



International Alliance for Biological Standardization

IABS and DCVMN
Opportunities for Collaboration

website: www.iabs.org
e-mail: iabs@iabs.org



WHO WE ARE

- Scientific Society established in 1955
- Headquartered in Switzerland
- Recognized as a nonprofit organization in Switzerland and USA
- Officially recognized by WHO as a non-governmental organization (NGO) that is in an official relationship with them



OUR MISSION

To promote consensus building on contemporary and emerging issues related to medical, scientific, and technological developments in human and veterinary biologicals, through interdisciplinary discussions, conferences, publications and partnerships.



OUR CORE ACTIVITIES

- ***Meetings***

More than 130 conferences and workshops have been organized to date.

- ***"Biologicals"***

An international journal focused on biological product development and issues; published 6 x per year by Elsevier.

- ***Proceedings of Conferences***

– Published as Supplements to *Biologicals* **starting in 2014**



HOW WE ARE ORGANIZED

➤ Membership

- Individuals >300
- Institutions 12 (**DCVMN**)

➤ Structure

- General Assembly – meets once every 2 years
- Board of Directors (15) – meets twice a year
- Executive Committee – meets as needed, acts for BoD
 - President, 2 VPs, Sec., & Treasurer
- Committees
 - **Human Vaccines**, Veterinary Vaccines, Biotherapeutics, Cell & Gene therapy



HOW WE ARE ORGANIZED

Human Vaccines Committee

Members

Bernard Fritzel & Teresa Aguado (co-chairs)

Ian Gust, University of Melbourne, Australia; **Brigitte Autran**, Université Pierre & Marie Curie, Paris, France; **Paul-Henri Lambert**, University of Geneva, Switzerland; **Steven Black**, University of Cincinnati, Ohio, USA; **David Lewis**, University of Surrey, UK; **Jan Bonhoeffer**, Brighton Collaboration, Switzerland; **Pieter Neels**, EMA, UK; **William Egan**, Novartis, USA; **Volker Oeppling**, PEI, Germany; **Jim Robertson**, UK (retired); **Martin Friede**, WHO, Geneva; **Rebecca Sheets**, USA (NIH, retired); **Nathalie Garçon**, GlaxoSmithKline Biologicals, Belgium; **Emanuelle Trannoy**, Sanofi Pasteur, France; **Giuseppe Del Giudice**, Novartis, Italy; **David Wood**, WHO, Geneva; **Michel Goldman**, IMI, Brussels



HOW WE ARE ORGANIZED

Human Vaccines Committee

How It Functions

- **Selects conference topics**
- **Selects meeting organizer(s) - committee**
 - **Develop meeting agenda**
 - **Invite speakers/session chairs**
- **Meets by teleconference; communicates by email**



VACCINE MEETINGS

2013

- Predictive Markers of Safety and Immunogenicity of Adjuvanted Vaccines
18-19 April 2013, Rockville (USA)

2014

- New Technologies for New Vaccines (cosponsored with Fraunhofer Center for Molecular Biotechnology)
23-26 March 2014, Wilmington DE (USA)
- Human Challenge Trials in Vaccine Development: Scientific and Regulatory Issues
Fall of 2014, venue to be determined



Example of the Impact of an IABS Conference

- 2004 Conference on cell substrates for vaccine production – especially CCLs
 - ✓ Recommendation: WHO should revise its guidance document on cell substrates
 - ✓ WHO established a Study Group in 2006
 - ✓ Draft revisions developed and made available for public comment
 - ✓ Final draft adopted by WHO ECBS in 2010
 - ✓ WHO implementation workshop in Beijing 2013



Example of the Impact of an IABS Conference

- 2011 conference on adventitious agents and risk assessment (followup to finding PCV in rotavirus vaccines)
 - ✓ Consideration of WHO draft risk assessment document
 - ✓ Public comments
 - ✓ Development of Case Studies (past examples)
 - ✓ 2013 WHO workshop
 - ✓ Publication of principles of risk assessment & case studies in *Biologicals* (early 2014)
 - ✓ WHO Guidelines in preparation for 2014 ECBS



IABS / DCVMN Opportunities

Short-Term

- Participate in IABS vaccine committee
 - ✓ Provide DCVMN perspective on issues/topics that should be considered at future conferences
- Individual companies and/or staff within companies may wish to become IABS members

Long-Term

- Education related to vaccine quality management systems and compliance with regulatory requirements
 - ✓ Workshops, Meetings, Conferences



IABS / DCVMN Opportunities

Next Steps

- Vaccine Committee
 - ✓ Select a DCVMN representative
- Companies/individuals may consider membership in IABS
- Education
 - ✓ Explore feasibility, roles and responsibilities, and consider an administrative framework as well as funding mechanisms