



International Association for Biologicals

**Presentation to Japanese Biologicals Forum
by Tony Lubiniecki**

Tokyo, 16January2008



- **Scientific Society** established in 1955
- **Headquartered** in Switzerland
- **Recognized** as a non-profit organization in Switzerland and USA
- **Recognized** by the WHO (*World Health Organization*) and by the OIE (*Organisation Mondiale de la Santé Animale - World Organisation for Animal Health*) as an official non-governmental organization (NGO) that is in an official relationship with them.
- **Is in an official relationship** with IFPMA.

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



Governance is by an elected Board and by the Executive Committee chaired by the president, and includes 2 vice-presidents - one for Human Biologicals and one for Veterinary Biologicals - , the secretary, and the treasurer.

Operational via:

- ◁▷ Human Therapeutics Committee
- ◁▷ Human Vaccine Committee
- ◁▷ Blood Committee
- ◁▷ Publication Committee
- ◁▷ Veterinary Scientific Conference Committee
- ◁▷ Finance and Resource Development Committee
- ◁▷ Ad hoc working groups

Mission / Objectives



- ***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
- ***Objectives:***
 - To create an ongoing interface among leaders in clinical and basic research, biological product development, public health, manufacturing , and regulation
 - To educate healthcare professionals on topics relating to biological product discovery, development, and regulation
 - To provide a unique forum where consensus can be reached on topics of importance to medical scientists and other healthcare professionals
 - To promote the Association among those who work on the scientific issues in the biopharmaceutical industry, public health organizations, regulatory bodies, and academic medicine and research.

Activities



- The journal "***Biologicals***"

An international Journal published 6 x per year by Elsevier

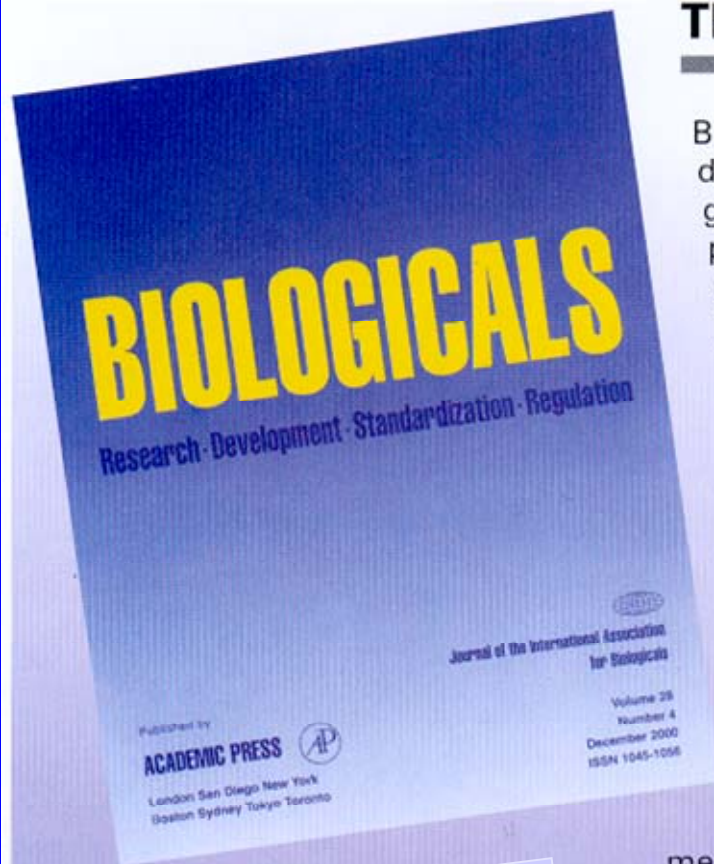
- The ***Newsletter***

An IABs publication which reports the activities and news items to the members

- ***Meetings***

More than 125 meetings and workshops have been organized

- ***Proceedings*** are published in the *IABS symposia series - Development in Biologicals* published by Karger or as special issues of *Biologicals* in full or abstracts and summaries.



**Editor:
Girish Vyas,
San Francisco**

THE JOURNAL

BIOLOGICALS is a major international journal devoted to the timely publication of broad ranging reports relevant to the development, preparation and quality control of biologicals used in human and veterinary medicine. The journal is also intended to be an important forum for debate and news concerning all aspects of biological preparation, standardization and regulatory requirements. Reports on biologicals derived from the new technologies (gene-transfer and expression, monoclonal antibodies, etc.) and other contemporary approaches are especially encouraged.

Three types of papers are acceptable: Original research reports, short papers and review articles dealing with topics of current interest. In addition the journal will assure prompt publication of comments and letters to the editor, book reviews, meeting and patent/licence reports, and information on regulatory and other new publications.



Meetings

The goals of meetings are to:

- **Exchange and update information**
- **Discuss issues**
- **Identify unresolved issues and priorities**
- **Reach recommendations**
- **Disseminate outcomes**



Recent meetings

- **Advances in Transfusion Safety**
 - Sydney (Australia)
- **State of the art analytical methods for the characterization of biological products and assessment of comparability**
 - Bethesda (USA)
- **New cells for new vaccines**
 - Miami (USA)
- **CMC specifications**
 - Bruxelles (Belgium)



In 2006 IABS initiated a Symposia Series on:

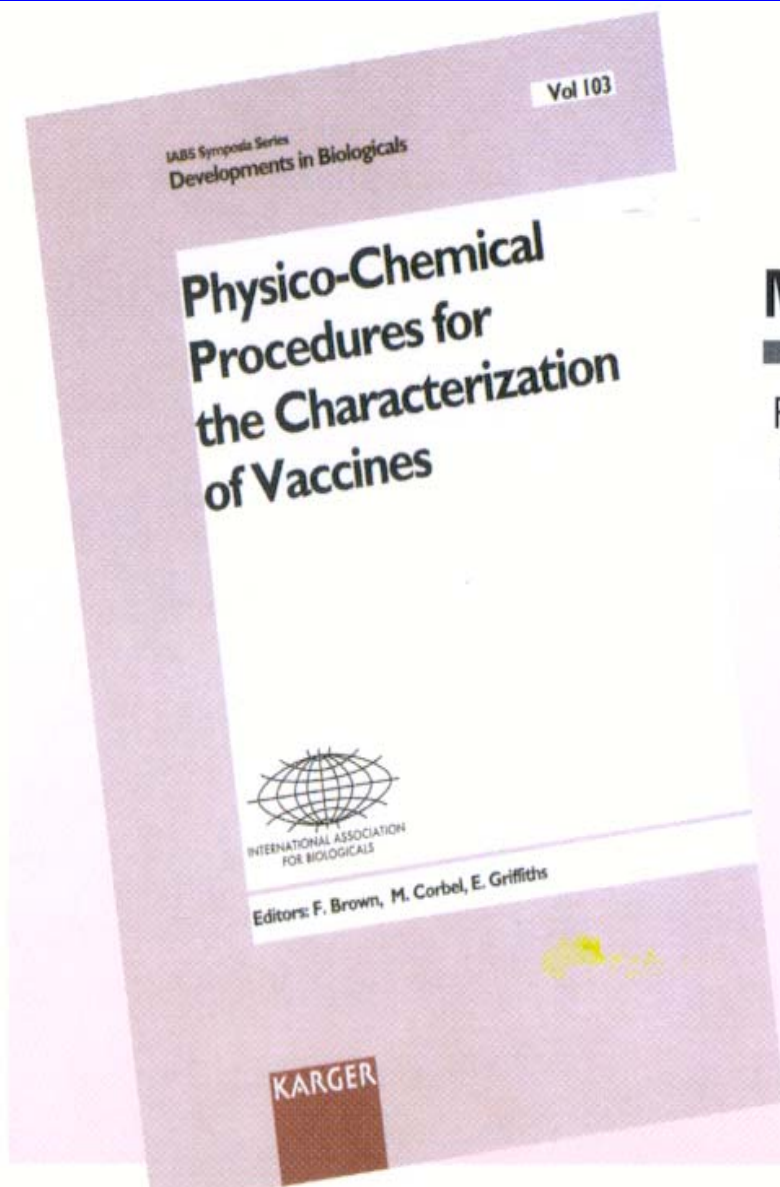
Biological Crisis Management in Human and Veterinary Medicines

First Symposium was on

**Emerging Diseases and Bioterrorism: Preparedness and
Implementation Issues**

This was held in November 2006 in Lyon, France.

It was cosponsored by: WHO, OIE, NIAID (NIH)



MEETINGS AND PROCEEDINGS

From 1955 to 1965, the proceedings of the first meetings were issued from various sources and are no longer available. In 1965, S. Karger was selected as the official publisher of the Association. Since that time, the IABS has convened more than 100 international meetings of contemporary interest in human and veterinary medicine followed by the publication of the proceedings.

Past achievements



- 1960s** Led the effort to convince regulators of the safety of viral vaccines produced in human diploid cell lines.
 - 1970s** Led the effort to convince regulators that purified viral and protein products could be prepared safely from continuous cell lines (e.g., Vero, Namalva for human biologicals & BHK-21 for veterinary vaccines).
 - 1980s** Led the effort to convince regulators that safe monoclonal antibodies and rDNA products from continuous cell lines (e.g., CHO) can be produced.
 - 1990s** Organized key scientific meetings on genetic stability, virus safety, specifications, cell substrates ... that led to the successful development of many of the WHO and ICH quality documents.
 - 2000s** Organized conferences in collaboration with regulatory agencies on transfusion safety issues and international veterinary regulatory requirements that resulted in improved regulatory decision-making.
- Currently organizing discussions of novel cell substrate issues and reviewing issues associated with the potential immunogenicity of biotech products - particularly « follow-ons ».**
- Involved in discussions at different levels, leading to regulatory guidelines of biosimilars, and on INN issues. Most recently participated at WHO advisory meetings on these topics.**

Current IABs Officers invite you to
consider IABS membership –
Visit our Website: www.iabs.org for
details



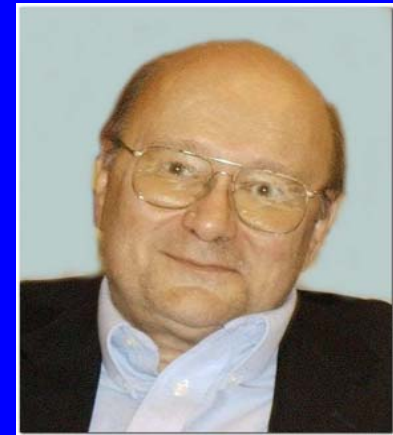
Aliza Eshkol
President

John Petriccianni
Human VP

David Espeseth
Veterinary VP

Daniel Gaudry
Secretary

Tony Lubiniecki
Treasurer





Thank you