



ISPE Bylaws

Revised and Approved by the Board of Directors 7 December 2016

Article I: Organization

Sec. 1. Name. The name of this organization shall be International Society for Pharmaceutical Engineering, Inc. ("ISPE" or "Society").

Sec. 2. Seal. The corporate seal shall have inscribed thereon the name of the Society, the year of its incorporation, and the state of incorporation.

Sec. 3. Affiliates and Chapters. In order to facilitate more frequent information exchange and networking among members of the industry, the Society shall form national or regional Affiliates and local Chapters. These groups shall be chartered by the Society, said charter to be approved by the ISPE Board of Directors and reviewed and signed annually by Affiliate and Chapter leadership. Affiliate and Chapters shall draft bylaws to guide their operation, consistent with the bylaws of the Society, said bylaws to be approved by the ISPE Board of Directors. Affiliates and Chapters shall elect their own Board of Directors which is responsible to the ISPE Board of Directors for complying with the provisions of the Charter.

Article II: Purposes

Sec. 1. Promote Interests. To be the leading technical organization for professionals engaged in producing quality medicines and pharmaceutical devices throughout the lifecycle. All applications for membership are subject to review by the International Board of Directors for qualification based on job functions.

Sec. 2. Education Programs. To promote and support educational programs designed to enhance competence, compliance, professional performance and enable innovation.

Sec. 3. Information and Guidance. To provide information and guidance to regulatory authorities with respect to practices affecting the pharmaceutical, biotechnology, medical device, and diagnostic industries.

Sec. 4. Industry Integrator. To foster relationships and provide opportunities for interaction among individual members, industry constituencies including suppliers, government and academia.

Sec. 5. Information. To collect and disseminate information for its members.

Sec. 6. Establish Profession. To enhance the image of pharmaceutical science, engineering, and technology as a profession and promote its importance within the industry.

Sec. 7. Credentialing. To establish and administer credible credential programs to further and promote the interests of members, industry and the public.

Sec. 8. Not-for-Profit. ISPE is an incorporated organization operating on a not-for-profit basis.

Article III: Membership

There shall be nine classes of membership:

1. Industry Members
2. Regulatory Authority/Government
3. Young Professional Members
4. Student Members
5. Academic Members
6. Emerging Economy
7. Honorary
8. Emeritus
9. Hardship

Sec. 1. Industry Members. Any individual engaged in producing quality medicines and pharmaceutical devices throughout the lifecycle is eligible to become an Industry Member. Industry Members are entitled to the full rights of membership including to vote on matters pending before the Society, hold office, and serve as volunteers on behalf of the Society. Membership in one Affiliate/Chapter of the Society is included with each Industry membership. Industry Members have voting rights and may serve on committees and hold any office of the Affiliate/Chapter. Industry memberships are not transferable.

Sec. 2. Regulatory Authority/Government Members. Any individual employed full-time by a regulatory authority or government agency is eligible to become a Regulatory Authority/Government Member.

Regulatory Authority/Government Members will have access to all materials included in the Member- restricted section of the ISPE web site. Regulatory Authority/Government Members are entitled to the full rights of membership including to vote on matters pending before the Society, hold office, and serve as volunteers on behalf of the Society. Regulatory Authority/Government memberships are not transferable and will expire upon departure from the regulatory authority or government agency.

Sec. 3. Young Professional Members. Individuals engaged in producing quality medicines and pharmaceutical devices throughout the lifecycle are eligible to become Young Professional Members during the first four years they work in the industry. Young Professional Members are entitled to the full rights of membership including to vote on matters pending before the Society, hold office, and serve as volunteers on behalf of the Society. Membership in one Affiliate/Chapter of the Society is included with each Young Professional membership. Young Professional Members have voting rights and may serve on committees and hold any office of the Affiliate/Chapter. Young Professional memberships are not transferable and some benefits may be limited.

Sec. 4. Student Members. Individuals enrolled full-time in pharmaceutical science, technology, engineering, mathematics, or related disciplines at a recognized educational institution may enter the Society as Student Members while they are enrolled and for one year following graduation. Students attending at least half time are eligible if their primary concentration is education, such as a combination of class work and an internship. Student Members shall be entitled to limited benefits in the Society (International, local Affiliates, local Chapters) to include serving as volunteers on behalf of the Society and voting on matters pending before the Society. Student Members may not hold office at the local or International levels. Membership in one Student Chapter of the Society is included with each Student membership. Student Members have voting rights in the Student Chapter and may serve as officers, directors, and volunteers.

Sec. 5. Academic Members. Any individual employed full-time by an educational institution that agrees to promote educational programs aimed at developing pharmaceutical science, technology, engineering, mathematics, or related disciplines is eligible to become an Academic Member. Academic Members are entitled to the full rights of membership including to vote on matters pending before the Society, hold office, and serve as volunteers on behalf of the Society. Membership in one Affiliate/Chapter of the Society is included with each Academic membership. Academic Members have voting rights and may serve as volunteers on behalf of the Society and hold any office of the Affiliate/Chapter. Academic memberships are not transferable.

Sec. 6. Emerging Economy Members. Individuals engaged in producing quality medicines and pharmaceutical devices throughout the lifecycle in countries that the Society shall classify as Emerging Economies are eligible to become Emerging Economy Members of the Society. Membership in one Affiliate/Chapter of the Society is included with each Emerging Economy membership. Emerging Economy Members are entitled to limited Society benefits, including to vote on matters pending before the Society, hold office, and volunteer on behalf of the Society. Emerging Economy memberships are not transferable.

Sec. 7. Honorary Members. The ISPE Chair and CEO/President may designate Honorary Members in order to accommodate those who are able to make special contributions to the Society. Honorary Members shall be entitled to limited Society benefits, including to vote on matters pending before the Society, hold office, and serve as a volunteer on behalf of the Society. Honorary memberships are not transferable.

Sec. 8. Emeritus Members. Any individual who has held membership in the Society for five consecutive years, upon full retirement from business and professional activity, shall be eligible for emeritus status with a reduced dues rate. Emeritus Members shall be entitled to limited Society benefits, including to vote on matters pending before the Society, hold office, and volunteer on behalf of the Society. Emeritus memberships are not transferable.

Sec. 9. Hardship Members. Any individual who is an active Member, upon becoming unemployed may request reduced annual dues until employment is found. These individuals shall be entitled to limited Society benefits, including to vote on matters pending before the Society, hold office, and serve as a volunteer on behalf of the Society. Contribution to the Society will be considered along with length of membership.

Article IV: Meetings

Sec. 1. Annual Meeting. An annual membership meeting will be held each year. The time and place of the annual membership meeting of this organization shall be determined by the Board



of Directors. The Secretary shall cause to be mailed to every member in good standing at his address as it appears in the membership roll book of this organization a notice telling the time and place of such Annual Meeting.

Sec. 2. Special Meetings. Special meetings of this organization may be called by the ISPE Chair when (s)he deems it for the best interest of the organization. Notices of such meetings shall be mailed to all members at their addresses as they appear in the membership roll book at least thirty (30) days before the scheduled date set for such special meeting. Such notice shall state the reasons that such meeting has been called, the business to be transacted at such meeting and by whom called. At the request of two-thirds members of the Board of Directors, the ISPE Chair shall cause a special meeting to be called, but such request must be made in writing at least thirty (30) days before the requested scheduled date. No other business but that specified in the notice may be transacted at such special meeting without the unanimous consent of all present at such meeting.

Sec. 3. Quorum. A simple majority of the members of the Board of Directors shall constitute a quorum.

Article V: Voting

Sec. 1. Voice Vote. At all meetings of this Society, issues requiring a vote for resolution shall be referred to the eligible voting Members there present for a voice vote determination of the majority position.

Election of Officers and Directors of the Society shall be an exception in which the voting process will require secret ballot. Unless specified otherwise in these bylaws, results of voting will be determined by a simple majority.

Sec. 2. Other Voting Procedures. At any meeting, the presiding officer may require or a majority of those voting members present may request a vote be by show of hands or by secret ballot.

Sec. 3. Inspectors of Election. The Nominating Committee shall appoint one or more persons to act as "Inspector(s) of Election." The Inspector(s) shall at the conclusion of balloting certify in writing to the Chair the results. A copy of the results shall be physically affixed to the minutes of the meeting.

Sec. 4. Inspector Conflict. No inspector of election shall be a candidate for office or shall be personally interested in the question voted upon.

Article VI: International Board of Directors

Sec. 1. Board Organization.

- a) The Board of Directors shall be composed of not less than three (3) and not more than fifteen (15) voting members including the Officers of this organization. The Directors shall be elected prior to and inducted at the Annual Meeting of this organization. The Directors shall serve a term of two (2) years effective upon election, the Officers for one (1) year. A Director may not sit on the Board for longer than four (4) consecutive years unless that individual is elected an Officer. The

CEO/President shall serve as a regular, ex-Officio, non-voting member of the Board of Directors, regardless of the total number of Board members.

- b) Director Special Appointment. In order to insure appropriate skills and diversity within the Board to execute business strategies as defined in our ISPE Strategic Plan, the board shall reserve the right to appoint by majority vote, one Director, to an open position in the Board of Directors, during the established election cycle and prior to the actual election. This appointment will not cause the number of Board Directors to exceed 15 nor shall it cause the sum total of appointed Director Positions to exceed 1 in any Board cycle. This Director shall be subject to the same tenure process as an elected Director, however this Director cannot be appointed for a second term if Director is subsequently not re-elected by the membership. This Director is not eligible to be a candidate for an officer position during the appointed term. If the Director is re-elected to a second term by the members, (s)he is eligible to be considered as an officer candidate. This selection process shall be governed by the Nominating Committee.

Sec. 2. Function. The Board of Directors shall govern the affairs and business of this organization. Such Board of Directors shall only act in the name of the organization when it shall be convened or assigned by the Chair.

Sec. 3. Meetings.

- a) A simple majority of the members of the Board of Directors shall constitute a quorum. The act of a majority of the Directors present at a meeting at which a quorum is present shall be the act of the Board of Directors, unless the act of a greater number is required by law or by two thirds majority to change these bylaws. Directors may attend a meeting by telephonic or similar equipment by means of which all persons participating can hear each other. Meetings of the Board of Directors shall be held not less than four times per year. Notice for each meeting of the Board of Directors shall be issued not less than thirty (30) days prior to the time appointed for such meeting.
- b) Special meetings of the Board of Directors may be called by the Chair or the CEO/President, or by the majority of the voting Directors then in office who may fix any place as the place for holding any special meeting. Notice of any special meeting shall be given at least two (2) days previous thereto by written notice delivered personally or sent by mail, e-mail or facsimile to each Director. The purpose of the special meeting shall be stated in the meeting notice.

Sec. 4. Vacancies. Unscheduled vacancies in the Board of Directors may be filled by a vote of the majority of the remaining members of the Board of Directors for the balance of the unexpired term. Officer vacancies will be filled from among the most qualified Directors, if possible.

Sec. 5. Removal. A Director may be removed when sufficient cause exists for such removal. The Board of Directors may entertain charges against any Director. Removal must be effected by not less than two-thirds majority of the entire Board of Directors by secret ballot.

Sec. 6. Board Votes. Each Director shall have one vote and voting shall not be done by proxy. Should the ISPE Chair deem a vote of the Board of Directors to be necessary to occur between meetings of the Board, such a vote may be cast by telephone, facsimile, e-mail, or mail. The

results of such a vote will be included in the minutes of the next regularly scheduled meeting of the Board.

Article VII: Officers/Executive Committee

The primary responsibility of each Officer shall be to oversee the affairs, funds, and property of the Society, while advancing ISPE's intent to be the leading technical organization for professionals engaged in producing quality medicines and pharmaceutical devices throughout the lifecycle. The Officers of the organization shall be as follows:

1. Chair
2. CEO/President (non-voting Member)
3. Vice Chair
4. Treasurer
5. Secretary
6. Past Chair

Sec. 1. Chair. The ISPE Chair shall preside at all Board and membership meetings. (S)he shall present at each Annual Meeting of the organization an annual report of the work of the organization. (S)he shall appoint chairpersons of all committees, temporary or permanent, with the approval of the Executive Committee. (S)he shall assure that all books, reports and certificates as required by law are properly kept or filed. (S)he shall be one of the Officers who may sign the checks and drafts of the organization. (S)he shall have powers as may be reasonably construed as belonging to the Chair of the Board of any organization.

Sec. 2. The CEO/President shall be authorized to execute the annual business plan approved by the Board of Directors, enter into agreements on behalf of the Society, and manage the daily operations of the Society. The Board of Directors shall hire the CEO/President. The Executive Committee shall fix the compensation of the CEO/President and conduct an annual performance review. The CEO/President shall be responsible for hiring and supervising all members of the International Staff and shall serve as Chief Executive Officer of the Society. (S)he shall be one of the Officers who may sign the checks and drafts of the organization and shall be the official spokesperson for the Society.

Sec. 3. Vice Chair. (S)he shall perform the duties of the ISPE Chair in the Chair's absence and shall succeed the ISPE Chair in the event that the Chair is unable to complete his/her tenure of office.

Sec. 4. Treasurer. The Treasurer shall have the responsibility to monitor the collection and disbursement of all monies belonging to the organization and shall be assisted by the Staff of the Society with such monies or securities of the organization. (S)he shall cause to be deposited in an insured financial institution the funds of the Society. (S)he may be one of the Officers who may sign checks or drafts of the organization. (S)he shall render at such stated periods as the Board of Directors shall determine a written account of the finances of the organization and such report shall be physically affixed to the minutes of the Board of Directors of such meeting.



(S)he shall prepare for the Board of Directors' approval an annual operating budget, said budget to cover the forthcoming Society year.

Sec. 5. Secretary. The Secretary shall keep the minutes and records of the Board of Directors and of the Society. It shall be the duty of the Secretary to file any certificate required by any statute, federal or state. (S)he shall give and serve all notices to members of this organization. (S)he shall be the official custodian of the records and seal of this organization. (S)he may be one of the Officers authorized to sign checks and drafts of the organization. (S)he shall attend to all correspondence of the organization and shall exercise all duties incident to the office of Secretary.

Sec. 6. Past Chair. (S)he shall provide continuity and guidance to the ISPE Chair and other officers.

Sec. 7. Director Compensation. No elected Director shall by reason of his/her office be entitled to receive any salary or compensation. Reasonable expenses incurred by a Director of the Society while conducting business for the Society will be reimbursed. Prior approval from the ISPE Chair or President as specified in the policies of the organization is necessary.

Article VIII: Staff

The Board of Directors shall establish total Staff compensation as part of the annual budgeting process and approve personnel policies.

Article IX: Committees and Other Volunteer Groups

The governance committee chairpersons of this organization whose identities are not specified in the Board-approved Governance Structure shall be appointed by the ISPE Chair, with approval by the Executive Committee, and their terms of office shall be for a period of one (1) Society year or until their successors are appointed. The chairpersons of operating committees shall be recommended by the CEO/President. Operating Committees, Councils, Teams, Forums, and Communities of Practice may be established as deemed necessary by the CEO/President in consultation with ISPE Chair or International Board of Directors.

Sec. 1. Rules for Governing Committees. At least 50 percent of committee members shall constitute a quorum for transaction of committee business. Only members of the Society may be appointed to serve on committees. Committee chairpersons shall ensure that minutes are taken for all committee meetings and distributed to the ISPE Chair.

Sec. 2. Nominating Committee. This committee will consist of the Board Officers plus three Past Chairs, one young professional, one Chapter Chair, one Affiliate Chair, the CEO/President, and any appropriate additional representatives as determined by the ISPE Chair. The committee shall thoroughly review the active membership in recommending a final slate. The final list of nominees shall be reviewed by the International Board of Directors for final approval prior to being voted on by the full membership. The proposed candidates shall be contacted to determine their interest and have their responsibilities explained. The Nominating Committee shall also advance recommended candidates for the appointed Board Director position to the Board of Directors when an appointed position is deemed necessary by the Board.

Sec. 3. Executive Committee. This committee will consist of all elected Officers, the immediate Past Chair, and the CEO/President, who shall not have a vote. The Committee may exercise the powers of the International Board of Directors when the Board is not in session, reporting to the Board at its succeeding meeting on any action taken.

Article X: Dues

Sec. 1. The dues of this organization shall be payable on the anniversary date of ISPE membership, or as determined by the International Board of Directors. The amount of the dues shall be determined by the Board of Directors. A portion of the membership dues determined annually is allocated for a non- deductible subscription to the Society's Magazine, Pharmaceutical Engineering.

Sec. 2. Annual dues are payable on receipt. Any member who has failed to remit dues payments within 30 days shall be sent a second billing along with notification that membership will automatically be canceled unless remittance is received within 30 days.

Article XI: Amendments

These bylaws may be altered, amended, or repealed and new bylaws may be adopted by no less than 10 and a two thirds majority of the Directors present at any regular meeting or at any special meeting, if at least seven days' written notice is given of intention to alter, amend, or repeal or to adopt new bylaws at such meeting.

The Board of Directors will adopt a Governance Structure to further define, clarify, add oversight of strategic implementation, and provide guidance to programs and policy formulation. This governance structure may be adopted, altered, amended, or repealed by a simple majority of the Directors present at any regular meeting or at any special meeting.

Article XII: Indemnification

Sec. 1. Every Officer, Director, employee of the Society and such others as specified by the International Board of Directors, shall be indemnified by the Society against all expenses and liabilities including counsel fees, reasonably incurred or imposed upon them in connection with any proceeding to which they may be made a party, or in which they may become involved by reason of being or having been an Officer, Director or employee of the Society, or any settlement thereof, whether the person is an Officer, Director or employee at the time such expenses are incurred, except in such cases wherein the Officer, Director or employee is adjudged guilty of willful misfeasance or malfeasance in the performance of duties.

The foregoing right of indemnification shall be in addition to and not exclusive of all rights to which the indemnified may be entitled.

Sec. 2. The International Board of Directors shall have the power to purchase and maintain, at the Society's expense, insurance on behalf of the Society and on behalf of others to the extent that power to do so has been or may be granted by statute, and give other indemnification to the extent not prohibited by law.



Article XIII: Gender

Whenever used in these bylaws, the singular shall include the plural, the plural shall include the singular, and pronouns shall be read as masculine, feminine or neuter as the context requires.

Article XIV: Procedure

The rules contained in the most recent edition of Robert's Rules of Order shall provide the rules of procedure for the Society where they are not inconsistent with the provisions of the Articles of Incorporation or these bylaws.