



**MINUTES OF THE 30th GENERAL ASSEMBLY OF THE
INTERNATIONAL ALLIANCE FOR BIOLOGICAL STANDARDIZATION**

held on September 29th, 2014 at the EDQM facilities, Strasbourg, France;

Sixteen members were present.

Apologies and proxies were sent by 31 members.

The quorum required by the Constitution of the Alliance being reached, the General Assembly was validly constituted.

I. NOTICE OF THE MEETING:

The agenda of the meeting was sent by mail to all members during the first days of July 2014.

II. MINUTES OF THE 29TH GENERAL ASSEMBLY:

The Minutes, published on the IABS website were accepted as a correct record.

III. REPORT OF THE PRESIDENT (J. Petricciani):

1. IABS Conferences:

Our primary activity is organizing and sponsoring international conferences on selected topics with the objective of developing a consensus on technical issues as well as recommendations that could be considered by relevant organizations with decision-making responsibilities. Specific information on the IABS conferences held during the past two years will be presented by the Vice-President for human biologicals, Dr Becky Sheets; but overall we have had a successful series of conferences.

As pointed out in 2012 by Professor Loewer in his President's Report, most of our conferences cannot be financed solely by registration fees, which makes it necessary to raise additional funds in order to cover all costs. Although we have made progress, this is an area that needs more attention in the coming years, in terms of the process and timeliness of our fundraising activities.

During the past two years we have enhanced our infrastructural support for meeting organizers and we have refined our internal processes. Specifically, the guidelines for the organization of an IABS conference were updated in 2013 and distributed to our committee chairs, and our website has been re-organized to better promote upcoming meetings.

2. Infrastructural improvements:

Dodet Bioscience (DBS) decided not to renew its contract with IABS in 2013. However, Abigail Charlet, who was working for IABS through DBS, was recruited to become the Scientific Secretariat Manager. She is located in Lyon, and IABS records were transferred from DBS to her. The transition went quite smoothly, and we are very pleased with the changes that have been proposed and implemented by Ms. Charlet in cooperation with Dr. Gaudry who supervises the Secretariat.

Significant progress has been made to bring IABS up to date using the internet. We now have on-line registration available for our conferences, and in the near future we plan to expand our on-line capability to include membership renewals as well as voting in the next election (2016). These advances are the direct result of the close working relationship between Abigail Charlet and our webmaster, Guillaume Soubrier.

3. Co-operation with other organizations:

Close cooperation with WHO has continued during the past two years. WHO has participated in several of our conferences, IABS representatives have participated in the WHO Expert Committee on Biological Standardization, and IABS participated in the World Health Assembly by providing written and verbal comments on two resolutions dealing with strengthening national regulatory agencies in developing countries, and ensuring the quality of biosimilar products.

Memoranda of Understanding to establish a framework for long-term cooperation were finalized with the Fondation Mérieux and the Brighton Collaboration.

4. Structural changes:

The most important action that we took recently is the establishment of a European affiliate (IABS-EU) with headquarters in Lyon, France. This is a landmark event in the history of IABS, and represents a significant amount of work on the part of Joris Vandeputte, Abbie Charlet, and Daniel Gaudry. IABS-EU is now officially recognized by French authorities as a nonprofit organization. As such, it can participate with EU partners in scientific activities such as the European 2020 initiative to fund research in the biologicals field through consortia.

We also established the position of Executive Director, and recruited Joris Vandeputte to help guide IABS through the next year, particularly in our relationship with IABS-EU and developing working relationships with other organizations with similar interests.

In order to carry out these changes, we also have proposed several changes or modifications to the IABS Constitution.

As mentioned in his report, the chair of our Publications Committee and Editor-in-chief of *Biologicals*, Dr Girish Vyas, will be stepping down from those positions in January of 2015. We are very grateful to Girish for his invaluable work over the past decade to enhance our journal and to bring it to its current stable position. We have selected a successor to Girish, and the next several months will be a transition period during which he will become familiar with the responsibilities. A formal appointment and announcement will be made in January 2015. In addition, we terminated our relationship with Karger, and have consolidated our publications with Elsevier (the publisher of *Biologicals*). As a result, proceedings of IABS conferences will no longer be published as books by Karger. Instead, proceedings will be published as supplements to the journal.

Finally, we established a new scientific committee: Cell and Gene Therapy, which is chaired by Prof. Takao Hayakawa. The committee is currently working with WHO on the development of a guidance document for cell therapy.

5. The future of IABS:

IABS has a long history in the field of biologicals, and is well-recognized as having made important contributions through its many conferences that provide a neutral platform for the exchange of information, experience, and ideas. We have now entered a new phase in the development of the organization. There is a great potential for both expanding our activities and for financial stability in the years ahead, and I look forward to helping the Alliance reach those objectives.

IV. REPORT OF THE VICE PRESIDENT FOR HUMAN BIOLOGICALS (R. Sheets):

The Vice President for Human Biologicals of IABS is responsible for the three committees that cover a range of human biologicals – vaccines, biotherapeutics, and cell and gene therapies. Each of these committees had a very active year, as may be noted by the individual reports from the chairpersons:

- Human Vaccines Committee: Teresa Aguado de Ros and Rebecca Sheets
- Biotherapeutics Committee: Tony Mire-Sluis
- Cell and Gene Therapies Committee: Takao Hayakawa

Each committee organized and held one or more international workshops and a list of conferences sponsored or co-sponsored by IABS during the 2013/2014 year appears below with brief summaries. As with all IABS conferences, outcomes of the various activities throughout this year inform and facilitate regulatory standardization.

Human Vaccines Committee: the conference organized for this year will be held in the days immediately following the General Assembly in 2014. Thus, outcomes cannot yet be reported, but some verbal updates will be provided at the appropriate time regarding attendance. It is expected that due to significant sponsorships of the conference, this conference will finish “in the black.” It is anticipated that the on-going effort by WHO to update their clinical guidance document could take into account the outcomes of this conference by inclusion of a section on human challenge trials in the revised guidance. Thanks to the strong chairmanship of Teresa Aguado de Ros for gaining significant sponsorship for this conference.

Biotherapeutics Committee: Two conferences were organized and held during this year by this committee. The net income to IABS for these conferences was positive. The first of these on Setting Specifications was co-sponsored by FDA and was well-attended by regulators and industry. The second on Statistical Methods was

better attended by industry with somewhat lower regulatory attendance, but still a fair margin. Thanks to the strong chairmanship of Tony Mire-Sluis for gaining good participation, attendance, and sponsorship.

Cell and Gene Therapies Committee: This committee hosted an important conference to tackle the difficult issue for standardization in the field of cell therapies. The outcome of the conference was so positive that work has begun on a potential guidance document and consideration for a 2015 follow-on conference potentially co-hosted with WHO is taking place. This could lead to a WHO guidance document for cell therapies, which is quite needed. Thanks to the strong chairmanship of Takao Hayakawa for advancing this area into a sound deliverable and for gaining the sponsorship of the Japanese Science and Technology Agency in these endeavors.

MEETINGS SPONSORED OR COSPONSORED BY IABS 2013/2014:

1. ***Setting Specifications for Biotechnology Products: Facing Evolving Challenges***, Bethesda, USA (25-26 September 2013) -

This meeting was to bring together regulators, scientists, academia and industry to discuss guidance on how to control the quality of medicines through specifications during development and post marketing.

2. ***NFID 16th Annual Conference on Vaccine Research*** (Baltimore, USA (22-24 April, 2013)
-Co-sponsored meeting with NIAID-

The Annual Conference on Vaccine Research provides high-quality, current reports of scientific progress featured in both invited presentations and submitted oral abstracts and posters. By drawing upon an international audience of scientists and researchers, healthcare professionals and trainees, veterinarians, vaccine manufacturers, and public health officials, the conference organizers aimed to encourage the exchange of ideas across a broad range of disciplines. The opening Keynote Presentation featured Dr. D.A. Henderson discussing Eradication of Disease through Vaccination, and symposium include: Malaria Vaccines-Current and Future, and Prospects for New Tuberculosis Vaccines.

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

This two-day workshop provided the participants with a better understanding of the progress that has been made in this challenging field and the new orientations in the development and evaluation of adjuvants and adjuvanted vaccines.

4. ***NCNV-VII – Protein to Product***, Wilmington, USA (17-20 March, 2013)

Conference topics included New Developments in Production Strategies; Progress in Clinical Product Development, Target Design and Engineering; Formulation; Assays and Evaluation; Sustainability and the Global Regulatory Environment.

5. ***Challenges Toward Sound Scientific Regulation of Cell Therapy Products***, Kyoto, Japan (March 7-8, 2014) --Co-sponsored with Japan Science and Technology Agency (JST)-

The meeting intended to promote international dialogue and exchange of information and points of view in this evolving field. The starting point was to share a common recognition of the essential scientific elements for early product development, evaluation and control of cell therapy products. Then we will move on to identify very critical points/issues to be solved, improved, and/or developed in terms of technical as well as scientific regulation in order to facilitate the availability of products in a rational and timely manner, which will be valuable globally to public health.

6. ***Statistical and Data Management Approaches for Biotechnology Drug Development***, Rockville USA (27-28 Aug 2014) Co-organized by IABS and FDA

This meeting was organized to help resolve existing challenges in ensuring the quality of biotechnology medicinal products and to bring high quality medicines to patients. Guidance on how to use statistics for a variety of activities required during biotechnology product development such as method development, improvement and replacement, product comparability, biosimilarity exercises and stability program development were provided by the speakers and panel members. In addition, the complexity of the types of data and the volume being analysed is ever increasing and how best to manage such data were discussed.

Among the challenges that were explored:

- Statistical Challenges with showing Comparability and Biosimilarity (Equivalence, small data sets, tolerance intervals etc.)
- Using statistics for assay methods (Statistics for development, qualification, validation and transfer of methods)

- The use of statistics and modeling when using Quality by Design (DoE, Bayesian, partial least squares, prior knowledge data sets)
- Managing large and/or complex datasets (Large data sets for monitoring variation, complex analytical methods – Mass Spec, NMR, historical data sets)

7. ***Human Challenge Trials in Vaccine Development: Scientific and Regulatory Issues***, Strasbourg, France (29 September - October 1, 2014):

Human challenge trials can help overcome some of the hurdles inherent in vaccine development as the results obtained in these studies have more relevance than those obtained in animal models. Nevertheless, human challenge studies also face a series of scientific, ethical and regulatory issues related to the design, the execution and the use of these studies. The volunteers, healthy adults, may not represent the final target population of the vaccine, in terms of age, status of immunity and environment. The microbial strains used for challenge may behave differently from the wild pathogens. Experiments that induce infections in healthy volunteers give rise to significant ethical and regulatory issues.

This IABS workshop will bring together representatives from academia, industry, regulatory and public health agencies to discuss the scientific, ethical and regulatory framework required for safe and ethical conduct of challenge trials. In addition, the workshop is expected to provide guidance on the best use of challenge trials for the definition of potential correlates of protection and for preliminary efficacy evaluation of investigational vaccines.ss

V. REPORT OF THE VICE PRESIDENT FOR VETERINARY BIOLOGICALS (C. Gay):

The Vice President for Veterinary Biologicals of IABS is responsible for the Veterinary Scientific Committee (VSC) and other relevant issues that pertain to animal health and One Health initiatives. The products that are the focus of the VSC include diagnostics, vaccines, biotherapeutics, and feed additives that enhance the health of animals. During the 2013-2014 timeframe, the VSC has been in a transition period with emphasis given to three specific strategic objectives, as noted in the individual VSC report from the chairperson:

- Expand the membership of the VBC to include leaders in their field representing academia, government laboratories, pharmaceutical industry, regulatory agencies, and stakeholder institutions.
- Support research institutions organizing important meetings relevant to the mission of the IABS by cosponsoring conferences and publishing results of the conference outcomes
- Organize IABS conferences on priority issues for the animal and public health communities.

The expansion of the VSV is progressing and considered critical to ensure IABS remains relevant to our members and stakeholders. The VSC added four new members 2013-2014. Efforts to recruit new members continue with emphasis given to the international regulatory community and scientists from academia, government laboratories, and industry.

During 2013-2014, IABS partnered with several government and science organizations and co-sponsored and contributed to the five conferences summarized below. As with all IABS conferences, outcomes from the various activities inform the animal health and public health communities on critical issues that impact research and development of biological products and facilitate regulatory standardization.

MEETINGS CO-SPONSORED BY IABS 2013/2014:

1. USDA Workshop, Avian Influenza Virus Gap Analysis (*Athens, Georgia, 25-27 March 2013*)

- *In collaboration with the Global Strategic Alliances for the Coordination of Research on the Major Infectious Diseases of Animals and Zoonoses (STAR-IDAZ), the UK Biotechnology and Biological Sciences Research Council (BBSRC), and IABS.*

IABS co-sponsored this international workshop to conduct a gap analysis of animal influenza viruses. Both veterinary and human influenza experts from public and private research institutions, including industry, academia, and government, were invited to participate in the workshop. The report from this workshop was posted on the IABS website and provides an in-depth analysis of available countermeasures to contain and mitigate the threat of a disease outbreak caused by emerging animal influenza viruses with epizootic and/or pandemic potential.

2. NFID 16th Annual Conference on Vaccine Research (*Baltimore, Maryland, USA, 21-24 April, 2013*)

- *In collaboration with IABS, USDA, CDC, FDA, NIH, AVMA, One Health Initiative, the International Vaccine Institute, Edward Jenner Society, Emory Vaccine Center, Sabin Vaccine Institute.*

The 16th Annual Conference on Vaccine Research provided high-quality, current reports of scientific progress featured in both invited presentations and submitted oral abstracts and posters. The conference encouraged the participation of all the disparate fields of vaccinology in both its human and veterinary domains in order to facilitate valuable cross-fertilization of ideas and approaches among researchers often narrowly focused on their specific diseases or methods. Keynote presentation featured by D.A. Henderson, Eradication of Disease through Vaccination: The 35th Anniversary of the Last Case of Smallpox, including symposia on Challenges for Future Disease and Eradication by Vaccination, and Vaccine Discovery and New Technologies.

3. USDA Workshop, Orbiviruses Gap Analysis (Manhattan, Kansas, 16-17 May 2013)

- *In collaboration with the United States Department of Interior, the Center of Excellence for Emerging and Zoonotic Animal Diseases (CEEZAD) and IABS.*

IABS co-sponsored this international gap analysis workshop on *Orbiviruses*. This workshop was organized at the request of the United States Animal Health Association (USAHA) to determine research needs and identify and prioritize intervention strategies to control *Orbiviruses*, which are responsible for several important vector-borne diseases of livestock, including bluetongue and epizootic hemorrhagic disease. An international team of *Orbivirus* experts from public and private research institutions, including industry, academia, and government, were invited to participate in the workshop. The workshop participants prepared a report that has since been submitted to USAHA and posted on several websites. The report identifies knowledge gaps, provides an in-depth analysis of available countermeasures, and identifies research priorities to fill the gaps in our scientific knowledge, and advance the research and development of new technologies.

4. NFID 17th Annual Conference on Vaccine Research (Bethesda, Maryland, USA, 28-30 April, 2014)

- *In collaboration with IABS, USDA, CDC, FDA, NIH, AVMA, One Health Initiative, the International Vaccine Institute, Edward Jenner Society, Emory Vaccine Center, Sabin Vaccine Institute.*

The 17th Annual Conference on Vaccine Research provided high-quality, current reports of scientific progress and best practices in the research and development of vaccines and associated technologies for disease control through immunization. By drawing upon an international audience of scientists and researchers, healthcare professionals and trainees, veterinarians, vaccine manufacturers, and public health officials, the conference was designed to encourage the exchange of ideas across a broad range of disciplines. Keynote presentation featured Gregory A. Poland, MD, Mayo Clinic and Foundation, Vaccinology 2.0: An Evolving Paradigm in the 21st Century, and included several symposia on emerging issues; e.g., Innovations in Influenza Vaccines.

VI. REPORT OF THE SECRETARY (D. Gaudry):

1. 29th General Assembly:

The 29th General Assembly was held on May 10th, 2012 at the Hyatt Regency Hotel, Baltimore, USA

2. Meetings of the Board:

The Board has met on three occasions since the 29th General Assembly: on May 10th, 2012 at Baltimore, USA, on April 20th at Rockville, USA and on September 28th at Strasbourg, France.

3. Meetings of the Executive Committee :

The Executive Committee has met via tele-conferences on 17 occasions:

- In 2012, on June 14th, September 15th and November 9th
- In 2013, on February 11th, April 19th, May 7th, June 4th, June 26th, August 1st, August 23rd, September 13th and October 31st,
- In 2014, on January 8th, February 19th, April 24th, June 26th and September 17th.

4. Scientific Secretariat activity:

Betty Dodet resigned as Scientific Manager in July 2013. Abbie Charlet was named Manager of the Scientific Secretariat. Following the resignation of Betty Dodet, the Secretariat was moved from Caluire to Lyon, the current address being: IABS, 15 rue de la Balme, 69003 Lyon.

During the past year, the Secretariat has assisted the Chairmen of the three IABS conferences organized this year: Cell & Gene Therapy, Kyoto, Japan (March); Statistics & Data Management in Rockville, Maryland (August); and Human Challenge Trials in Strasbourg, France (September).

The Secretariat records all financial information and sends them to the Treasurer on a monthly basis.

In addition, the Secretariat assisted the Secretary and the Executive Director in the setting up of the new IABS European entity: IABS-EU.

The Secretariat also worked in close cooperation with the webmaster Guillaume Soubrier not only to enhance the website but also to address the two hacking incidents that occurred in 2013 and again in 2014. As the webmaster had created a very secure system, no confidential information was lost, but he keeps a close watch on the system so as to immediately spot any unfriendly visits.

The Secretariat continued to build the IABS database by integrating lists of contacts that the scientific committee chairpersons send in subsequent to meetings / conferences they attend.

Finally, the Secretariat sent out an invitation to the 2014 General Assembly to all the IABS members together with the ballot for the Board elections.

VII. ELECTIONS OF THE MEMBERS OF THE BOARD FOR THE TERM 2012-2018 (D. Gaudry):

1. Preparation:

B. Fritzell had resigned from the board in November 2013. I. Gust and J. Robertson wished to retire from the board. The three candidates, C. Jungbaeck, J. Vandeputte & G. Vyas, who were members of the 2012-2014 board with a term ending on September 29th, 2014, wish to continue their service for the board. The final list was approved by the Executive Committee at its meeting on Feb. 19, 2014.

143 postal ballots & various documents including a statement of the candidates were dispatched in July 2014.

2. Results:

57 postal ballots were received. All candidates were elected. Consequently, pending on the General Assembly approval, the members of the new board for the period 2014-2016 will be:

IABS BOARD MEMBERS FOR THE 2014-2016 PERIOD		
EGAN William	<i>Novartis</i>	USA
GAUDRY Daniel	Retired	France
GAY Cyril	<i>U.S.D.A.</i>	USA
GRIFFITHS Elwyn	Retired	United Kingdom
HAYAKAWA Takao	<i>Kindai University</i>	Japan
JUNGBÄCK Carmen	<i>Paul Ehrlich Institute</i>	Germany
LÖWER Johannes	Retired	Germany
LUBINIECKI Anthony	<i>Centocor</i>	USA
PETRICCIANI John	Retired	USA
SHEETS Rebecca	<i>Grimalkin Partners</i>	USA
VANDEPUTTE Joris	<i>Trivarop</i>	Belgium
VYAS Girish	<i>UCSF School of Medicine</i>	USA

The results of the elections of the new Board were approved unanimously by the General Assembly.

VIII. REPORT OF THE TREASURER:

IABS is a non-profit organization. This status does not mean that the Alliance cannot make profit, but it means that the profit can only be used for pursuing the objectives as described in Article 2 of the Constitution. The profit cannot be transferred, like in companies, to the “owners” or the members for their private use, but it is not excluded that members of the Alliance are compensated for the work they perform for the Alliance and its objectives. This possibility is now clearly described in the Revision of the Constitution proposed to the General Assembly 2014.

According to the auditor's report for 2013, there was a small profit of 16,000 CHF which together with the profit of 2012 (42,000 CHF) covers formally the loss of 2011 (58,000 CHF). On the short term, there is no increase in the assets of the Alliance which correspond to approximately 300,000 CHF, an amount in the range of the yearly budget. From the Treasurer's point of view, it would be more reassuring if the assets could be increased.

It might be interesting to compare the proposed budget for 2013 which predicted a loss of 100,000 CHF with the final balance for 2013. When I presented the balance I urged the chairpersons of our committees to organize not only scientifically but also financially successful conferences. Thanks to their commitment the income by symposia was twice the amount expected. Also a significant reduction in the expected expenses contributed to a balanced budget. A financially helpful contribution, but otherwise unfortunate event was the termination of the contract with Karger on the book series which led to the discontinuation of the item "Editorial fees". Also the "Printing expenses" decreased by 10,000 CHF. The consulting fees were 30,000 CHF lower than expected. All these elements contributed to the fact that the expected significant loss was turned to a moderate profit.

All these developments were taken into consideration when the budgets for 2014 and 2015 were drafted. A major change was caused by the termination of the contract with DBS which led to a reduction of the ISS expenses by 50%. On the other hand, there was a need to increase the consulting fees which include also the compensation for the specific work of officers and other members of the Alliance. In summary, the expected expenses are in the same range as in previous years and, again, financially successful conferences are needed in order to prevent losses.

As agreed by the Board in 2013 the constitutory accounting is now performed by our fiduciary "CR Gestion et Fiduciaire SA" in Geneva while Abigail Charlet, the ISS manager, does a sort of analytical accounting, especially a very clear accounting for each of the conferences. Her activities allow a much better view on the financial side of the conferences and generally of the Alliance. She definitely earns our gratitude.

IX. THE BUDGET FOR 2015:

2015 IABS BUDGET	
29 Sept. 2014	
INCOME ☐	Swiss Francs
Commissions Karger	2,500
Commissions Elsevier	100,800
Membership fees	9,700
Conferences surplus	60,500
TOTAL INCOME	173,500
EXPENSES ☐	
Travel	36,300
Rent (Homebox storage)	400
Personnel expenses	117,600
Scientific Secretariat	66,500
Administrative expenses	6,000
Computer	600
Website	8,500
Bank charges	1,800
Taxes (Canton Geneva)	400
TOTAL EXPENSES	238,100
PROJECTED LOSS	64,600 CHF

The 2015 budget was approved unanimously by the General Assembly.

X. REPORT OF THE AUDITORS:

Report of the statutory auditors on the limited statutory examination

As statutory auditors, we have examined the financial statements (balance sheet, income statement and notes) of International Alliance for Biological Standardization, Geneva, for the year ended December 31, 2013.

These financial statements are the responsibility of the Treasurer. Our responsibility is to perform a limited statutory examination on these financial statements. We confirm that we meet the licensing and independence requirements as stipulated by Swiss law.

We conducted our examination in accordance with the Swiss Standard on the Limited Statutory Examination. This standard requires that we plan and perform a limited statutory examination to identify material misstatements in the financial statements. A limited statutory examination consists primarily of inquiries of company personnel and analytical procedures as well as detailed tests of company documents as considered necessary in the circumstances. However, the testing of operation processes and the internal control system, as well as inquiries and further testing procedures to detect fraud or other legal violations, are not within the scope of this examination.

Based on our limited statutory examination, nothing has come to our attention that causes us to believe that the financial statements and the proposed appropriation of available earnings do not comply with Swiss law and the company's articles of incorporation.

Geneva, June 30th, 2014

CR Gestion et Fiduciaire S.A.

F. A. Zegato
Licensed Audit Expert

XI. CONSTITUTION:

The President read, one by one, all the modifications proposed by the Board. The General Assembly approved each of the modifications.

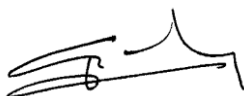
The Secretary reported that the proposed modifications were sent to all IABS members in July. No comment on the modifications was received from the membership. .

The proposed Constitution was approved unanimously by the General Assembly.

XII. MEMBERSHIP DUES :

The General Assembly approved the membership dues proposed by the Board for the period 2014-2016. :

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| • Organization members | no fee |
| • Individual members: | 120 SFr |
| • Individual member Developing Country | 10 SFr |
| • Student | 10 SFr |



Daniel Gaudry
IABS Secretary

Following the General Assembly, the new board met and elected as officers : John Petricciani (President), Rebecca Sheets (Vice President Human Biologicals); C. Gay (Vice President Veterinary Biologicals), Johannes Löwer (Treasurer), Daniel Gaudry (Secretary), J. Vandeputte (Executive Director).