ByLaw of the International Alliance for Biological Standardization (IABS) 2025

I. NAME, SEAT, PURPOSE, MEANS AND RESSOURCES

II. MEMBERSHIP

III. GOVERNANCE AND ORGANIZATION, THE EXECUTIVE COMMITTEE, OTHER COMMITTEES, AFFILIATES

IV. THE GENERAL ASSEMBLY

V. THE BOARD OF DIRECTORS (BOARD) , OFFICERS

VI. MISCELLANEOUS AND FINAL PROVISIONS

I.NAME, SEAT, PURPOSE, MEANS AND RESOURCES

Article 1 NAME AND DURATION

An association within the meaning of Articles 60 et seq. of the Swiss Civil Code ("CC") is hereby created under the name "the International Alliance for Biological Standardization (IABS)" (hereafter, the "Association").

The Association is created for an indefinite period of time.

The former names of the association were International Association for Biological Standardization and subsequently the International Association for Biologicals, both also known under the acronym "IABS". In 2011 the term "Alliance replaced the term "Association".

Due to the international nature of its activities, English shall be used as the primary language for written and spoken communication within the Alliance. However, according to the Statutes, French is the legally binding language.

Article 2 SEAT

The Association's seat is in the Canton of Geneva.

The Association is registered with the Register of commerce.

Article 3 PURPOSE

The Association is created to:

- host conferences and workshops, facilitate communication, and develop consensus on key contemporary issues related to biologicals among those who discover, develop, produce and regulate biological products for human and animal health;
- foster evidence-based science as the standard for improving and ensuring the quality and the safety of biological products;
- share scientific advancements and innovative regulatory solutions through our journal *Biologicals*;
- offer assistance to national and international organizations active in this field.
- Offer training environment to young collaborators in diverse institutions around the world, in high, medium & low income countries

The Association has no profit purposes.

Article 4 MEANS

The Association may pursue all lawful activities to achieve its purpose.

Article 5 RESSOURCES

Resources of the Association may come from donations, legacies, sponsorship, partnerships, public subsidies, membership fees, revenues generated by the Association's assets, as well as any other resources authorised by the law.

All resources of the Association shall be used exclusively for its not-for-profit purposes.

II. MEMBERSHIP

Article 6 Members

Members of the Association (the "Members") shall consist of individuals or institutions who have an interest in the purpose and the activities of the Association and wish to support them.

Should the Association be required to register with the Register of commerce, it shall keep a list of its members mentioning the name and surname, or the company name, as well as the address of each member (art. 61a CC). The details of each member and any supporting documents shall be retained for five years after the member has been removed from the list (art. 61a para. 3CC).

Members shall be persons interested in research, characterization, standardization, quality control, production, or clinical assessment and the marketing authorization of biological products. In addition, members with knowledge in areas such as legal and financial areas to support an NGO association like IABS are welcomed as well.

Each member must formally subscribe to the mission of the Alliance, as described in Article 3.

The Alliance shall be composed of the following individual members:

A. *General members:* individuals active in the field of biological whose membership application has been approved. General members have voting rights and they pay dues. Attendees to an IABS meeting may be offered a free membership for a one -year period with possible renewal. During their free membership time, general members have no voting rights. Upon expiration of their free membership time, they may become voting General members upon application to the Secretary.

B. *Contributing members:* individuals involved in IABS activities, such as, but not limited to, Board and Committee members, individuals active in the publication process of *Biologicals*… subject to confirmation of their membership by the Secretary. They pay no dues during their mandate and have voting rights.

C. *Distinguished members:* individuals no longer active in IABS operations, who are recognized for their exceptional contributions to the Alliance. They are nominated for life time by the Board upon proposal from at least three Board members. They pay no dues and have voting rights.

Article 7 BEGINNING OF MEMBERSHIP

The founders are the initial Members of the Association.

Additional Members may join the Association by submitting a written application to the Board.

The Board shall review applications, before submitting them to the General Assembly for approval.

The applications should be checked in advance by the officers, who will make a decision proposal to the Board.

Article 8 END OF MEMBERSHIP

Membership ceases:

- Upon the resignation of the Member addressed to the Board at least 6 months before the end of the calendar year (art. 70 para. 2 CC);
- Upon death of the Member if such Member is an individual and not the representative of an institution (art. 70 al. 3 CC); or
- By exclusion decided by the General Assembly, as proposed by the EC or the Board.

In any case, the fee for the current year remains due by the exiting Member.

A resigning or expelled Member has no right to the Association's assets.

Article 9 MEMBERSHIP FEE

The General Assembly decides on the principle of membership fees and their amount.

III. GOVERNANCE AND ORGANISATION, THE EXECUTIVE COMMITTEE, OTHER COMMITTEES, AFFILIATES

Article 10 BODIES OF THE ASSOCIATION

The bodies of the Association are:

- The General Assembly,
- The Board, and
- The External Auditors, insofar as required by Swiss law.
- Additional committees to facilitate the obligations of the Associations mission

The Committees' Chairs shall be appointed by the Executive Committee. Nominees' candidature shall be discussed by the Executive Committee before nominees be contacted.

The Chair of each Committee shall decide on the number of members of such Committee and appoint the members with the approval of the Executive Committee.

At each meeting of the Executive Committee and the Board, the Chair shall provide to the Executive Committee for approval an activity report as well as an action plan. The reports to the Executive meetings may be made orally, the reports to the Board in writing. Each Committee shall have as many members as necessary. The Board has the right to dismiss a Committee Chair or an entire Committee,

if, in the view of the Board, the Chair or the Committee fails to meet its responsibilities, or for other reasons that are in the interest of the Alliance.

- The Executive Committee

  The Executive Committee is constituted by the Chair (President), the Deputy Chair (Vice President), the Secretary, the Treasurer and the Chairs of the Committees. The Immediate Past Chair (Past President), the Chair (President) of each Affiliate and the Executive Director are *ex officio members* of the Executive Committee.

  The Executive Committee shall be presided over by the Chair (President) or in his absence by the Deputy Chair (Vice President).

  The Executive Committee shall have all of the powers and authority for the day-to-day operations of the Alliance subject to any limitations that may stems from decisions of the Board. This includes the authority to make decisions with regard to the engagement of permanent staff as well as concerning the day-to-day supervision and running of the operational staff, within the limits of the approved budget.

  The Executive Committee shall approve the programme of activities and coordinate the activities of the different Committees that are established by the Board.

  The Executive Committee may meet by teleconference or in person and make decisions at its meetings or by email. All decisions shall be documented by the Secretary in the minutes.The Executive Committee shall meet whenever requested by the Chair (President) with reasonable advance notice.

  A summary of the Executive Committee's activities will be contained in the general report made to the General Assembly by the Secretary.

- The Communications Committee:

  The Communication Committee of the Alliance will be responsible for:
  - Establishing a Publications Committee that shall be responsible for all publication activity.
  - Coordinating the mailing of information to be published on the website
  - Keeping contacts with selected organizations active.

  Any member may be appointed as Chair of the Communication Committee.

- Other committees that the Board determines as appropriate

- The Alliance may establish affiliates and may join other nonprofit organizations with similar interests.

  The Affiliates are IABS-EU (IABS–Europe) and IABS-NA (IABS-North America)

  The Affiliates are independent entities that have:
  - A legal structure with their own ByLaw that is consistent with the IABS ByLaw and with the policies and procedures of the Alliance.
  - Financial autonomy that respects the relevant laws of their Region.
  - The objective of the Affiliates is to support the mission and projects of the IABS in organizing conferences on specific needs and expectations in their region.

IV. THE GENERAL ASSEMBLY

Article 11 PRINCIPLES

The General Assembly is the supreme authority of the Association within the meaning of article 64 et seq. CC.

It is composed of all the Members.

Article 12 POWERS

The General Assembly delegates to the Board the power to administer and represent the Association.

The General Assembly remains with the following inalienable powers:

- Adoption and amendment of the present Statutes;
- Nomination, surveillance and revocation of the External Auditors;
- Approval of annual reports and audited accounts;

  The following items shall be presented to the General Assembly for approval:
  - the Minutes of the last General Assembly
  - the Report of the Chair (President)
  - the Report of the Secretary
  - the Report of the Treasurer
  - the Report of the Auditor
  - the Budget.
- Admission and exclusion of Members;
- Nomination, surveillance, discharge and revocation of Board members;
- Decision on the dissolution or merger of the Association; and
- Management of all matters that are not the responsibility of other bodies.

Article 13 MEETINGS

Ordinary meeting of the General Assembly. The Ordinary meeting of the General Assembly shall be held at least once every two years.

Extraordinary meeting of the General Assembly. Extraordinary meetings of the General Assembly may be called by the Board or at the request of at least 5 percent of all Members, in accordance with article 64 para. 3 CC.

Convocation. The Board shall convene the meetings of the General Assembly with a one-month notice. The agenda of the meetings must be sent with the invitations. The invitations may be sent by post or by e-mail.

Each member may, within a period of one week, can ask for an amendment or amendments to the agenda. The final agenda, including any amendments to the proposed agenda, shall be sent to the membership two weeks before the General Assembly. The General Assembly shall not take any decisions on items not included on the agenda.

Quorum. The General Assembly is validly instituted if at least 5 per cent of the members are present.

If a quorum is not present, a second Assembly shall be announced within a period of one week with the same agenda. This Assembly must be held not earlier than one week and not later than two weeks after the announcement has been sent to the membership.

This second Assembly is validly constituted whatever the number of members present or represented by proxy.

The Chair. The Chair (President), and in his/her absence the Deputy Chair (Vice President) (as defined in article 17 below), shall chair the meetings of the General Assembly.

Meeting modes. Meetings can be held either (i) onsite, whether in Switzerland or abroad, (ii) by visio conference, or (iii) in a hybrid manner (mix of onsite and visio conference), provided that all requirements for onsite general assembly meetings are fulfilled.

Independent representative. The appointment of an independent representative is not necessary for meetings taking place in Switzerland, online or in a hybrid form. For meetings taking place abroad, an independent representative shall be appointed, unless all members agree to waive this condition.

Article 14 DECISION MAKING AND VOTING RIGHTS

Voting rights. Each Member shall have an equal voting right at the General Assembly.

Power of attorney. Members may vote in person or by proxy to the Chair (President), the secretary or any other board member attending the meeting in question.

Process. Voting takes place by a show of hands or through an electronic voting process. Upon request of at least one-fifth of the Members, voting may take place by secret ballot.

Majority of votes. All decisions shall require a simple majority of all votes expressed (including votes by proxy), insofar as the present Statutes do not provide for a different majority.

Decisions by circular letter. Proposals to which all Members have adhered in writing (including by e-mails) are equivalent to decisions taken by the General Assembly, in accordance with article 66 para. 2 CC.

Conflict of interest. In accordance with article 68 CC, a Member may not vote for decisions relating to a matter or a legal proceeding regarding the Association where he or she, his or her spouse, parents or relatives in direct line are a party to the matter.

Minutes. The meetings of the General Assembly and its decisions are recorded in the minutes.

V. THE BOARD OF DIRECTORS (BOARD), OFFICERS

Article 15 PRINCIPLES

Role and powers. The Board is the executive body of the Association. It has the right and the duty to manage the affairs of the Association and to represent it in accordance with the Statutes (art. 69 CC). In particular, the Board shall take all necessary measures to achieve the purposes of the Association, ensure the correct application of the present Statutes and any other internal regulations, administer

the property, assets and resources of the Association, manage the accounts, engage and supervise a Director, if necessary, and convene and organise the General Assembly.

Pro-bono. Board members shall act on a pro-bono basis, with the exception of reimbursement of their effective costs and travel expenses. Potential attendance fees may not exceed those paid for official commissions of the Canton of Geneva. For activities that exceed the usual scope of the function, each Board member may receive appropriate compensation. Paid employees of the Association may only sit on the Board in an advisory capacity.

Article 16 APPOINTMENT OF THE BOARD

The initial Board members were appointed by the founders.

After that, the new members of the Board are appointed by the General Assembly.

Article 17 COMPOSITION

The Board shall be composed of 15 members.

To the extent possible, the Board should include scientific areas of consideration:

- Scientific fields: Human Vaccines, Human Biotherapeutics, Cell & Gene Therapy, and Veterinary Biologicals.
- Areas of service: Regulatory Authorities, Industry, and Academia
- Others: members with knowledge in areas such as legal and financial areas to support an NGO association like IABS are welcomed as well.

Unless the present ByLaw provides otherwise, any member in good standing may be nominated as a candidate for election to the Board by five Alliance members or two Members of the Board.

The Board designates amongst its members, a Chair, a Deputy Chair as well as any other function as it may deem necessary.

The Board shall elect the following Officers from among its members, each for a term of two years:

-The Chair, (President)

-The Deputy Chair, (Vice President)

-The Secretary

-The Treasurer

The **Chair** (President) is expected to serve as the Immediate Past Chair (Past President) at the conclusion of his/her term as Chair (President). The Immediate Past Chair (Past President) shall serve in this capacity and be an ex officio member of the Board for a term of two years, which may be in addition to his regular six-year term(s) as member of the Board. In that instance, he or she shall be a sixteenth (16th) member of the Board.

The Chair (President) and Deputy Chair (Vice President) may serve in the same office for no more than three consecutive terms of two years each. The other Officers are not limited in the number of terms they can serve.

The Board may approve reasonable compensation to some of the officers and members of the Alliance for their function and activity, in addition to reasonable expenses, as specified in internal guidance documents.

The Chair (President) shall preside over the meetings of the General Assembly, the Board and the Executive Committee. He/she shall represent the Alliance in negotiations with external bodies, but may delegate those responsibilities to other appropriate members of the Alliance when it is in the interest of the Alliance to do so. The Chair (President) directs the activities of the Alliance and takes all appropriate steps to implement, the decisions of the General Assembly and of the Board. In doing so, he shall be assisted by the Executive Committee. If the Chair (President) resigns during his/her term of office, he/she shall be considered also to have resigned from the Immediate Past Chair (Past President) position.

The Immediate Past Chair (Past President) shall assist the Chair (President), Executive Committee and Board as required.

The **Deputy Chair** (Vice President) shall assist the Chair (President) in the execution of his/her duties and shall preside at meetings of the Alliance, including the Board and Executive Committee meetings, in the Chair (President)'s absence. The specific tasks of the Deputy Chair (Vice President) shall be assigned by the Chair (President) and communicated to the Executive Committee.

The **Secretary** shall report to the Chair (President) and to the General Assembly regarding the administration of the Alliance. He/she also shall be responsible for recording the Minutes of meetings of the General Assembly, the Board and the Executive Committee.

The **Treasurer** shall be responsible for the financial administration of the Alliance including the implementation of the financial decisions of the Executive Committee, the preparation of the budget, and the statement of audited accounts for presentation at the General Assembly. The Treasurer shall assist in the preparation of the budget, help develop fundraising plans, and make financial information available to Board members and the public. The Treasurer shall present a report at each Board meeting.

If a vacancy arises among the Officers during such Officer's term of office, the Board shall elect one of its members to serve in that Officer's position until the end of the defaulting Officer's term of office. Time served to fill a vacancy does not count towards the maximum number of consecutive terms. In case of a vacancy in the Immediate Past Chair (President) position, the vacancy shall not be filled.

At least one member of the Board with individual signatory powers, or two members of the Board with collective signatory powers, must be domiciled in Switzerland and have access to the list of members (art. 69 para 2 CC).

The signature of two of the following: the Chair (President), the Deputy Chair (Vice President), the Secretary or the Treasurer, shall constitute a valid and binding commitment of the Alliance towards third parties. According to the Statuts the Swiss Resident Member of the Board is empowered to sign documents. Whenever signing by the Swiss Board Member will be obligatory one Officer has to sign as well.

Advisors to the Board (this text replaces SOP 2.4.3)

- The Board of Directors can select Advisors to the Board. The Advisors to the Board are IABS members whose expertise in specific areas of Biologicals is recognized by the Board.
- Board members can propose suitable candidates for appointment at a Board meeting. The proposal should be accompanied by the candidates CV.
- The Advisors to the Board are nominated every two years after the General elections for a two-year period which may be extended. The support of the Advisors to IABS issues should be analysed by the Officers every two years to decide on the extension.
- The advisors are invited occasionally upon decision of the President to the Executive Committee or Board meetings, especially when topics of their expertise are on the agenda.
- The advisors receive the meeting agendae and reports from the Executive Committee and from the Board. They are entitled to send comments and suggestions to the Secretary before and after the meetings.

- The advisors can serve on committees and should always strive to build upon the Alliance's mission.
- They need to be actively engaging with the its initiatives while also leveraging their connections and networks in order to further Alliance goal.
- The advisors pay no IABS membership fees
- The travel costs for attendance of onsite meetings will be reimbursed, when invited by the President.

Article 18 TERM

The Board members are appointed for a six year term, renewable twice.

Article 19 REMOVAL AND RESIGNATION

Removal. Board members may be removed by the General Assembly for just cause, in particular if the Board member has violated his/her obligations towards the Association or if the Board member is not in a position to exercise his/her functions correctly.

A Board member may be removed for excess absences from the Board if she/he has two unexcused absences from Board meetings in a year. A Board member may be removed for other reasons by a three fourth vote of the remaining Board Members.

Resignation. Board members may resign at any time by submitting a written declaration to the Chair, specifying when the resignation shall take effect.

Vacancy during the term of office. In the event of dismissal or resignation during the term of office, the Board may appoint a replacement member by co-optation, until the next meeting of the General Assembly.

Article 20 DELEGATION AND REPRESENTATION

Delegation. The Board is entitled to delegate certain of its tasks to one or more of the Board members, including to Board sub-committees, to third parties, or to hired employees.

Representation. The Board designates the individuals who are authorized to represent and bind the Association.

Article 21 BOARD MEETINGS

Meetings. The Board shall meet as often as required, but at least twice per year.

Process. Board members may validly participate in a meeting of the Board in person, by video or telephone conference or any other means decided by the Board. In-person meetings can take place in Switzerland or abroad.

Convocation. The Chair of the Board shall convene Board meetings at least fourteen days in advance. The Chair may convene the Board with three days' advance notice, where justified by urgent circumstances.

Article 22 DECISION MAKING

Votes and majority. Each Board member shall have one vote. Decisions are taken by a simple majority of all votes expressed, as long as the present Statutes or other internal regulations of the Association do not provide for a different majority. In case of a tie, the Chair shall have a casting vote.

Decisions by circular letter. Decisions may also validly be taken by written resolution, including by email.

Minutes. Board meetings and decisions will be recorded in the minutes of the Board.

VI. MISCELLANEOUS AND FINAL PROVISIONS

Article 23 SECRETARIAT

The Board may create a secretariat and/or appoint a Director to manage the day-to-day affairs of the Association.

Article 24 EXTERNAL AUDITORS

To the extent required by Swiss law, the General Assembly shall appoint the independent External Auditor in charge of (i) verifying the annual accounts of the Association and to submit a detailed report to the General Assembly and (ii) to ensure that the statutory rules of the Association (Statutes and internal regulations) are respected.

Article 25 BOOKKEEPING

Accounts. The Board must prepare for each financial year accounts as required by the applicable laws.

Fiscal year. The fiscal year begins on January 1st and ends on December 31st of each year.

Article 26 LIABILITY

The Association is solely liable for its debts and obligations, which are guaranteed by its assets, to the exclusion of all individual responsibility of its members.

Article 27 DISSOLUTION

The Association may only be dissolved by a two-third (2/3) majority vote of all Members.

In such a case, the Board shall proceed with the liquidation of the Association.

The assets of the Association shall first serve to pay its creditors.

Remaining assets will be entirely assigned to a non-profit entity, which pursues similar public interest purposes and which is tax exempted.

In no event may the assets of the Association be returned to its founding members or Members, nor should they use some or all of the assets for their own benefit in any way.

THIS BYLAW WAS APPROVED ON 19 NOVEMBER 2025 BY THE BOARD OF DIRECTORS AT ITS 207TH MEETING IN LYON