuvanted Vaccines: Progress, Roadblocks and a Vision for Non-Animal testing

Adjuvanted vaccines play a critical role in enhancing immune responses, enabling dose sparing, and improving efficacy in vulnerable populations. However, traditional animal-based potency testing methods face significant scientific, operational, and ethical limitations, including high variability, slow turnaround, and growing ethical concerns under the 3Rs principles. This presentation explores the progress, challenges, and vision for transitioning to non-animal potency testing frameworks for adjuvanted vaccines.

Recent scientific advances offers innovative non-animal strategies, including mechanism-based analytical assays, in vitro functional assays, immunochemical assays, and systems-based characterization. These approaches provide robust, predictive, and scalable alternatives to traditional methods. Integrated potency platforms tailored to specific adjuvant types, such as aluminum salts, oil-in-water emulsions, TLR agonists, and saponin-based adjuvants, have demonstrated reliability in evaluating antigen-adjuvant interactions and immune activation mechanisms.

Despite advancements, roadblocks remain, including complex antigen-adjuvant interactions, regulatory challenges, and manufacturing constraints. Addressing these issues requires international collaboration, harmonized regulatory acceptance, and the adoption of digital and AI-driven predictive models.

This presentation outlines a vision for a fully non-animal potency testing framework, emphasizing mechanism-informed vaccine design, multi-assay strategies, and global regulatory convergence. By integrating analytical, immunochemical, and functional assays, the path forward aims to achieve 100% non-animal potency testing, ensuring ethical compliance and advancing vaccine development.

Biosketch

Mihaela Buda

EDQM

Mihaela is a chemist with a PhD in pharmaceutical chemistry from the Ruprecht-Karls University of Heidelberg, Germany. After completing post-doctoral research at the University of Heidelberg's Institute for Pharmacy and Molecular Biotechnology, she joined the Institute for Reference Materials and Measurement at the Joint Research Centre (JRC) of the European Commission, where she focused on developing and certifying reference materials for quality control in bioanalysis. In 2013, she became a Scientific Programme Manager at the European Directorate for the Quality of Medicines & HealthCare (EDQM), contributing to the development of European Pharmacopoeia documentary standards for biotherapeutics (including monoclonal antibodies), mRNA vaccines, and plasma-derived medicinal products. She was actively involved in the early work of the Analytical Quality by Design Working Party, helping shape its strategic direction.

Since 1 January 2025, she has taken up the role of Head of Section for the Biological Standardisation Programme at the EDQM.

Abstract

Mihaela Buda

Session - Regulatory Perspectives on Progress in Method Acceptance

Tile: EDQM's support for the 3Rs – status update and insights into Ph. Eur. General Chapter 5.2.14

The EDQM is actively involved in promoting the application of the 3Rs principles in the quality control of vaccines. The European Pharmacopoeia (Ph. Eur.) General chapter 5.2.14. Substitution of in vivo method(s) by in vitro method(s) for the quality control of vaccines, provides a framework for introducing alternative in vitro approaches where traditional head-to-head comparisons with in vivo methods are not feasible or scientifically relevant. This presentation outlines the rationale behind the chapter, its guidance on demonstrating the relevance and performance of in vitro methods, and its role in facilitating regulatory acceptance of innovative approaches. Drawing on recent revisions of Ph. Eur. texts and projects from the EDQM's Biological Standardisation Programme projects, the presentation will also showcase practical examples of how EDQM and the Ph. Eur. are driving the transition toward animal-free testing, advancing both animal welfare and scientific integrity.

Abstract

Mihaela Buda

Session - A new pyrogenicity strategy: How MAT and recombinant BET are changing the approach to pyrogenicity

An EDQM update on pyrogenicity in European Pharmacopoeia

The European Pharmacopoeia (Ph. Eur.) has achieved a major milestone in pyrogen testing by eliminating the Rabbit Pyrogen Test (RPT) from all its texts, effective July 2025, with full removal of the chapter by January 2026. This marks a significant shift toward modern in vitro approaches for pyrogenicity testing such as the Monocyte Activation Test and Bacterial Endotoxins Test (BET), including the use of recombinant Factor C. The presentation provides an overview of the historical evolution of pyrogenicity strategies, the implementation of the RPT phase-out, and the integration of recombinant reagents into the Ph. Eur. It highlights ongoing revisions to chapters 2.6.14 and 5.1.13, harmonisation efforts within the Pharmacopoeia Discussion Group, and EDQM's initiatives to establish reference standards for BET and MAT. Perspectives from regulators, industry, and global stakeholders underscore the significance of this achievement for animal welfare, sustainability, and scientific innovation in quality control testing.

Biosketch

Dr. Jean-Michel Chapsal

Independent
195 Traverse des verdelieres, 69380,
Charnay, France

Email:jmchapsal@gmail.com
Tel: +33 07 82485065

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Dr. Jean Michel Chapsal has been working for 30 years at Sanofi Pasteur. Dr Chapsal has led a number of units, including Research and Development,Downstream Processing and Analytical Services-Regulatory Affairs Interface. He has also served as Director in Global Analytical Services. His areas of expertise include technical method development for vaccine control, application of emerging technologies in vaccinology, 3Rs alternative methods development, and analytical services in biochemistry, microbiology. Dr Chapsal received a PhD in Biochemistry. He also completed the general course of Virology at the Institut Pasteur in Paris and received an advanced postgraduate diploma in Virology at Université Paris Diderot. He completed a postdoctoral fellowship in the University of California, San Francisco. Dr Chapsal has been a member of the Working Group on Sera and Human Vaccines of the French Agency for the safety of Health Products (ANSM) and of the French Scientific Interest Group on Alternative methods (GIS). He was co-chair of the International Histamine Test Replacement Working Group for Pertussis vaccine in the frame of the consistency Vaccine Project of the EuropeanPartnership for Alternative Approaches to Animal Testing (EPAA). He is currently co-project leader for EDQM (BSP148) for the Rabies NIH test replacement.

Abstract

Jean-Michel Chapsal

Replacing the in vivo potency test for human rabies vaccines: a global collaborative initiative

Jean-Michel CHAPSAL 1 Sylvie MORGEAUX 2, Eriko TERAO 3
1 Independent, EPAA (Presenter), 2 ANSM, FR, 3 EDQM/BSP, Council of Europe

For over 70 years, the release of human rabies vaccines has relied on a potency test consisting of an intracranial challenge test in mice (NIH test). While it has proved useful, this test has major scientific and ethical issues. The global replacement of the NIH test is a high priority for the worldwide implementation of the 3R concept but is conditioned by the validation of a global standardised method. Given that the protection against rabies virus is induced by the native trimeric form of the virus glycoprotein G, the scientific community agreed that an ELISA based on highly characterised monoclonal antibodies would be the most appropriate replacement method. In a first step towards this aim, a small international study involving 5 laboratories was organised by the European Partnership for Alternative Approaches to Animal testing (EPAA) to identify and evaluate available rabies ELISAs for the potency control of human rabies vaccines. The study concluded that the GP rabies ELISA was the most promising replacement method. In a second step, a large collaborative study (BSP148) was organised by the Biological Standardisation Programme to standardise the method and evaluate its transferability to laboratories worldwide. During the first phase of BSP148, the 2 critical monoclonal antibodies were made available by 2 commercial suppliers, and a standardised protocol was elaborated. Thirty laboratories took part in the collaborative phase (Phase 2) of the study, using the standardised protocol with qualified batches of critical reagents and the WHO 7th International Standard for Rabies vaccine, to evaluate a common set of 11 vaccine samples covering 5 virus strains and various potencies. The data centrally analysed at EDQM indicated that the method is transferrable to laboratories worldwide, that the potency of all tested vaccines can be quantified (in IU/mL) and that the GP ELISA has a very satisfactory precision, repeatability and reproducibility. The Phase 3 of the study aims at evaluating the applicability of the GP ELISA to routine QC testing of commercial batches. The Phase 3 study report is in preparation. The results of these studies will support the proposal for the global replacement of the in vivo potency test by a standardised ELISA (i.e. future revision of pharmacopoeial texts and WHO guidelines)

Biosketch

Dr Emmanuelle Coppens

Sanofi

Dr Emmanuelle Coppens is a Global Analytical Expert in 3Rs and Immunology with the mission to coordinate removal of in vivo analytical testing for vaccines within Sanofi company. 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 a QC laboratory unit dedicated to analytical testing and animal derived reagents production and then moved to transversal activities. In parallel to being an 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.

Her fields of expertise are in vivo & in vitro bioassays, neurovirulence and safety in vivo testing, applicable to human vaccines and biologicals. She is a member of EPAA (European Partnership of Alternative Approaches) Industrial Steering Committee and of EPAA project “3Rs Harmonization in Biologicals” as well as a member of the International Steering Committee of the HIS project “Promotion of implementation plans forand was non-animal batch-release testing for human vaccines”. She was also a member of the expert working group within previous NC3Rs project “Review of animal use requirements in WHO biologics guidelines”.

Abstract

Emmanuelle Coppens

Session - Industry perspective on phasing in non-animal testing and efforts to promote global alignment

Title: Animal Testing Replacement: Global Human Vaccine Manufacturer Perspectives

A general introduction will give an overview of the Sanofi strategy and current situation for quality control analytical testing with scientifically relevant non animal based analytical testing. The presentation will then present what are the key challenges a global manufacturer still faces and what efforts are being made to promote worldwide alignment and acceptance for removal and replacement of animal testing and how reliance mechanisms also contribute to more reliable vaccine supply.

Session - A new pyrogenicity strategy How MAT and recombinant BET are changing the approach to pyrogenicity

Title: How Industry is Implementing in vitro Alternatives for Pyrogenicity testing

In the context of transitioning to non-animal based analytical testing Sanofi will present its strategy to avoid the rabbit pyrogen test (RPT), based on a pyrogens risk-assessment to determine which pyrogenicity test method is applicable between using a bacterial endotoxin test (BET) and/or a monocyte activation test (MAT). The current situation in regard to the implementation of the alternative non animal reagents for BET and the phasing out of RPT will be shared, as well as the remaining challenges and next steps for their implementation.

Abstract

Emmanuelle Coppens

Session - Safety Testing: from development to implementation and regulatory acceptance

Title: How industry is Phasing Out in vivo Safety Testing

In the context of transitioning to non-animal based analytical testing Sanofi will present its strategy to avoid in vivo safety testing and give an overview of the current situation on deleting obsolete or redundant testing and on what basis. We will then illustrate with some examples how industry and regulatory collaboration can contribute to the replacement of in vivo safety tests.

Session - Potency Testing: Achievements and next steps for implementation

Title: From in vivo to in vitro Testing for DTaP (Diphtheria, Tetanus, acellular Pertussis) Potency Testing

After highlighting the drawbacks and complexity to use in vivo methods for potency testing of DTaP combination vaccines, we will present how the IMI Vac2Vac consortium allowed to develop immunoassays and reagents intended to replace these in vivo assays. Then we will share how Sanofi, in conjunction with IMIVac2Vac, developed antigenicity assays for their products, how suitability is demonstrated and how validation is performed. We will briefly present the current status, the remaining challenges and next steps.

Biosketch

Dr. Pradip Kumar Das

Dr. Pradip Kumar Das is currently serving as General Manager, Quality Control at Biological E. Limited, Hyderabad, Telangana. He has extensive experience in analytical development, quality control, and stability functions within the vaccine industry.

At Biological E, he leads a Quality Control group focusing on bacterial and viral testing, batch release, and scientific monitoring of preclinical studies for new vaccines. He is also an active member of the NC3Rs focus group, working on the adoption of alternative in vitro assays for batch release in alignment with the 3Rs principles.

Dr. Das has successfully developed and implemented multiple analytical methods to support vaccine quality and regulatory compliance. Prior to joining Biological E, he worked with leading vaccine manufacturers including Indian Immunologicals Ltd. (IIL), Zydus Cadila, and the Government of India.

His key areas of interest include Microbiology, Immunology, Human and Veterinary Vaccines. He also contributes to national standard-setting as a member of the Indian Pharmacopoeia Commission.

Abstract

Pradip Das

Path To Remove and Replace Safety Testing In India

The evolution of vaccine manufacturing and regulatory science in India has created strong momentum toward modernizing safety testing and reducing dependence on traditional animal□based assays. Recent national and international reforms including the removal of the Abnormal Toxicity Test (ATT) and the shift from rabbit pyrogen testing to bacterial endotoxin testing highlight India's commitment to evidence-based, humane, and scientifically advanced quality control frameworks.

This abstarct examines the regulatory, scientific, and ethical pathways for replacing legacy in-vivo safety tests with validated in-vitro, molecular, and process-based approaches. It outlines the roles of key authorities such as the Central Drugs Standard Control Organisation (CDSCO) and the Indian Pharmacopoeia Commission (IPC), as well as alignment with global frameworks including the WHO and EDQM, in enabling these transitions.

By mapping the requirements for method development, assay validation, inter-laboratory harmonization, and regulatory acceptance, this article provides a practical roadmap for vaccine manufacturers seeking to integrate Quality by Design (QbD), Process Analytical Technology (PAT), and next-generation analytical tools into routine quality control.

Advancing toward non-animal, rapid, and sensitive testing systems not only strengthens vaccine quality assurance and accelerates product release but also enhances international regulatory convergence and supports India's leadership in ethical, sustainable, and modern biopharmaceutical manufacturing. The time is right to move decisively toward science-driven, 3Rs-aligned strategies that reflect global best practices and the future of vaccine quality control.

Biosketch

Dr Fitra Yovita Delviona

Indonesian FDA

Fitra is a Doctor of Veterinary Medicine (DVM) specializing in the dual areas of biological product quality assurance and laboratory animal welfare. Currently serves at the National Control Laboratory (NCL) within the Indonesian Food and Drug Authority (Badan POM)

Core Expertise and Responsibilities

As a key member of the NCL team, she works in uniquely positioned at the intersection of regulatory compliance and scientific modernization. Key responsibilities include:

- Lot Release Evaluation: Performing critical lot release evaluation for both domestic and imported biological products, with direct experience in vaccine safety testing.
- Attending Veterinarian & 3R team: Serving as the Attending Veterinarian responsible for the management and welfare of the animal laboratory facility at the Indonesian FDA. This crucial role provides an authoritative perspective on the implementation and advancement of the 3Rs (Replacement, Reduction, and Refinement) principles.
- Method Development & Validation: Specializing in the development and validation of analytical methods, she proficient in both in vivo and in vitro laboratory techniques, with a strong focus on transitioning to modern, non-animal quality control schemes.

Biosketch

Professional Background and Focus

She earned the Bachelor and Doctor of Veterinary Medicine (DVM) degrees from the Faculty of Veterinary Medicine, IPB University. This foundation is complemented by certification as a Certified Laboratory Animal Practitioner (Cert.LAP) from the BNSP of Indonesia.

With five years of experience in medical device testing based on ISO 10993 (including systemic toxicity, pyrogen, bacterial endotoxin, and skin irritation), this expertise is now broadening toward complex biopharmaceutical products, such as biosimilars, blood products, and cell therapies. She maintains active membership in key professional organizations, including the Indonesian Veterinary Medical Association (PDHI), the Indonesian Association for Laboratory Animal Science (IALAS), and the Indonesian Laboratory Animal Veterinarians Association (ILAVA), reflecting a strong commitment to advancing the development of laboratory animal facilities and scientific standards in Indonesia.

Abstract

Fitra Yovita Delviona

Advancing Vaccine Quality Control through Non-Animal Testing at National Control Laboratory, Badan POM

This overview details the strategic initiatives undertaken by the National Control Laboratory (NCL) of Badan POM to transition vaccine batch release testing toward advanced, non-animal testing (NAT) methodologies. These efforts directly support the global commitment to ethical biological product quality control, aligning with forthcoming international standards such as the draft WHO Guidelines on the replacement or removal of animal tests. The NCL's program focuses on the high-priority replacement of conventional in vivo methods across three critical areas: pyrogenicity assessment, endotoxin detection, and the neurovirulence testing for novel polio vaccines (nOPV2).

Initial capacity building and validation trials have yielded crucial findings. For pyrogen testing, the Monocyte Activation Test (MAT) demonstrated successful implementation with superior sensitivity for both endotoxin and non-endotoxin pyrogens, paving the way for formal validation in 2026. Simultaneously, a trial for Recombinant Factor C (rFC) confirmed that existing infrastructure is an open system, strategically confirming the flexibility to adopt various quantitative reagent brands. To replace the Monkey Neurovirulence Test (MNVT), the NCL has invested in specialized training for Next-Generation Sequencing (NGS), establishing foundational technical expertise to handle complex genetic sequencing and data interpretation.

A comprehensive gap analysis identifies core hurdles to achieving full implementation, primarily stemming from the significant investment required for state-of-the-art infrastructure, the limited commercial access and high cost of specialized NAT reagents, and the continuous need to develop highly competent human resources. To mitigate these challenges, the NCL's 2026 roadmap prioritizes the formal validation of the MAT method, executing further rFC/RcR trials with partners, initiating the procurement of essential NGS supporting equipment, and hosting focused workshops to accelerate the final implementation of these modern control systems.

Biosketch

Alan Fauconnier

Alan Fauconnier spent several years working in academic laboratories before joining the Belgian regulatory authority as a quality/CMC assessor in the early 2000s. In 2018, he joined WHO's vaccines prequalification team, and later moved to the Local Production and Assistance Unit, where he applied his expertise to support vaccine and biotherapeutic manufacturers. He subsequently served as Team Lead of the Laboratory Networks and Services team, which focuses on strengthening the capacities of official quality control laboratories for medicines and vaccines. Most recently, he was appointed ad interim Team Lead of the Regulatory Systems Strengthening team, supporting countries in building regulatory capacity in line with good regulatory practices and promoting regulatory cooperation, convergence, and transparency through networking, work-sharing, and reliance.

Biosketch

Juliana Galvão da Silva

Fundacao Butantan Brazil

Juliana Galvão is a biomedical scientist with a Ph.D. in Biochemistry and over 11 years of experience in the development and validation of analytical methods for antivenoms and vaccines. She currently works at Instituto Butantan, one of the leading Latin America producers of immunobiologicals. Her team work focuses on method development, analytical quality, and regulatory compliance, with a strong commitment to implementing alternative approaches that reduce or replace animal use in quality control testing.

Abstract

Juliana Galvão da Silva

Advancing 3Rs in Quality Control of Immunobiologicals: Butantan's Strategy for Implementing MAT and Recombinant Endotoxin Testing

This presentation details the strategic roadmap of the Butantan regarding the implementation of alternative methods for quality control in immunobiologicals. Aligned with the 3Rs principle (Replacement, Reduction, and Refinement), the strategy focuses on transitioning from the in vivo Rabbit Pyrogen Test (RPT) to the in vitro Monocyte Activation Test (MAT) and from the LAL test to the Recombinant Endotoxin Testing (rCR and rFC). The presentation outlines the regulatory landscape in Brazil, including compliance with ANVISA and CONCEA resolutions, validation processes, and the timeline for implementation of these alternative methodologies.

Biosketch

Sunil Goel

DCVMN (Serum Institute of India)

Dr. Sunil Kumar Goel is a microbiologist by training and is related to the field of Human Vaccines for the last 38 Years. He is a Ph D in Microbiology.

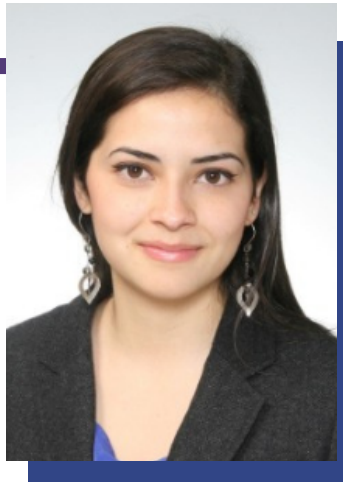
After having served Government of India at National Control Lab (CDL) / Central Research Institute, Kasauli for 27 years he got voluntary retired from Government service and joined in Quality Control Department of Serum Institute of India at Pune in 2015 and is working there as an Additional Director - QC Site Head.

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 which was successfully accomplished.

He is an Expert Working Group member on 3Rs and Vaccines & Antisera of Indian Pharmacopoeia and member of various groups working on 3Rs like Humane Society International, NC3Rs and IABS etc. He had been a visiting Faculty at various forums, a Life Member of Association for Prevention and Control of Rabies in India, a Life Member of Indian Academy of Vaccinologists and Immunobiologists. He was also a member of National AEFI Committee and a part of team for developing guideline for handling of AEFI cases.

Dr Goel has 22 Publications in National and International Journals and 7 Patents to his credit.

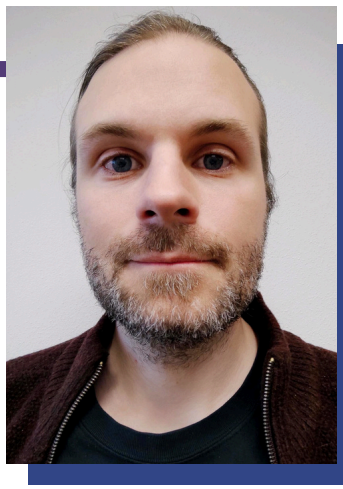
Biosketch



Dr Juliana Gutierrez

Dr. Juliana Gutierrez is Scientific Affairs Manager at bioMérieux, where she provides scientific and regulatory expertise to support the Pharma Quality Control segment across Asia. She holds a Ph.D. in Molecular Biology and has authored several peer-reviewed papers in the field. Juliana is an active member of the International Society for Cell & Gene Therapy (ISCT), serving on the ISCT Asia Pacific Industry Committee, and a member of the Parenteral Drug Association (PDA). She is also a frequent guest speaker at international conferences.

Biosketch



Bernhard Illes

Bernhard Illes received his PhD in chemistry at the LMU in Munich, specializing in nanoparticles and photoactivation of proteins. He joined Microcoat as a project leader in 2021 as part of the Endotoxin Service. His projects focus on developing endotoxin detection methods for challenging samples that exhibit LER with a focus on recombinant BET. He accompanies the samples from initial feasibility studies and method development until method validation and GMP release testing. He is currently a group leader in the Endotoxin Services

Abstract

Bernhard Illes

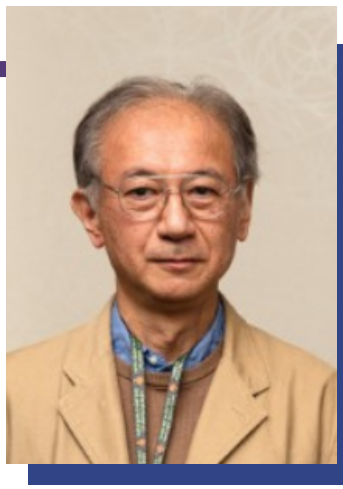
Navigating the Transition: Regulatory and Practical Perspectives on Implementing the Monocyte Activation Test

The landscape of endotoxin and pyrogen testing is undergoing a significant transformation as the industry moves away from traditional animal-based methods—such as the Limulus Amebocyte Lysate (LAL) and Rabbit Pyrogen Test (RPT) — toward fully animal-free alternatives. Recombinant bacterial endotoxin tests are increasingly replacing LAL, while the Monocyte Activation Test (MAT) has emerged as the key in vitro alternative to the RPT in Europe.

For decades, the RPT has been the compendial standard for detecting pyrogens in pharmaceutical products. However, in line with global efforts to enhance animal welfare and the principles of the 3Rs (Replacement, Reduction and Refinement), the European Pharmacopoeia (Ph. Eur.) has introduced the MAT, based on human immune cell responses, as the new approach. With Ph. Eur. chapter 5.1.13 now in effect and the complete phase-out of the RPT in the European Union by 2026, the implementation of the MAT as a replacement has become a priority.

This presentation will provide a high-level overview of how companies can navigate this transition. Key topics will include the essential steps for developing and implementing MAT-based strategies—from method development, to validation including risk assessment and QC testing. In addition, we will summarize regulatory requirements, discuss feedback to submissions, and provide practical strategies to meet regulatory expectations. Selected case studies will illustrate real-world experiences, demonstrating a successful path towards the implementation of the MAT.

Biosketch



Masaaki Iwaki

Research Scientist

Masaaki Iwaki, PhD, is a Japanese microbiologist and toxinologist. Born in Tokyo in 1959, he earned a BSc in Plant Pathology (1982), an MSc in Microbiology (1984), and a PhD in 1990 from the University of Tokyo, with a dissertation on aflatoxin B1-binding macromolecules in experimental animals and cultured cells.

He began his career in 1984 as a research scientist at the National Institute of Health (Tokyo), then pursued postdoctoral training at the Institut Pasteur in Paris between 1993 and 1995. Returning to Japan, he continued as a research scientist at the National Institute of Infectious Diseases, focusing on bacterial toxins, toxoids, and antitoxins until 2020. From 2020 to 2025, he was affiliated with the Research Center for Biosafety AND EXPERIMENTAL ANIMALS of the same institute, before joining the Japan Institute for Health Security as a research scientist in the Department of Quality Control.

His research has centered on laboratory testing of diphtheria and tetanus toxoids, the development of alternative methods to animal testing (3Rs) for vaccine and antitoxin quality control, and the pathogenicity of Corynebacterium diphtheriae and Corynebacterium ulcerans. He has elucidated toxin modes of action, contributed to vaccine potency assays such as ELISA systems, and investigated zoonotic transmission of toxigenic corynebacteria from animals to humans.

Abstract

Masaaki Iwaki

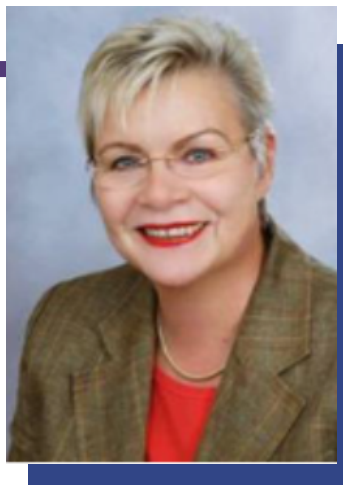
Implementation of 3Rs to quality control of biologicals and lot release tests in Japan

Animal experiments have been taking essential parts in tests for quality control and lot release of biologicals for a long time and remain indispensable at present. On the other hand, the increasing requirement for animal welfare is the driving force for us to implement the 3Rs (Replacement, Reduction and Refinement) in biological QC and lot release.

In Japan, efforts for the implementation of 3Rs so far resulted in the removal of tests (typically the innocuity test) and improvement of methods (potency test etc.) in Japanese Minimum Requirement for Biological Products.

The framework for the implementation is :
(1) accumulation of sufficient data for removal or modification of animal tests, in many cases by collaborative studies with manufacturers.
(2) proposal for the removal/modification of tests to the internal committee of NCL=NIID (now JIHS).
(3) proposal to the superior committee that includes the NCL and NRA=MHLW (Ministry of Health, Labour and Welfare), PMDA (Pharmaceuticals and Medical Devices Agency).
(4) approval and public notice in the Official Gazette.

Biosketch



Dr Carmen Jungbäck

Dr Carmen Jungbäck graduated from the Tierärztliche Hochschule, Hannover with a degree in Veterinary Medicine. In 1981, after a few years as an animal surgeon she joined the Paul-Ehrlich-Institut, (Federal Agency for Sera and Vaccines), Langen, Germany, where she was Head of the section Veterinary Virology 1 until retirement in 2016. The section's area of activities comprises vaccinelicensing and testing, with special expertise in viral vaccines for poultry. In this context, the practical testing of vaccines during licensing and for official batch release is one of the major responsibilities.

She was also member of a number of advisory boards to the EDQMOMCL Network, Ph.Eur Group 15V and CVMP-IWP and JEG3R at EMA dealing with IVMPs under various aspects. At IABS she is member of the board and Chair of the Veterinary Biologicals Committee and Vice-President of IABS - EU. She is organizing IABS meetings focusing on the veterinary field. As member of IABS-EU she is involved in the IMI projects (ZAPI and Vac2Vac).

Biosketch

Dr. M. Kalaivani

M.Pharm., Ph.D
Principal Scientific Officer,
Indian Pharmacopoeia Commission,
Ministry of Health and Family Welfare, Govt. of India,
Ghaziabad- 201 002, UP, INDIA

Dr. M. Kalaivani is Principal Scientific Officer and Officer-in-charge, Biologics Division, Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Govt. of India. She holds a PhD in Pharmaceutical Sciences from The TN Dr. MGR Medical University, Chennai, India. She is working with IPC since year 2010 and has been instrumental in establishing a separate division and laboratory facility for biologics at IPC. Biologics division at IPC develops IP monographs for rDNA therapeutic products, Vaccines and immunosera for human and veterinary use, Blood and blood related products and activities related to implementation of Alternatives to animal methods in Indian Pharmacopoeia. She is closely associated with National and International Organizations Such as National Institute of Biologicals (NIB), Central Drugs Standard Control Organization (CDSCO)/Central Drugs Laboratory (CDL), World Health Organization (WHO), United States Pharmacopoeia (USP) etc in various activities related to Biological derived therapeutics. She is certified assessor for compliance of ISO/IEC 17025:2017 by National Accreditation Board for Testing and Calibration Laboratories (NABL), Quality Council of India. She authored more than 65 scientific papers in journals, books and conference proceedings. Dr. Kalaivani also contributed in National Formulary of India (NFI), 2011, NFI 2016 and responsible for publication of NFI, 2021.

Abstract

Muthusamy Kalaivani

Indian Pharmacopoeia perspectives on alternatives to animal methods in testing of vaccines for human and animal use

The global shift toward replacing animal-based vaccine testing is accelerating, driven by scientific advancements, ethical imperatives, and the integrated principles of One Health. Indian Pharmacopoeia Commission (IPC), an Autonomous Institution under the Ministry of Health and Family Welfare, Govt. of India, has taken proactive steps to implement 3Rs principles (Replacement, Reduction, Refinement) through Indian Pharmacopoeia (IP). During implementation of alternatives to animal methods, IPC adopts one or more strategies like Comparability and applicability of suitable non-animal method or test in place of current in vivo method or test. Recent edition of IP 2022 and upcoming edition IP 2026 have progressively aligned with global pharmacopoeia's and WHO "Guidelines on the replacement or removal of animal tests for the quality control of biological products". IP implements and promotes alternate method approaches to reduce use of animal in tests such as in vivo potency, safety, and pyrogen tests with non-animal methods such as in-vitro assays, Bacterial endotoxin tests, and other validated tests. Key forward-looking priorities for the IP are to include expanded monograph updation, structured pathways for alternative method validation, and collaborative data generation with industry. These efforts position the IP to play a pivotal role in accelerating India's transition toward sustainable, science-driven, and internationally harmonized non-animal testing and approaches for vaccines.

Biosketch

Naree Ketusing

Dr. Naree Ketusing, DVM, PhD

Dr. Naree Ketusing serves as the Sub-Regional Representative for South-East Asia at the World Organisation for Animal Health (WOAH), based in Bangkok. In this role, she leads strategic initiatives to strengthen veterinary services, enhance regional cooperation, and support WOAH Members in implementing international standards for animal health and welfare.

With over 15 years of experience in veterinary public health and international collaboration, Dr. Ketusing brings expertise in policy development, technical project management, and capacity building. She holds a PhD in Veterinary Public Policy (Virginia Tech), an MSc in Veterinary Epidemiology (Colorado State University), and a DVM (Chulalongkorn University).

Her work focuses on advancing WOAH's mission to improve animal health globally through projects on disease prevention, risk assessment, and emergency preparedness. She has successfully coordinated regional programs, facilitated expert missions, and supported Members in achieving disease-free status for transboundary animal diseases. Fluent in Thai and English, Dr. Ketusing is committed to fostering partnerships among governments, international organizations, and stakeholders to build resilient animal health systems.

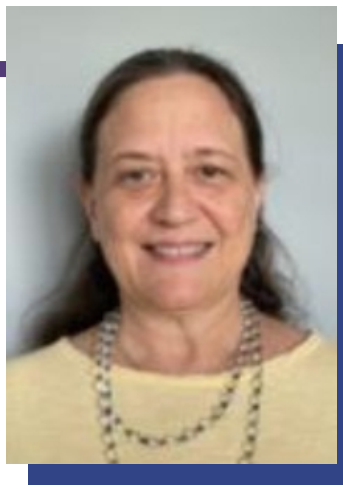
Biosketch

Dianliang Lei

WHO

Dr Dianliang Lei has been working at World Health Organization since 2003 as a scientist working in Health Product Policy and Standards department, responsible for development of WHO international standards including measurement standards and written standards for 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, Guideline for regulatory oversight of pandemic vaccines, Guideline on the replacement and removal of animal tests for the QC of biologiclas and Manual for establishment of national standards. Dr Lei, before joining WHO, was a 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) for biologicals, standards, specification for vaccines and lot release system. He obtained a PhD in medical science in Medical School of Osaka University Japan in 1996.

Biosketch



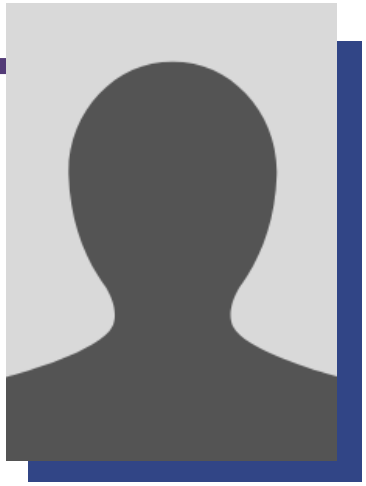
Robin Levis

CBER-FDA

Dr. Robin Levis 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 currently licensed NIH potency test.

In addition to her work in the Office of Vaccines at CBER, she serves as the CBER representative to ICCVAM, as an observer to EDQM Group 15 for vaccines, 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.

Biosketch



Alexandrine Maes

Alexandrine Maes is a pharmacist and has a master in Laboratory Animal Science. She worked for more than 10 years at Sciensano, the Belgian NCL where she was responsible for the in-vivo tests and the lot release of bacterial vaccines. She joined Laboratory Networks and Services Team at WHO (now Market Serveillance and Control team) in 2020 where she is responsible for the testing activities of vaccines performed by WHO contracted laboratories and the management of the WHO-National Control Laboratory Network.

Biosketch

Kutub Mahmood

DCVMN

Kutub Mahmood, PhD, is PATH's Scientific Director, at the Center for Vaccines Innovation and Access (CVIA). Currently, leading projects for polio vaccines development and scaleup for OPV, Sabin IPV (sIPV) and hexavalent vaccine, reference standards development for novel OPV and sIPV. His other projects at PATH includes work related to measlesrubella, influenza, RSV, Yellow fever, live rotavirus, and SARS-CoV2 with technologies including whole virion, inactivated, vectored, live attenuated, VLPs and subunit vaccines. He holds national and international patents on VLP technology for influenza and RSV vaccines and include publications in peer-reviewed journals. At PATH, his work includes generating international reference standard for Sabin IPV, universal reagents for IPV potency testing and providing strategic and scientific support to other projects including RSV, COVID-19, influenza vaccine.

Dr Mahmood is a seasoned leader with expertise in viral vaccines with over 30yrs experience in vaccine development. Before joining PATH, he was a key contributor to the development of FluMist, a live intranasal influenza vaccine, at Medimmune. At Novavax, he was the Executive Director, Biologicals Product Discovery, and worked on virus like particles for influenza, RSV viruses. While at Novavax, Dr. Mahmood played a pivotal role in entering into a collaborative partnership with Cadila Pharmaceuticals, India where he transitioned as Vice President, Vaccines and Biologics, overseeing the tech transfer of H5N1 VLP vaccine and product development in India.

Biosketch

Dr. Mahmood did his doctoral thesis on flaviviruses at National Institute of Virology, India and later pursued postdoctoral training at MIT, USA. He has been in vaccine industry for over two decades before joining PATH. He presently serves on several scientific panels advisory board for biotech companies in Europe, for national and international vaccine meetings, and serves as scientific reviewer for leading scientific journals.

Biosketch

Dr Laurent Mallet

European Directorate for the Quality of Medicines & HealthCare (EDQM)

Laurent Mallet is the Head of the Biological Standardisation, OMCL Network and HealthCare Department at the European Directorate for the Quality of Medicines and HealthCare (EDQM) since 1 December 2019.

Laurent Mallet obtained his Master of Science in Biochemistry from Claude Bernard University, Lyon (France) and completed his PhD work in Virology and Molecular Biology under the co-direction of Professor Michèle Aymard (National Reference Center for Enterovirus, Lyon) and Dr François Pelloquin (Sanofi Pasteur, formerly Pasteur Mérieux-Connaught).

He obtained his PhD in 1996. After several positions within Sanofi Pasteur in France and in Canada, he was appointed Global Head of Analytical Sciences at Sanofi Pasteur, where he remained until November 2019. He joined the EDQM in December 2019. He was a member of several expert committees,including EDQM/European Pharmacopoeia Group of Experts 15 (Human vaccines and sera), and a stakeholder in the French Pharmacopoeia Committee for “Biological Products and Innovative Therapies”. He was also involved in several WHO working groups on vaccines, including the WHO Study Group on Cell Substrates.

Biosketch

He currently represents the EDQM on the WHO Expert Committee on Biological Standardisation (ECBS), and in the NC3Rs Steering Committee reviewing animal testing requirements in WHO biologicals guidelines, the COVAX Regulatory Advisory Group and the implementation working group for the ICH Q5A revision. He is also a member of the IABS Board;

Biosketch

Laure Martinez

Laure Martinez is a Doctor in Veterinary Medicine by training and practiced as such during 10 years before joining the industry. She is now a technico-regulatory expert in the Research and Development of Veterinary Biologicals at Virbac, France. She is also in charge of the life cycle management of these products for safety and efficacy parts as well as geoextensions. In this role, she also represents Virbac in several industry associations for regulatory surveillance and additionally focused on the regulatory acceptability of non-animal methods. She therefore joined 3Rs task force from Animal Health Europe and the 3Rs group from Health for Animals and leads Virbac's internal 3R group. Since January 2024, she has also been leading the VICH Batch Potency Testing Subgroup, which is developing a harmonized guideline on replacing in vivo vaccine potency tests with in vitro methods.

Driven by the 3Rs principle (Replace, Reduce, Refine animal use) and supported by international harmonization through VICH/WOAH guidelines, safety batch testings (TABST or LABST) for veterinary vaccines have been successfully waived or deleted depending on the countries. Challenges remain due to product diversity and varied regulatory environments. HealthforAnimals and industry is engaged in promoting global elimination of these tests and understanding the global picture and the remaining hurdles and sharing experiences are prerequisites. Ultimate goal is to promote availability of vaccines worldwide without duplicating tests on animals, rationalizing time and costs.

Biosketch

Javier Martin

Javier is a Principal Scientist at MHRA South Mimms, where he leads the Polio Laboratory Group. He earned his PhD from the Universidad Autónoma de Madrid, developing a novel method to generate genetically modified synthetic influenza viruses for prospective vaccine design. He then spent four years as a postdoctoral scientist at the National Institute for Medical Research (Mill Hill, London), continuing his work on influenza. In 1998 he moved to the National Institute for Biological Standards and Control (now MHRA), where he heads the WHO Global Specialized Polio Laboratory, supporting the Global Polio Eradication Initiative in disease surveillance as well as vaccine control, standardisation, and development. In recent years, Javier's group at MHRA has focused on next-generation sequencing for whole-genome characterisation of poliovirus vaccine strains and surveillance isolates, with the dual aims of establishing robust quality-control methods for vaccine release and deepening understanding of the genetic stability of classic and novel live-attenuated vaccines, including pathways of reversion to virulence. His work has also enabled the establishment of direct detection sequencing methods for poliovirus surveillance, shortening the time to virus identification and accelerating public-health response.

Abstract

Javier Martin

Next generation sequencing as an alternative to neurovirulence tests in animals for the quality control of live-attenuated viral vaccines

This work explores next generation sequencing (NGS) as a replacement for animal neurovirulence tests (NVTs) in the quality control of live-attenuated viral vaccines, with a primary focus on oral poliovirus vaccine (OPV) and extension to other vaccines such as yellow fever. Genetic attenuation of Sabin OPV strains is maintained by a limited set of key mutations, and current safety control relies on in vivo NVTs in monkeys or transgenic mice, complemented by MAPREC (Mutation Analysis by PCR and Restriction Enzyme Cleavage) assays targeting hot-spot mutations in the 5′ non-translated region. These approaches are ethically challenging, costly, and of limited throughput.

High-throughput NGS enables deep, quantitative measurement of single nucleotide polymorphisms (SNPs) across the whole viral genome, generating a detailed “molecular fingerprint” for each vaccine seed and lot. We conducted stepwise studies to (Phase 1) evaluate NGS as a replacement for MAPREC in quantifying critical 5′-NTR revertant mutations in OPV1 and OPV3, and (Phase 2) assess whether whole-genome SNP profiles can serve as surrogate markers for neurovirulence and overall molecular consistency, ultimately enabling removal of routine animal NVTs from lot release.

Multi-laboratory collaborative studies showed strong concordance between independent NGS pipelines and strong correlation with established MAPREC readouts. Whole-genome analysis demonstrated highly consistent SNP profiles for most OPV products from the same manufacturer, while distinguishing products derived from different seeds or cell substrates. On this basis, candidate WHO reference reagents for OPV1 and OPV3 have been characterized with defined mutation frequencies suitable for assay calibration and validation.

Abstract

We propose a future control paradigm in which historical NGS data from consistency lots define acceptable genomic variability, allowing routine lot release based on conformity to predefined SNP profiles, with animal NVTs reserved only for out-of-trend investigations. This NGS-based framework offers a scientifically robust, animal-free approach aligned with One Health and 3Rs principles for global vaccine quality control.

Biosketch

Catherine Milne

EDQM

Catherine Milne 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, UK 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 to work in the fields of Official Control Authority Batch Release (OCABR) and biological standardisation. In her role as an EDQM Biological Standardisation Programme (BSP) administrator, she coordinated numerous projects for the establishment of reference standards and methods for the evaluation of human and veterinary biologicals with a focus on the 3Rs. In 2018 she was appointed as head of the section covering activities in the BSP, international standards for antibiotics (ISA) and OCABR of human and veterinary vaccines and medicinal products derived from human blood and plasma. Since January 2025 she is the Head of the Networks Division in the Intergovernmental Committees and Networks Department which supports the Official Medicines Control Laboratories' and the Official Cosmetics Control Laboratories' networks to foster common working methods, work sharing and mutual recognition through different activities. She represents EDQM as an observer at the EMA BWP, CAT and the 3Rs Working Party and is a member of the IABS VBC.

Abstract

Catherine Milne

Safety tests for vaccines; Strategies to remove and replace animal tests in the European Pharmacopoeia (Ph. Eur.)

Dr. Catherine Milne, Head of Networks Division, ICND, European Directorate for the Quality of Medicines and Healthcare, Council of Europe

Safety is a key quality parameter for vaccines for human and veterinary use. During regular production and quality control, tests are put in place to ensure that each batch is as safe and efficacious as those used in the clinical/field trials and approved. Traditionally many of these tests have involved the use of animals however it is recognised that in vitro tests can provide a scientific advantage for the consistency control in place of the in vivo assays which are generally more variable. Numerous in vitro opportunities are now available. When assessing the possibilities to replace or remove animal tests for safety, a holistic approach that considers evidence from the product development phase and evaluates the whole production and control process is recommended. Successful strategies depend on well characterised and standardised products and production processes and use of appropriate, validated, added-value quality control tests applied at the most appropriate stage of production. A careful review can identify tests which may be replaced with an in vitro alternative, removed due to redundancy in the testing scheme or removed after re-evaluation of the scientific added value in the current context. The presentation reviews different kinds of safety tests that may be used to assess vaccines and how the European Pharmacopoeia (Ph. Eur.) has evaluated the testing strategies for different products and tests to apply these principles. Examples include removal of general safety tests like the abnormal toxicity test and the target animal batch safety test and removal of the rabbit pyrogen test as part of the new pyrogen strategy outlined in Ph. Eur. chapter 5.1.13, in force from 01/07/2025. Other examples include toxicity testing for diphtheria , tetanus, acellular pertussis vaccines for human use and clostridial vaccines for veterinary use, residual live virus tests for veterinary vaccines and use of next generation

Abstract

sequencing for extraneous agents testing, which is facilitated by the new Ph. Eur. general chapter 2.6.41 High throughput sequencing for the detection of viral extraneous agents, as well as possibilities to use HTS to assess genomic consistency for assessment of neurovirulence. All decisions for change are based on sound scientific principles and consultation and EDQM is committed to continue to assess opportunities for advances in 3Rs and improved analytical tools.

- https://www.edqm.eu/en/alternatives-to-animal-testing
- https://www.edqm.eu/en/-/ph.-eur.-bids-adieu-to-rabbit-pyrogen-test-in-its-monographs
- https://www.edqm.eu/en/-/proceedings-of-workshop-on-alternatives-to-animal-testing-in-quality-control-of-veterinary-vaccines-now-available
- https://www.edqm.eu/en/-/ph.-eur.-to-replace-histamine-sensitisation-test-hist-for-residual-pertussis-toxin-testing
- https://www.edqm.eu/en/-/binacle-assay-for-tetanus-neurotoxin-outcomes-of-project-bsp136-2
- https://www.edqm.eu/en/-/epc-adopts-cutting-edge-hts-chapter-to-enhance-viral-contaminant-detection-in-biological-products

Biosketch

Ms. Shawn Novick

IABS

Shawn Novick has worked in the biotherapeutic field for over 30 years. She spent the first half of her career in analytical sciences, characterizing products for clinical and commercial approval including a number of cytokines, monoclonal antibodies, Fc-fusion proteins and protein conjugates. The second half of her career she was the Sr. Director of Quality Control at Seattle Genetics, where she built a Quality group from 4 to 50 analysts, working on an array of antibody drug conjugates. Shawn has contributed to a number of commercial products including Enbrel, Leukine, Bexxar, and Adcetris. She has written or edited multiple regulatory submissions and worked on successful CMC strategies for multiple products.

In addition to her day job, Shawn has organized and co-chaired workshops and conferences, including the annual WCBP conference held in Washington D.C. which brings together over 800 regulators and biotherapeutics professions for 3 days of close interaction. Shawn has published and presented on protein characterization and specification management and currently is consulting for biotechnology companies. She lives in Seattle, Washington.

Biosketch

Ole F. Olesen

Independent Expert

Following studies at the universities of Aarhus, Denmark and Cambridge, UK, as well as Copenhagen Business School, Ole worked for over 10 years in the pharmaceutical industry as group leader and Global Project Director for pre-clinical and clinical development of vaccines and injectables. Having subsequently held positions as director in the European & Developing Countries Clinical Trials Partnership (EDCTP), affiliated professor in global health at Copenhagen University and executive director of the European Vaccine Initiative (EVI), Ole has gained considerable experience in conducting and managing large international projects on vaccine development and applying new vaccinology methodology. Currently affiliated with the European Commission, Ole´s main responsibility includes the development and implementation of the EU´s strategy in the area of NAMs.

Biosketch

Dr. Henk-Jan Ormel

Henk Jan Ormel is the Chair of the Dutch Authority on Animal Testing (Centrale Commissie voor Dierproeven, CCD). He was from February until July 2024 a Member of the European Parliament (MEP) for the European People's Party (EPP), replacing an outgoing MEP. Before becoming a MEP, he participated for the World Health Organization (WHO) as Senior One Health Expert in 15 WHO Joint External Evaluations (JEE) of the International Health Regulations (IHR-2005). In 2023 he was the Lead of a team of 15 international experts, performing the JEE of Nigeria. From 2012 to 2022 he worked as Senior Veterinary Policy Advisor of the Chief Veterinary Officer of the Food and Agriculture Organization of the United Nations (FAO). He coordinated One Health and antimicrobial resistance (AMR) activities of FAO and was the global coordinator of the Tripartite Secretariat, a cooperation mechanism on One Health of WHO, FAO and WOAH (World Organization on Animal Health). He also coordinated the secretariat of the Global Framework on the progressive control of Transboundary Animal Diseases (GF-TADs) and represented FAO in the Global Agenda for Sustainable Livestock (GASL). From 2002 to 2012 he was a Member of Parliament of the Kingdom of the Netherlands. During his parliamentary career, he was closely involved in developing laws on Health, Agriculture and One Health and he was also involved in the annual financial decision-making processes of the budgets of the Ministries of Health, Agriculture and Foreign Affairs. In addition, he was Chairman of the Standing Parliamentary Committee on Foreign Affairs from 2007 - 2010 and Vice President of NATO Parliamentary Assembly from 2008-2010.

Biosketch

Upon resigning from Parliament in September 2012, Her Majesty the Queen bestowed upon him the Knight in the Order of Oranje Nassau. Before entering Parliament, he practiced for 19 years in the Dutch countryside as a general practitioner specialized in dairy cows. He graduated from The Faculty of Veterinary Medicine of the State University of Utrecht in 1983.

In April 2025 Henk Jan Ormel was elected Vice-President of IABS-EUROPE

Biosketch

Katarzyna Osetek-Müller

PhD Katarzyna Osetek-Müller

Katarzyna Osetek-Müller, PhD, is a scientist specializing in immunoassays, molecular biology, and genetics. At Bavarian Nordic in Martinsried near Munich, she leads the development of an ELISA assay to replace animal testing in quality control of the Tick-Borne Encephalitis (TBE) vaccine and evaluates immunoreactivity of the Chikungunya Virus-like Particle (CHIKV VLP) vaccine. Previously, Katarzyna was Team Lead and Deput Head of Reproductive Genetics at MVZ Martinsried GmbH (Medicover Genetics), where she managed an international team and advanced molecular diagnostics for reproductive health. Her expertise includes assay development and validation, whole genome amplification, next-generation sequencing, and diagnostics for monogenic disorders and infertility. She earned her PhD in Regenerative Sciences from Hannover Medical School, studying pluripotent stem cell induction and genetic stability, and a Master's in Biology from Jagiellonian University, focusing on gene mapping in mouse gametes. Outside the lab, Katarzyna enjoys skiing, dancing, and traveling.

Abstract

Katarzyna Osetek-Müller

Gyrolab-Based In Vitro Immunoassay for Potency and Quality Control of Chikungunya VLP Vaccine: A Sensitive Alternative to Animal Models

As the regulatory standards move toward replacing animal-based safety assays, robust in vitro methods form the foundation of vaccine quality control. VIMKUNYA is a single dose vaccine containing highly purified Chikungunya virus-like particles (CHIKV VLP) produced in a cell line and adjuvanted with aluminium. While pre-clinical and early development data were generated using in vivo experiments, routine quality control of the vaccine aimed to solely rely on animal-free tests. Monoclonal antibodies can be suitable for assessing key quality attributes and ensure comparability of commercial batches to those originally demonstrated to be safe and efficacious in clinical studies. Due to interference from the adjuvant, biolayer interferometry (BLI) was not suitable for measuring vaccine potency. Therefore, an automated in vitro assay using microfluidic in nanoliter-scale was established to quantify intact epitopes relative to total protein. This sandwich immunoreactivity assay utilizes well characterized CHIKV specific neutralizing antibodies—biotinylated mAb 10-18 for capture and AF-647 conjugated mAb 242-5 for detection. Parallel studies comparing the in vitro assay to the mouse immunogenicity model, by testing formulations with decreasing protein concentration, demonstrated a similar dose-dependent response. Additionally, accelerated temperature studies indicated a good correlation between the in vivo and in vitro assay. These experiments demonstrated that the in vitro immunoassay has greater analytical sensitivity compared to mouse immunogenicity model and can detect small changes in product quality before they become biologically significant. These findings confirm that the in vitro assay reliably detects varying amounts of immunologically relevant epitopes, accurately reflecting the intended biological activity of the CHIKV VLP vaccine. This provides rationale for quality control exclusively based on the in vitro assay, while product potency is represented by the ratio of immunoreactivity (as measured by the microfluidic assay presented) to total protein concentration.

Biosketch

In-Sook Park

Dr. In-sook Park is the Director General of the Korea Regulatory Science Center (K-RSC), where she leads efforts to strengthen regulatory science and support innovation in Korea's bio-health sector. Over her 20+ year career at the Ministry of Food and Drug Safety (MFDS)—including her tenure as Director General of Biopharmaceutical and Herbal Medicine Evaluation Department—she played a pivotal role in shaping Korea's regulatory framework. Her leadership was instrumental in establishing the country's Investigational New Drug (IND) system and facilitating expedited approvals of medical products during the COVID-19 pandemic.

Dr. Park is also an affiliated professor at K-NIBRT, Yonsei University, and actively contributes to global regulatory capacity-building. She holds a Ph.D. in Pharmacology from Chungbuk National University, an M.S. in Social Pharmacy from Sookmyung Women's University, and both an M.S. in Pharmaceutical Life Science and a B.S. in Pharmacy from Yeungnam University.

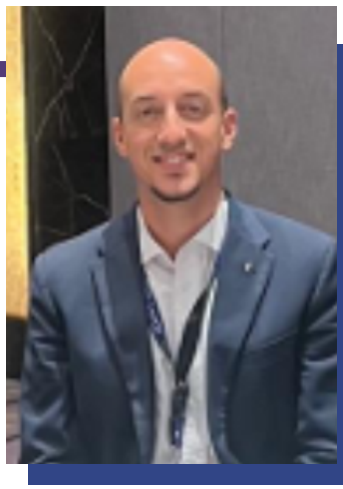
Biosketch

Corinne Philippe

Corinne Philippe leads the global Regulatory Intelligence, Policy and Communications team at Boehringer Ingelheim Animal Health. She is a Doctor of Veterinary Medicine and holds a master's degree in Regulatory Affairs (TOPRA M.Sc. Reg Aff.), with over 20 years of experience in the animal health pharmaceutical industry, particularly in regulatory affairs (EU and international), biologicals development, team leadership, and trade association engagement. She has chaired the company's French ethical committee since 2021.

Passionate about animal health, the environment, 3Rs, and One Health, Corinne has held various membership and chair roles in European and international trade associations since 2006.
Deeply engaged in efforts to increase regulatory acceptance of alternative methods, she actively contributes to HealthforAnimals, AnimalhealthEurope and SIMV working groups on the 3Rs, including regular presentations at related events.

Biosketch



Luca Porfiri

Laboratory Specialist, FAO RAP ECTAD

Luca Porfiri is the Regional Laboratory Specialist at the Emergency Centre for Transboundary Animal Diseases (ECTAD), Regional Office for Asia and the Pacific (RAP), Food and Agriculture Organization of the United Nations (FAO). He coordinates regional laboratory capacity-building programmes across Asia and the Pacific, supporting countries in strengthening their animal health systems and laboratory networks. In this role, he has facilitated the ASEAN Regional Animal Health Laboratory Technical Advisory Group (Lab-TAG) meetings, represented FAO at the ASEAN Laboratory Directors' Forum, and served as a technical lead for national laboratory systems and biosafety and biosecurity in WHO Joint External Evaluations in Nepal, Kyrgyzstan, Indonesia, Maldives, and the Philippines.

Luca has organized and led multi-stakeholder initiatives such as the Animal Health Laboratory Strategic Roadmap Workshops in Southeast Asian countries and One Health events including Breaking Silos: A Multi-Sectoral Approach to Biosecurity. His technical expertise spans biosafety and biosecurity, laboratory governance, vaccines, quality assurance, and digital innovation, including support for the deployment of the SILAB Laboratory Information Management System in Southeast Asia.

Before joining FAO, Luca worked for over five years at the Joint FAO/IAEA Centre of Nuclear Techniques in Food and Agriculture in Austria, contributing to global research and capacity-building in veterinary diagnostics, immunoassays, and gamma-irradiated vaccine development for transboundary animal diseases such as African swine fever and avian influenza.

Biosketch

He has authored scientific papers, technical guidelines, training materials, and biosafety protocols.

He holds a Master of Public Health from the University of Edinburgh, a Master's degree in Biological Sciences (Nutrition and Functional Food) from the University of Camerino, and a Bachelor's degree in Biological Sciences from the University of Rome Tor Vergata.

Abstract

Luca Porfiri

Building Competence in Non-Animal Testing Strategies for Vaccine Quality Control

The global transition toward replacing, reducing, and refining animal testing in vaccine quality control requires not only scientific innovation but also strong and coordinated efforts to build competence and confidence in alternative testing strategies. Drawing on previous experience as an immunologist at the Animal Production and Health Section of the Joint FAO/IAEA Centre and current work as a laboratory specialist with FAO ECTAD in Asia and the Pacific, this abstract outlines practical pathways for National Control Laboratories to develop, validate, and adopt non-animal testing approaches, including in-vitro assays and immunoinformatic, to predict and/or evaluate vaccine efficacy.
Key enablers such as robust quality systems, strategic and sustained capacity building, and strengthened regional collaboration are highlighted, with examples from ongoing FAO-supported initiatives in the Asia Pacific region. The presentation will propose a structured and progressive roadmap consisting of assessment, pilot implementation, mentorship, and institutionalization to guide countries in transitioning toward modern, humane, and more reproducible vaccine testing strategies. These efforts promote animal welfare, enhance vaccine supply chain resilience, advance One Health objectives, and reinforce preparedness for emerging and re-emerging infectious diseases.

1. Determination of Vaccine Immunogenicity Using Bovine Monocyte-Derived Dendritic Cells - PubMed
2. Irradiated Non-replicative Lactic Acid Bacteria Preserve Metabolic Activity While Exhibiting Diverse Immune Modulation - PubMed

Biosketch

Dr Dieter Pullirsch

Dr. Dieter Pullirsch is Head of the Group Analytics of Vaccines and Plasma Pools at the Austrian OMCL and Deputy Head of the Department Analytics of Biological Medicines. He is assessor for official control authority batch release of vaccines and blood products. He is an expert in working groups of the European pharmacopoeia and EMA and groups related to OCABR activities. He received his doctoral degree in genetics from the University of Vienna. After postdoctoral research positions at the Institute Pasteur and the University of Vienna, he joined the Austrian Medicines Agency in 2010. As a science-driven person he is strongly involved in standardization and optimization of test methods and 3R projects.

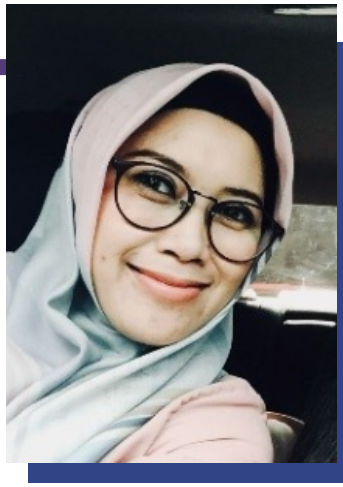
Abstract

Dr Dieter Pullirsch

Potency testing of aluminium adjuvanted tick borne encephalitis virus vaccines

Within the Innovative Medicines Initiative 2 project Vaccine batch to vaccine batch comparison by consistency testing (VAC2VAC), non-animal potency assays based on ELISAs were developed for tick borne encephalitis virus (TBEV) vaccines. TBEV belongs to the genus Orthoflavivirus and is endemic in Middle, Eastern and Northern Europe as well as in Northern Asia. Licensed vaccines in the EU are inactivated, whole-virus formulations adjuvanted with aluminium hydroxide. We present the development of ELISA assay systems that have the potential to replace the lethal mouse challenge assay for batch release testing as well as for stability studies.

Biosketch



Irma Riyanti

Personal Statement

I have worked in the pharmaceutical industry since 2002 and joined Bio Farma since September 2002 as a bacterial vaccine quality control staff, and responsible for biological testing related to vaccines and serum, such as testing for potency, toxicity, identity (in vivo and in vitro), vaccine stability programs, development of new test methods and validation/verification of test methods.

In 2005 I moved to chemical and physical quality control department, responsible for chemical and physical testing of vaccines (bacteria and viruses), sampling and testing of raw materials & packaging and testing of water monitoring used in production and QC. In 2019 I moved back to the bacterial vaccine quality control department.

I am involved in several project teams including the project auction team, the energy saving team, innovation committee, vaccine technology transfer, both as a technology recipient and as a technology provider/sender, such as with Biovac-South Africa (Pentavalent liquid vaccine), Arabio (Td vaccine), Sanofi and Biken (IPV/sIPV vaccine), Luzhu (Meningitis), and ALS-Ghana (Td vaccine).

From 2005 to present I have been a team of internal and external auditors of Bio Farma, including auditors related to GMP aspects, ISO (9001, 14001 and 18001) including as a BNSP auditor (professional certification auditor). Experienced in external audits both domestically and abroad, including supplier vendors such as raw material and packaging material, external calibration laboratories and several visits to external vendors for benchmarking (Klockner Pentaplast-Thailand) and visit of Pentavalent RTF production capability (Cadilla-India).

Biosketch

Several test collaborations that have been carried out are related to protein testing of Hepatitis B with Berna Biotech (Korea), SII and BBIL (India). Until now, I have actively participated in collaborations related to new biological standard candidates with NIBSC/MHRA, for example for several new candidate biological standards, and proficiency testing (ATP for BCG vaccine, IBP Thailand)

In 2019 I joined the 3Rs DCVMN working group and participated in several projects such as PSPT (Pertussis Serological Potency Test) and multi dilution assay (MDA) for potency testing. The results of this PSPT collaboration have been published in journals published in WHO Drug Information and Preprints.

From 2022 until now I have joined HSI (Human Society International) as a Steering Group and in this Steering Group we discuss all issues related to 3Rs, regulation and what are the obstacles in implementing 3Rs.

As industry representative, I actively participate in reviewing, correcting the draft of the Indonesian pharmacopoeia that is currently being prepared, TRS draft related to 3Rs, providing corrections, suggestions and input regarding implementation and obstacles in the field before this document is ratified and used. Participate in WHO workshop, DCVMN meeting also HSI meeting as steering group member.

I have been a speaker at the Indonesian NRA event, with the topic QC related such us sampling (products, raw materials and packaging) and have also been a speaker on vaccine quality control (Imapac, Singapore, 2022), providing training to NRA on several new tests and collaboration for standardization of national reference standard with NRA

Contibute in developed a new test related to the 3Rs principle, the development of specific toxicity tests and irreversibility tests on bulk diphtheria and tetanus with cell base method. In addition, exploring the change of tests from pyrogen to MAT (Monocyte Activation Test), change of Multi Dilution Assay (MDA) to Single Dilution Assay (SDA) in potency test.

Several trainings related to production, QMS, project transfer, process validation, cleaning validation, GMP aspects, vaccine quality testing, test method validation, data integrity have been attended both domestically and abroad.

Biosketch

In summary, I have the expertise, leadership, training, experience related to the biopharmaceutical industry, especially vaccines and motivation in learning new things and new projects.

Citations:
1. Christina, VH., Tim, S., Irma., R (2023). Potency Testing of Whole Cell Pertussis Containing Vaccines : Lesson Learned in a Multi Laboratory Assesment of the Pertussis Serological Potency Test. Preprints. DOI : 10.20944

B. Positions, Scientific Appointments, and Honors

- 2023 - Present HSI (Human Society International), Steering Group Member
- 2020 - 2022 DCVMN, PSPT Consortium Member
- 2019 - 2022 DCVMN, 3Rs Working Group Member
- 2023 - Present Td Transfer Project Team, BF- ALS Ghana
- 2005 – Present Bio Farma Auditor Team
- 06/2019 – Present Bio Farma, Head of Bacterial Vaccine QC Department
- 09/2006 – 06/2019 Bio Farma, Head of Chemical and Physical QC Department
- 07/2005 – 07/2006 Bio Farma, Chemical and Physical QC Staff
- 10/2002 – 06/2005 Bio Farma, Bacterial Vaccine QC Staff
- 01/2002 – 09/2002 Sanbe Farma, Beta lactam and Cephalosphorine IPC supervisor

C. Contributions to Science

1. My initial publication was related to the PSPT project organized by DCVMN. In the project, Bio Farma became one of the organizations participating in this project to conduct PSPT tests and compare the test results with existing methods (Challenge method / Kendrick Test) with varied test materials.
The test results from participants were used as the basis for determining the next stage when this method would be used and implemented. The final project was met in New Delhi on 5-6 July 2022 and the results of this project were submitted to a journal that had been published through preprints (Nov 2023) and had been included in WHO Drug Information (2024).

a. Christina, VH., Tim, S., Irma., R (2023). Potency Testing of Whole Cell Pertussis Containing Vaccines : Lesson Learned in a Multi Laboratory Assesment of the Pertussis Serological Potency Test. Preprints. DOI : 10.20944 ; WHO Drug Information Volume 38, Number 4, p. 981 - 1009

Biosketch

2. The next publication is to actively participate in the WHO workshop on standard references, problems and how to maintain standard references in each manufacturer and discussions on the problem solving provided. The workshop was held in Bali, November 2023 with a published workshop report.

a. WHO, Dianliang Lei, Irma R, Report of a WHO workshop on implementation of the WHO manual for the preparation of reference materials for use as secondary standards in antibody testing, 2023,14-16 November, Denpasar, Indonesia. https://cdn.who.int/media/docs/default-source/biologicals/report-who-workshop-secstd-manual_final.pdf?sfvrsn=36229937_1&download=true

3. Actively participate in reviewing, correcting, analyzing the latest reference draft before it is approved and published. Participation in the WHO TRS review of the 3Rs policy which is still in draft status and will be finalized in 2025, October.

a. WHO, Dianliang Lei, Irma R ; Guidelines on the phasing out of animal tests for the quality
control of biological products (draft).,
https://cdn.who.int/media/docs/default-source/biologicals/call-for-comments/who-guideline-on-3rs---draft-1-version-29-nov-2024-pc_clean.pdf?sfvrsn=7809e18d_1

4. Actively participate in the collaboration of the latest NIBSC/MHRA biological standard candidates and report the results of the collaboration to the organizers.

a. Laura Hassall, Peter Rigsby, Paul Sticking, Irma Riyanti; Collaborative study for the calibration of a replacement International Standard for Diphtheria Antitoxin Equine, 2023, Biologicals https://pubmed.ncbi.nlm.nih.gov/37149975/

b. Shalini Rajagopal, Robert Tierney, Peter Rigsby, Paul Stickings, Dori Ugiyadi; Collaborative study: Calibration of 1st WHO Reference Reagent for Tetanus Antitoxin Equine for use in Flocculation Test; https://cdn.who.int/media/docs/default-source/biologicals/bs-documents-(ecbs)/2022-documents/new-2022-document-susan/bs-2022.2431_rajagopal--s_who-rr-for-tetanus-antitoxin-for-flocculatin-test_final.pdf?sfvrsn=1e942761_1&download=true

Biosketch

Charles Sandy

Charles Sandy is a public health physician and researcher (orcid: 0000-0003-0264-7900) with expertise in national and regional communicable disease programme and policy leadership as well as health product regulatory policy design and capacity building. This includes specific experiences in Primary Health Care, HIV/AIDS, Tuberculosis, Neglected Tropical Disease, Occupational Health and Safety, Clinical Trials and Research Ethics Ecosystems Strengthening.

Biosketch

Dr. Gautam Sanyal

After receiving his Ph.D. in Chemistry from the University of Virginia, USA, Gautam held academic faculty positions at the University of Florida, Mayo Clinic and Hamilton College before moving to pharmaceutical industry. During the 27 years that Gautam spent in pharmaceutical industry, he headed R&D departments and groups at Merck, AstraZeneca and MedImmune (AstraZeneca Biopharmaceuticals). For the past several years, Gautam has focused his efforts on global health initiatives. He is a CMC Subject Matter Expert with the Gates Foundation and has been associated with other global health organizations such as CEPI, PATH and the International Vaccine Institute.

Gautam is a scientific expert in development of analytical and biophysical methods that are essential to batch release and characterization of vaccines and biopharmaceuticals. His expertise extends to rational formulation design, as demonstrated by delivery of several safe and effective formulations to clinical trials for recombinant protein based VLPs and attenuated viral vaccines as well as therapeutic proteins and oncolytic viruses. More recently, Gautam has been involved in advisory roles on projects emerging from the newer vaccine technologies, with a focus on analytical characterization and assays for mRNA vaccines. Apart from his extensive work on vaccines and biologics, Gautam led biochemistry, biophysics and protein science teams in target-based discovery of antibacterial therapeutics. He has an extensive record of highly cited publications including original research papers, review articles and book chapters.

Abstract

Gautam Sanyal

In vitro Analytical Characterization based Quality and Potency Assessment of mRNA Vaccines

Robust in vitro potency assays have successfully replaced animal-based (in vivo) tests for lot release of a few recombinant protein-based vaccines after correlation between in vitro and in vivo assays was established. mRNA vaccines differ from protein subunit or virus like particle vaccines in requiring a cell transfection step for translation of mRNA to express the encoded protein antigen. To evaluate in vitro-in vivo correlation, test samples of varying target potencies ranging from 100% to 0% can be created by inducing gradual structural degradation under stress conditions such as thermal stress. These samples can be tested in parallel by an in vitro cell transfection assay and in vivo antibody induction and immune response in vaccinated mice. This technique has been used for recombinant protein-based vaccines, which have the advantage of a single step in vitro assay that does not require cell-based protein expression. Nevertheless, such a systematic evaluation is entirely possible, as it has been demonstrated that changes in structural integrity of mRNA constructs encapsulated in lipid nanoparticles, are correlated with expression of functionally intact proteins in cells. Furthermore, robust analytical characterization assays may be developed with the ability to correlate primary and higher order structures of mRNA constructs with immunologically relevant functionality of the expressed protein. These analytical assays may, in future, eliminate the need for a “potency assay” for well-characterized mRNA vaccines.

Biosketch

Dr Kota Sato

National Veterinary Assay Laboratory

Executive Research Officer/Section Leader (for Immunology and Pathology)
Biotech/Regenerative Medicine Team Director
National Veterinary Assay Laboratory, Ministry of Agriculture, Forestry and Fisheries of Japan

Dr. Kota SATO is a research officer of National Veterinary Assay Laboratory, Ministry of Agriculture, Forestry, and Fisheries of Japan. He is in charge of regulatory affairs, especially for biotech/regenerative medicinal products and biologicals including vaccines. He is also the chairperson of the Expert Working Group for Biologicals of VICH.

Work history

- Associate Professor (Hokkaido University, 2006-2016)
- Research Fellow (Immunology) (University of Texas Southwestern Medical Center at Dallas, 2003-2005)
- Assistant Professor (Tottori University, 1996-2006).
- Researcher (Ministry of Agriculture, Forestry and Fisheries of Japan, 1994-1995)
- DVM, PhD, Hokkaido University

Abstract

Kota Sato

National Veterinary Assay Laboratory, Ministry of Agriculture, Forestry and Fisheries of Japan

The Veterinary International Convention on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) is a program initiated by the EU, Japan, and the United States to harmonize technical requirements for the registration of veterinary medicinal products. While typically developing technical guidance necessary for registration, it has also established several exceptional guidelines aimed at achieving the goal of the 3Rs principles in animal testing. These guidelines are administrative guidance to advance the 3Rs rather than technical requirements for the registration. Guidelines concerning the replacement of batch potency testing (BPT) were proposed by the EU based on this concept. However, under the agreement that they would serve as technical guidance, the concept paper was finalized by the VICH Steering Committee in 2023. In the EU, this concept is already implemented as European Pharmacopoeia monograph 5.2.14 “Substitution of in-vivo method(s) by in-vitro method(s) for the quality control of vaccines.” In the Unite states, requirements for using in vitro tests are specified in 9CFR § 113.8 “In Vitro Tests for Continuous Release Testing,” and validation of these tests is conducted according to Veterinary Services Memorandum 800.112. In Japan, alternative test methods to in vivo potency testing for vaccines are approved as long as they are reasonable. Thus, while the replacement of in vivo BPT with in vitro testing is fundamentally possible, international harmonization requires further discussion within VICH member countries. The task of drafting the guidelines was assigned to the Biologicals expert working group/BPT subgroup, which has held several meetings to date. Several conceptual and scientific issues have been identified and discussed extensively. The draft guidelines are currently under review by members, aiming for finalization by the EWG.

Biosketch

Heidemarie Schindl

Heidemarie Schindl, Dipl.-Ing., is Head of the Department of Analysis of Biological Medicinal Products at the Austrian Official Medicinal Control Laboratory (OMCL), part of the Austrian Federal Office for Safety in Health Care (BASG). She also serves as Deputy Head of the Institute for Assessments and Analytics and as an assessor for biological medicinal products.

Before joining BASG, she held senior positions at Baxter BioScience in Vienna, including Head of QA/Assessments and Audits and GMP Officer for plasma protein production.

She earned her Diplom-Ingenieur degree in Food and Biotechnology from the University of Natural Resources and Life Sciences (BOKU) in Vienna.

Her expertise includes quality control of biological medicines, official control authority batch release of vaccines and blood products, and GMP compliance.

Heidemarie is an EMA expert and actively contributes to several international bodies, including the EDQM Group 15 (Vaccines), the European Pharmacopoeia Commission, and the WHO National Control Laboratory Network for Biologicals.

She also contributed to the IMI2 VAC2VAC project on vaccine batch consistency testing, which promotes the 3R principles for animal welfare in scientific research

Biosketch

Dr. Shahjahan Shaid

GSK, Head Novel Analytical Technologies

Dr. Shahjahan Shaid currently leads the team of Novel Analytical Technologies within the Global MSAT organization of GSK aimed at enabling the company strategy to introduce new analytical technologies which covers reduction of animal testing and animal derived materials by substituting them with state-of-the-art technologies.

Shahjahan joined Novartis Vaccines, now GSK, in 2013 to lead and implement innovative technologies in the Quality Control of the company. Prior to that, he worked for diagnostics of zoonoses at the German Federal Health Robert Koch Institute.

Shahjahan holds a PhD in Biology with a focus on immunology and host pathogen interaction and has experience in the pharmaceutical vaccine industry with an extensive knowledge of introducing novel assays in cGMP.

Biosketch

Dr Sarah Sheridan

Dr Sarah Sheridan is a Technical Consultant at Merck, providing scientific, technical and regulatory consultancy within the BioReliance ® Biosafety Testing business of Merck. Drawing on over 30 years of experience in the human and animal health biotech industries, Dr Sheridan provides biosafety testing consultancy for the company's global client base to support pre-clinical to commercial phase biosafety testing of client manufactured products spanning monoclonal antibodies to vaccines and novel gene therapies. Dr Sheridan has a Ph.D. in Veterinary Virology from the University of Cambridge, UK and a B.Sc. Honours degree in Life Science.

Biosketch

Rabindra Prasad Singh

Dr Rabindra Prasad Singh contributed immensely on animal vaccines (PPR, Sheeppox, Bluetongue, Rabies, Canine distemper, FMD), monoclonal antibody based/molecular/ point of care diagnostics (Rinderpest, PPR, Rabies, CDV, Brucella, FMD), disease epidemiology (PPR, Rabies, CDV & FMD), host pathogen interaction (CDV, PPRV) & antiviral strategies for rabies. Integrated application of PPR vaccine and diagnostics at mass scale during last 2 decades for PPR control/eradication reduced disease incidence significantly in India (75-90 % reduction) leading to livelihood/nutritional security and small ruminant population gains. Similarly, Dr Singh's effort in balancing FMD vaccine potency vis-à-vis availability for mass application combined with application of indigenously developed diagnostics led to minimum FMD incidences, in the country during recent years, which was never experienced before. Dr Singh's contribution on animal science based start-ups, entrepreneurship development & IP management is noteworthy and became sustainable practices in India. Dr Singh is recognized globally for his contributions on PPR, FMD and other transboundary animal diseases. He has been chairman and Member of several National Committees on Rinderpest. FMD and PPR. He has been involved in several committee at international level constituted by FAO of United Nations and World Organization of Animal Health (WOAH) under the umbrella of GF-TADs viz i) Member PPR Eradication Programme: Global Advisory Committee, ii) member Partnering and Financing Panel (PFP), iii) Member joint Advisory Committee (JAC) on Rinderpest, iv) Member OiE adhoc group on rinderpest, v) Regional resource person of OIE/WOAH etc.

Abstract

Rabindra Prasad Singh

Application of VP2 & VP4 mAb-based Indirect ELISA for Potency and Stability - Assessment of Indian Trivalent Vaccine Formulations

Jitendra Kumar Biswal[1], Jajati. Keshari Mohapatra[1], Manoranjan Rout[1] , Shyam Singh Dahiya[1], Mamata Pasayat[1], Ramakant Acharya[1], Sagar Sangam Rautaray[1], Amina Yasmin[2], Chloe Grant[2], Eva Perez[2], Santina Grazioli[3], Anna Ludi[2], Stephen Berryman[2], Toby Tuthill[2], Donald P. King[2], Rabindra Prasad Singh*[1]

[1]ICAR-National Institute on Foot and Mouth Disease, Bhubaneswar, India
[2]The Pirbright Institute, United Kingdom
[3]IZSLER, Brescia, Italy
*Correspondence: Rabindra Prasad Singh, rpsvirology@gmail.com, rabindra.singh@icar.org.in

Developing a simplified in vitro assay to estimate the antigenic content and structural integrity of formulated vaccines to infer potency is considered an important advancement in FMD vaccine quality control. This study evaluated an indirect-ELISA using a mAb directed against the VP4 protein of FMDV to estimate the total 146S antigen content in a serotype-independent manner. Using another mAb specific to VP2 in parallel, the total viral structural antigenic mass regardless of capsid integrity was estimated. Detection and quantification of intact whole virion capsids 146S vs. dissociated pentameric 12S form could assess the potency of the formulated vaccine with more than 90% confidence when correlated with post-vaccination thresholds defined for vaccine release using serum SN_{50} titres for cattle at 28 days. These VP4 and VP2 mAb ELISAs were applied to antigen extracted from fourteen batches of formulated trivalent vaccine (containing O, A and Asia1 Indian strains) before and after acid treatment for quantification of intact virus particles (146S) vis a vis total antigen in serotype-independent manner. In VP4 ELISA, all cattle QC passed batches revealed an absorbance A_{490} value of > 1.2 at 1:2 dilutions before acid treatment, except for only one batch wheredespite vaccine passing QC through cattle serology, it revealed an OD of 0.7. All cattle QC failed batches generated lower OD_{490} values below 0.7. Some of the cattle potency QC failed batches, despite revealing higher OD_{490} (>2.5) in VP2 ELISA, showed

Abstract

considerably less absorbance in VP4 ELISA, suggesting possible disintegration of the whole 146S viral antigen during manufacturing or subsequent storage of the vaccine. In view of this, the VP4 ELISA could be a useful indicator for vaccine potency and an in-process assay for vaccine manufacturing as well. To make the assay more robust for quantitative assessment of intact whole viral antigen and to decide the absorbance threshold for inducing protective antibody titres in target hosts, a series of purified whole viral antigen preparations of known quantity may be required to run in parallel as reference standards. Also, this assay can generate credible first-hand information on expected vaccine potency rapidly before cattle testing, thereby saving valuable time and resources invested in the routine batch release process.

In addition to potency estimation, the stability upon storage of structural antigen in QC-passed vaccine formulations from two different vaccine manufacturers in India, were also investigated using the VP4 mAb ELISA. From these vaccine batches, two scenarios emerged. i) the vaccines with a higher initial quantity of antigen, equivalent to approximately 6 $PD_{50,}$ may be stable up to 12 months by the time they reach to $3PD_{50}$, ii) the vaccines passed at a marginally higher than threshold SN_{50} value, may be stable enough for about 6-8 months to induce protective antibodies. Currently in India, all the vaccine preparations are invariably used in the field within 6 months after batch release certifications due to demand from the ongoing biannual intensive vaccination programme. However, in a scenario when vaccine banks are established for any emergency response in view of creation of disease-free zones, a high potency vaccine (may be above 6 PD_{50}) would be required for implementing ring vaccination to check the spread of virus. Such an assay to rapidly evaluate the stability of intact viral capsid in the stored vaccines before deployment in the field could add a lot of value under those scenarios. Also these assays may be useful to check vaccine antigen integrity in conditions when stringent maintenance of cold chain system is questionable in an administrative unit.

Biosketch

Dean Smith

IABS

Advisor to the Director and Sr. Evaluator in the Center for Vaccines, Clinical Trials and Biostatistics at Health Canada. He has over 25-years of experience in research and regulatory science in support of innovation for vaccine development, manufacturing and quality control. He is active in the development / implementation of related guidance, and has a wide range of biologics-based scientific and regulatory experience from his Sr. Scientific Evaluator and management roles in Centre Divisions including Viral and Bacterial Vaccines, Hemostatic Agents & Blood Substitutes, as well as the Clinical Evaluation Division-COVID.

Representing Health Canada, he has contributed to WHO's smallpox and rabies vaccine guidance, the Extended Controlled Temperature Conditions (ECTC) guidance in support of innovative vaccine stability
assessment for vaccination campaigns over the "last mile" with limited cold chain. Additionally, he contributed to WHO's R&D Blueprint International COVID-19 vaccine consultations during the pandemic, and since 2018 has been engaged in the regulatory / industry patient-centric harmonized specification exchanges in line with an assumed intent of ICH Q6B.

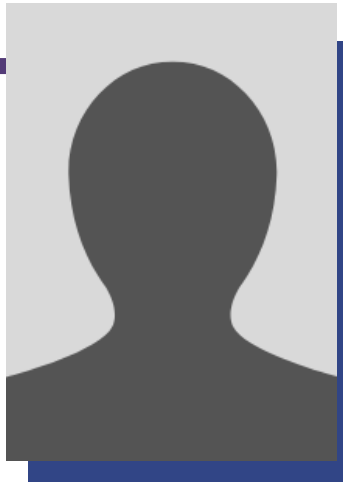
Smith is Health Canada's representative to the European Directorate of Quality of Medicines (EDQM) Group 15 (Vaccines and Sera) of the European Pharmacopeia. He has served on the Science and Ethics.

Biosketch

Advisory Committee for VAC2VAC under the European Vaccines Initiative to substitute more appropriate in vitro QC methods for existing in vivo vaccine QC methods, on the Regulatory Advisory Group to WHO and CEPI (Coalition for Epidemic Preparedness Innovations) during the COVID-19 pandemic, and most recently on the current EDQM mRNAVAC-Working Party.

Smith's Ph.D. in Immunology is from the University of Alberta, Canada, where his research dealt with vaccine antigen discovery, autoimmunity and viral vector-based gene therapy. He was a Research Associate at the National Research Council's Institute of Biological Science, Vaccine Design Group in Ottawa, prior to joining Health Canada.

Biosketch



Paul Stickings

MHRA

Dr Stickings is Head of Vaccine Reference Materials at the UK Medicines and Healthcare products Regulatory Agency and has extensive experience in the development of biological reference materials and analytical methods used for vaccine quality control testing. Research interests have focused on the development and validation of cell-based assays for bacterial toxins and immunochemical assays for toxoid vaccines, as well as development and characterisation of novel therapeutic monoclonal antibodies. He is a member of the European Pharmacopoeia Commission Expert Group on Vaccines and Sera and the United States Pharmacopoeia Expert Committee on Complex Biologics and Vaccines and was a Principal Investigator on the VAC2VAC project, leading the work package related to development
of immunochemical methods for vaccine control as part of a consistency approach.

Abstract

Paul Stickings

A cell-based assay for tetanus toxin as an alternative to animal models used in safety testing of tetanus toxoid

A cell-based assay for tetanus toxin as an alternative to animal models used in safety testing of tetanus toxoid

Ceyda Caliskan[a], *Paul Stickings[b], Shalini Rajagopal[b], Charlotte Leese[a], Peter Rigsby[b], Kevin Markey[b], Paul Stickings[b], Ciara Doran[a,*], Andrew Peden[a,*]

[a]University of Sheffield, School of Biosciences, Sheffield, S10 2TN, UK; [b]Science and Research Group, Medicines and Healthcare Products Regulatory Agency, South Mimms, Potters Bar, Hertfordshire, EN6 3QG, UK

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Chemically inactivated tetanus toxin (TeNT), known as tetanus toxoid, is the active component of vaccines and batches of tetanus toxoid undergo routine batch testing to confirm absence of specific toxicity. This testing is currently done in animals and has a 21-day observation period. As a potential alternative non-animal model, we have developed a sensitive and specific TeNT cell-based assay (CBA) based on LAN5 neuroblastoma cells that were genetically modified to express a NanoLuciferase-VAMP2 reporter (because VAMP2 is the intracellular target for TeNT). The CBA is highly sensitive to TeNT and specific for the tetanus holotoxin. Specificity has also been shown using tetanus antitoxin which completely prevents the VAMP2 cleavage caused by the toxin, suggesting that the CBA has potential additional utility as a potency test for measurement of functional anti-tetanus antibodies.

Abstract

Based on preliminary observations from studies using representative batches of tetanus toxoid from manufacturers of human and veterinary tetanus vaccine, we will discuss the potential utility of the CBA as a routine batch control test for safety testing of tetanus toxoid and considerations for its implementation.

Funding: This study was funded by NC3Rs grant NC/Y000978/1.

Abstract

Catrina Stirling

One Health drives for New Approach Methodologies (NAMs) approaches for Vaccine Batch release

The talk will cover at a high level why vaccines and the continuity of supply of consistent high quality, cost effective, safe and efficacious vaccines is so critical for One Health. Addressing the challenges with current animal based batch release tests in delivering this and how a transitions to NAMs in vitro approaches can help us deliver this.

Biosketch

Danilo Tagle

Danilo Tagle is currently Director, Office of Special Initiatives at the National Center for Advancing Translational Sciences (NCATS) of the National Institutes of Health (NIH) where he leads efforts in developing innovative tools and technologies that can greatly accelerate development of diagnostics and therapeutics. These programs involve interdisciplinary collaborations between intramural and extramural components of NIH, and entail partnerships with other agencies, such as FDA, NASA, and DARPA, as well as with private sector. Some of the programs include tissue chips, 3D bioprinting, automated chemistry, electronic nose technology for disease diagnosis, quantum technologies, and the isolation and analyses of exosomes for biomarker and therapy development. He has served on numerous advisory and review committees and editorial boards.

He currently serves on the Biological and Physical Sciences Federal Advisory Committee, on the White House OSTP Microgravity Science and Technology Interagency Working Group, and serves as the point-of-contact for the liaison to the NASA/NIH/Department of Health and Human Services partnership. Dan obtained his PhD and MS in molecular biology and genetics from Wayne State University School of Medicine. He was an NIH National Research Service Award postdoctoral fellow in human genetics at the University of Michigan. Dan has authored many scientific publications and has garnered numerous awards, including more recently the Roscoe O. Brady Award for Innovation and Accomplishment; the Henry J. Heimlich Award for Innovative Medicine; the HHS Secretary's Award for Distinguished Service: Rapid Acceleration of Diagnostics (RADx) Initiative, and the NASA Silver Group Achievement Award.

Abstract

Danilo Tagle

The Pre-clinical (and Clinical) Utilities of Microphysiological Systems as In Vitro NAMs in Drug and Vaccine Development

New Approach Methodologies (NAMs) has recently seen a surge as model systems in biomedical research, and as tools for safety and efficacy studies, particularly following announcements by regulatory bodies like the FDA and EPA, and funding agencies like the NIH, to replace or reduce animal testing. The current NAMs landscape includes advanced technologies, such as in vitro microphysiological systems (MPS) or tissue chips, organoids, in silico computational models powered by AI, and in chemico assay systems, which are reshaping drug discovery and chemical risk assessment. Current methods used to predict safety and efficacy of candidate drugs accounts for as much as 90% failure rate. Approximately 30% of drugs have failed in human clinical trials due to adverse reactions, and another 60% fail due to lack of efficacy. A number of these failures can be attributed to poor predictability of human response from animal and 2-D in vitro models. Recent systematic studies on the predictive value of animal models have demonstrated a poor correlation between animal data and human outcomes owing to substantial interspecies differences in key disease pathways and disease-induced changes in gene expression profiles, highlighting the critical need for alternative methods to model complex human-relevant conditions. To address this challenge, the NIH Tissue Chips program have been supporting the development of MPS as better risk assessment tools that can provide more reliable readouts of toxicity and efficacy of candidate therapies. MPS are bioengineered 3-D microfluidic platforms utilizing chip technology and human-derived cells and tissues that are intended to mimic tissue cytoarchitecture and functional units of human organs and systems. In addition to drug development, these microfabricated devices are useful for modeling human diseases, and for studies in precision medicine and environmental exposures.

Abstract

By emulating human physiology, these chips have the potential to increase the predictive power of preclinical modeling, which in turn will move the pharmaceutical industry closer to clinically relevant and ultimately animalfree drug discovery. MPS as an innovative preclinical modeling platforms offer improved clinical predictions of human response, provide a more efficient approach to mechanistic investigation, early safety liability screening and translationally relevant modeling of drug distribution and metabolism. One promising area in bridging the gap between innovation and real-world application is in vaccine development and testing. Influenza virus infections cause significant global morbidity and mortality and pose a serious pandemic risk due to the virus's propensity for reassortment and mutation. Current influenza vaccines elicit strain-specific responses and are only 10-60% effective depending on the year. There is an urgent need for a broadly protective influenza vaccine that elicits robust, persistent, and broadly cross-reactive B and T cell responses. MPS platforms that includes peripheral and lymphoid tissue in static platforms have been developed to study the innate and adaptive response to vaccination, as well as a lymphoid-follicle-on-chip under dynamic flow which produces antigen-specific antibodies to vaccination. These platforms are also being used to study the interplay between vaccine and adjuvant reactogenicity and innate immune stimulation, and thereby derisk vaccine targets by elucidating their inflammatory profiles prior to advancement to clinical trials. This presentation will summarize the decade of NIH investments in developing MPS as a NAMs tool for safety and efficacy assessments, in modeling diseases, in building confidence with regulatory and industrial partners, in facilitating regulatory acceptance, and ultimately in community adoption and use of MPS in biomedical research.

Biosketch

Lorenzo Tesolin

Lorenzo Tesolin is working at Sciensano, the Federal Health Institute in Belgium, in the division of Quality of Vaccines and Blood Products, where he is responsible for vaccine batch release and evaluation of the quality part of registration and variation dossiers of vaccines and biologicals. At Sciensano, he is also the manager of the in vivo & immunology testing unit. Lorenzo is actively involved in scientific advice procedures at national and European level and participates as product expert in GMP inspections on the request of the Belgian and European (EMA) Medicine Agencies.

Lorenzo Tesolin is a member of the Vaccine OCABR drafting group of the European Directorate for the Quality of Medicines (EDQM). Lorenzo works as auditor for the EDQM, where he is frequently asked to participate in Mutual Joint Audits of European control laboratories. He is also in firm collaboration with the World Health Organization (WHO) as temporary advisor in the framework of the regulatory strengthening of regulatory authorities (NRA training) and is involved in the WHO National control Lab Network (WHO-NNCL). He is also a temporary expert for the evaluation of products (Product Summary File evaluation) and manufacturers (site audits) for the prequalification procedure for assessing the acceptability, in principle, of vaccines for purchase by UN agencies.

Lorenzo Tesolin did his Master in Organic Chemistry in 1995 at the University of Louvain-La-Neuve in Belgium and then worked for four years as Project Manager and then Production Manager at Galactic Belgium, in the food adjuvant industry.

Biosketch

He obtained a Master in Business Management in 2004 at the Louvain School of Management while working as QC manager for Benechim (API toll manufacturer) for 6 years. In April 2006, he then joined the institute of public health (now Sciensano) as the laboratory coordinator before taking over the batch release and assessment responsibilities in 2008.

Abstract

Lorenzo Tesolin

How to Build NCL Competences? A Case Study from the Belgian National Control Laboratory

Competence development within Official Medicines Control Laboratories (OMCLs or NCLs) is essential for ensuring regulatory robustness, scientific reliability and public trust in vaccines. This case study presents a structured framework for building and sustaining expertise in complex analytical and regulatory environments. It highlights key enablers such as targeted training, method transfer protocols, and reference & reagent supply. Emphasis is placed on harmonizing technical aspects and promoting peer learning. Practical examples illustrate how competence building supports assay validation and replacement of in vivo testing by non-animal testing.

Biosketch

Janette Turner

Jan's PhD was in genetic toxicology but she has spent a large part of her career in the Life Science industry, as both an R&D scientist and in global product management, providing tools and reagents to pharma in high throughput screening and safety assessment functions. Latterly, Jan has worked in the cell therapy area, providing equipment and support for production of these new therapies. She has worked extensively with iPSCs for cardiotoxicology and neuro degenerative diseases and participated in the FDA CiPA initiative from 2013. As Prinicpal, Medicines at Humane World for Animals, Jan has initiated the medicines workstream to change the way medicines are tested from animal based methods to new approach methodologies (NAMs), globally and with harmonization across regions.

Biosketch

Dr. Joris Vandeputte

Past President IABS

Joris Vandeputte was elected President of IABS (International Alliance for International Alliance for Biological Standardization Biological Standardization) in June 2016. He is founding member of IABS-EU the European affiliate of IABS. IABS-EU implements the objectives of IABS at European level. IABS-EU is partner of the EU IMI (Innovative Medicines Initiative) projects ZAPI and VAC2VAC (www.IMI.eu, www.zapi-imi.eu, www.vac2vac.eu.

IABS hold its founding congress in Lyon in 1955. It is the global independent platform, interface, where stake-holders meet for exchange of science and issues related to vaccines, cell and gene therapy and human Biotherapeutics. IABS stimulates consensus building which might eventually be translated in regulatory frameworks and advises to decision makers.

Joris Vandeputte is also founder and president of TRIVAROP, a public affairs consultancy advising companies and associations in the area of global health care. Joris has more than 40 years industry and
international organisation's experience in vaccines, conceiving and developing vaccine policies at global level and towards developing countries in particular. Working with European institutions and policymakers on innovation, health and development is his main activity.

Biosketch

Ms Laura Viviani

Consultant
HSI/SciEthiQ

Laura has been working in the field of implementation of new non animal based assays in vaccines and biologicals since 2011, first in Novartis International, then in Novartis Vaccines and Diagnostics, GSK Biologicals and in the Developing Countries Vaccine Manufacturers Network. Since 2017, she works as consultant for many international organizations on the promotion of global regulatory alignment on implementation of non-animal approaches for human and veterinary biological products. In particular, she is supporting Humane Society International in non-animal methods implementation and acceptance. She is engaged in analyzing dynamics in how biomedical research is opening on new models and methods (organoids, in silico, etc.) and in general in supporting organizations in project creation and management.

Biosketch

Wipawee Wongchana

Wipawee Wongchana, Ph.D. is a medical scientist at the Institute of Biological Products, Department of Medical Sciences, Thailand. Her work focuses on the regulatory system for vaccines, specifically lot release, laboratory testing, and reviewing the Chemistry, Manufacturing, and Controls (CMC) of vaccines. Her expertise extends to both Polio and COVID-19 vaccines, including those based on the mRNA platform. A significant aspect of her work is the development of new testing methods to ensure the consistency of vaccine quality and safety. Her work also involves developing alternative testing methods to replace animal testing. Her academic background in biotechnology and immunology provides a strong foundation for her research, with a focus on molecular and cellular immunology, particularly the role of macrophages and inflammatory responses.

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