

PRESIDENT'S LETTER (Dec 2008)

Dear Colleague,

As your newly elected President, I would like to share with you my views on the IABS, past, present and future.

In the early days of IABS, other than WHO, there were no focal points for discussion of international regulatory issues for biological products. IABS clearly filled that void and was seen as a major contributor in the field. However, in more recent times, the FDA, EU and the EMEA have emerged as strong and active organizations, along with the ICH & VICH. Those organizations have essentially filled most of the gap that IABS used to fill. In addition, IABS formerly had little, if any, competition. Today, it must compete with commercial organizations that are generally better funded and have better infrastructures.

Therefore, the IABS board recently launched a survey to see if we are still of interest to our stakeholders (regulatory affairs, industry and international association such as WHO, OIE) in the human and veterinary biologicals areas.

The outcome of the survey showed clearly that:

- The interest in IABS remains high because we can contribute in some very specific areas to the resolution of issues that are not being adequately addressed by ICH, WHO, EMEA, FDA, USDA, OIE...
- A significant element that would differentiate IABS from other organizations would be to focus on what has been termed "regulatory science" (techniques and studies that are aimed at scientific issues that bear directly on regulatory decision-making).
- The topics should be related to biological issues, and the participants should include leaders from Industry, Regulatory Affairs and recognized scientists working in the field. Academic participation in IABS-sponsored conferences is seen as a real plus.
- The last session of IABS meetings be dedicated to the preparation of *Conclusions & Recommendations (Position Paper)*, which should be put in writing, published and submitted to the Regulatory Authorities. This may become an "identity mark" of the IABS meetings, if correctly advertised..

Consequently, IABS has no other choice than to redirect its strategy, select specific fields and let the scientific community know about our strategy. I intend to recommend to the Board that we focus on the following items:

- *Organization of meetings:* (workshops & large scientific conferences) within the scope defined by the recent survey on the role of the IABS: scientific meetings on technical issues, gathering Academics along with Regulatory and Industry experts to develop recommendations set up at the end of the meeting, and publish them soon after the meeting.
- *Publications:* improve the process for the publication of books, including the setting up of on-line publication.
- *Optimization of our relationship with "partners":* Industry in both areas Human & Veterinary areas; State agencies with a limited number of agencies including WHO, EMEA, FDA, NFID, and OIE.
- *Resource development:* clearly define the resource strategy, which should allow the IABS to meet the expectations of our partners.
- *Increasing the visibility of the IABS:* the Association is generally not known in the different fields of Industry, and when it is known, its interface with other groups and its objectives are not clear. In brief, the value of the IABS is not perceived.

Succeeding in these objectives requires time and effort from many of us - not only from the board members. We also are seeking your active involvement. Any suggestions or observations related to the activity of the IABS will be welcomed.

Best regards



Daniel Gaudry
President IABS