Animal testing for vaccines - Implementing Replacement, Reduction and Refinement: Challenges and Priorities

Organized by
The International Alliance for Biological Standardization
IABS
Bangkok, Thailand
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Scientific Committee

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Dr. Robin Levis	FDA / CBER, USA
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Dr. Thitawat Chanthaworn	National Institute of Animal Health, Thailand
Dr. Jim Webster	Ruakura Research Centre, New Zealand
Dr. Hilde Depraetere	European Vaccine Initiative (EVI), Germany
Dr. Sylvie Uhlrich	Sanofi-Pasteur Lyon, France
Dr. Carmen Jungbaeck	International Alliance for Biological Standardization (IABS), USA
Dr. Scott Craig	Therapeutic Goods Administrator, Australia
Dr. Bob Sitrin	Vaccine Development Global Program – APTH, USA

TUESDAY DECEMBER 3rd

08:00 Registration

09:00 Welcome Remarks
Nakorn PREMSRI, Director, National Vaccine Institute, Thailand
Joris VANDEPUTTE, President, International Alliance for Biological Standardization (IABS)
Hilde DEPRAETERE, CEO, European Vaccine Initiative (EVI), Germany

Animal use and 3Rs

Chairperson:
Coenraad HENDRIKSEN, Intravaac;

09:30 Animals in batch testing: need for 3Rs
Suresh JADHAV, Serum Institute of India, India

09:55 The (long) journey towards the implementation of the 3Rs – every step counts
Eriko TERAO, European Directorate for the Quality of Medicines & Healthcare (EDQM), France

10:15 Towards deletion of general batch safety tests: recent progress and next steps
Marlies HALDER, European Commission, Joint Research Centre, EURL ECVAM, Italy

10:30 Coffee break

Chairpersons:
Koji ISHII, National Institute for Infectious Diseases, Japan
Jim WEBSTER, OIE Collaborating Center, New Zealand

11:00 Monocyte activation test (MAT)
Elaine COCCIA, Istituto Superiore di Sanità,, Italy

11:15 Rabies potency testing: glycoprotein assay
Koraphong PINYOSUKHEE, Ministry of Public Health, Thailand

11:30 Potency testing and 3Rs: general overview
Sylvie UHLRICH, Sanofi Pasteur, France

11:50 When animals are still needed for Reduction and Refinement
Coenraad HENDRIKSEN, Intravaac, The Netherlands

12:10 Implementation of 3Rs in Quality Control testing of vaccines
Sunil GOEL, SIIPL, India

12:30 Lunch

Product development and in vitro production / analysis

Chairpersons:
Yeowan SOHN, Seoul National University, South Korea
Robin LEVIS, FDA / CBER, U.S.A.

14:00 Production of Japanese encephalitis vaccine using the Vero cell-line
Tuan DAT, Vabiotech, Vietnam

14:20 Development of cell-based pandemic influenza vaccine for national security
Parichat DUANGKHAE, Government Pharmaceutical Organization, Thailand

14:40 HPV vaccine in vitro / in vitro release test history and current situation
Robert SITRIN, PATH, U.S.A; Li Shi, Shanghai Zerun Biotechnology Co, China

Improved product characterization using non-animal methods

Chairpersons:
Gautam SANYAL, Vaccine Analytics, LLC, USA
Denis LAMBRIGTS, GSK Vaccines, Belgium

15:10 Product characterization by non-animal methods: general overview and the VAC2VAC project
Hilde DEPRAETERE, CEO, European Vaccine Initiative (EVI), Germany

15:35 Three samples of product characterization

15:35 – Tick borne encephalitis vaccine (TBEV)
Dieter PULLIRSCH, The Austrian Agency for Health and Food Safety (*AGES*), Austria

15:50 – DTaP vaccine
Paul STICKINGS, The National Institute for Biological Standards and Control (NIBSC) United Kingdom

16:05 – Towards the end of the NIH test for rabies vaccines
Jean-Michel CHAPSAL, European Partnership for Alternatives to Animal Testing (EPAA), France

16:20 Coffee break

Harmonization: challenges & opportunities

Chairpersons:
Richard HILL, International Alliance for Biological Standardization (IABS)
Wassana WIJAGKANALAN, BioNet-Asia, Thailand

16:50 What did we learn from the past?
Arnoud AKKERMANS, National Institute for Public Health and the Environment (RIVM), The Netherlands

17:10 Regulatory acceptance for the substitution of *In Vitro for In Vivo* vaccine potency and safety assays science versus the fear factor
Dean SMITH, Health Canada, Canada

17:30 Replacement of in vivo assays, from one to one replacement to the evolution of strategy on new products and beyond
Jean-François DIERICK, GSK, Belgium

17:50 Assessing the requirement for animal studies in WHO biologics guidelines: a proposal for integrating the 3Rs
Anthony HOLMES, NC3RS, United Kingdom

17:50 Meet the expert. Several experts will be available in an informal setting

WEDNESDAY DECEMBER 4TH

Harmonization: challenges & opportunities

Chairpersons:
Wassana WIJAGKANALAN, BioNet-Asia, Thailand
Richard HILL, International Alliance for Biological Standardization (IABS)

08:30 Statements from various international organizations
European Directorate for the Quality of Medicines & Healthcare (EDQM), France, Eriko TERAO
World Organization for Animal Health (OIE), New Zealand, Jim WEBSTER
Food and Drug Administration (FDA / CBER), U.S.A., Robin Levis
Humane Society International (HSI), Switzerlanad, Laura VIVIANI
Bill & Melinda Gates Foundation (BMGF), U.S.A., Gautam SANYAL
Coalition for Epidemic Preparedness Innovations (CEPI), United Kingdom, Gautam SANYAL
Developing Countries Vaccine Manufacturers Network
(DCVMN International), Switzerland, Sunil GOEL

09:45 Collaboration and communication of regulatory bodies and industry: panel discussion
Moderators:
Joris VANDEPUTTE, International Alliance for Biological Standardization (IABS)
Robert Sitrin, PATH, U.S.A.
Panelists:
Robin LEVIS, FDA / CBER, U.S.A.
Richard HILL, International Alliance for Biological Standardization (IABS), U.S.A.
Suresh JADHAV, Serum Institute of India, India
Guang Gao, PATH, China
William McCauley, Animal Health Institute, U.S.A.

10:45 Coffee break

11:15 Workshops (parallel) – Select one

Validation, acceptance, harmonization & implementation
Laura VIVIANI, Humane Society International (HSI), Italy
Marlies HALDER, European Commission, Joint Research Centre, EURL ECVAM, Italy
Jim WEBSTER, OIE Collaborating Center, New Zealand
Supaporn Phumianmorn, Ministry of Public Health, Thailand

Non-animal testing and product characterization
Hilde DEPRAETERE, CEO, European Vaccine Initiative (EVI)
Denis LAMBRIGTS, GlaxoSmithKline
Li SHI, Shanghai Zerun Biotechnology Company
Sunil Goel, SII, India

Needs of emerging economies (training, reagents, materials, etc.)
Suresh JADHAV, Serum Institute of India
Wassana WIJAGKANALAN, Bio-Net Asia
Yeowan SOHN, Seoul National University

12:45 Lunch

14:00 Workhops (parallel) – Select one

Validation, acceptance, harmonization, implementation
Non-animal testing and product characterization
Needs of emerging economies (training, reagents, materials, etc.)

15:30 Coffee break

16:00 Report of workshops and plenary discussion

17:00 The Way Forward
Coenraad Hendriksen, Intravaac, The Netherlands
Chair:
Joris VANDEPUTTE, International Alliance for Biological Standardization (IABS)
Supaporn PHUMIANMORN, Department of Medical Sciences, Ministry of Public Health, Thailand

17:30 End of meeting