

ISPE Bylaws – Revised 6 June 2011

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 reviewed annually. Affiliates 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 who are responsible to the ISPE Board of Directors for their actions.

Article II: Purposes

Sec. 1. Promote Interests. To further and promote the interests of professionals in the Pharmaceutical Industry, including Regulatory Agencies and Academia. This may entail design, supervision, service, supply or maintenance of production equipment systems or facilities utilized for the development or manufacture of pharmaceutical and biotechnology products, clinical materials, medical devices, or diagnostic equipment, and also may relate to research and development, manufacturing, quality control/assurance, supply chain management, and regulatory activities in those fields. 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. Not-for-Profit. ISPE is an incorporated organization operating on a not-for-profit basis.

Sec. 8. Certification. To establish and administer certification programs to further and promote the interests of development and manufacturing professionals in the pharmaceutical, biotechnology, medical device, and diagnostic industries.

Article III: Membership

There shall be eight classes of membership:

1. Industry Member
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 pharmaceutical science, engineering, or technology 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 on committees 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 on committees 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 pharmaceutical science, engineering, or technology 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 on committees 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, engineering, or other technical disciplines at a recognized educational institution may enter the Society as Student Members while they are enrolled and for one year following graduation. Part-time students 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 on committees 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 committee members.

Sec. 5. Academic Members. Any individual employed full-time by an educational institution that agrees to promote educational programs aimed at developing pharmaceutical science, engineering, or technology 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 on committees 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 on committees and hold any office of the Affiliate/Chapter. Academic memberships are not transferable.

Sec. 6. Emerging Economy Members. Individuals engaged in pharmaceutical science, engineering, or technology 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 serve on committees of the Society. Emerging Economy memberships are not transferable.

Sec. 7. Honorary Members. The ISPE Chairman and 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 on committees 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 retirement from business and professional activity, shall be eligible for emeritus status with dues waived. Emeritus Members shall be entitled to limited Society benefits, including to vote on matters pending before the Society, hold office, and serve on committees of the Society. Emeritus memberships are not transferable.

Sec. 9. Hardship Members. Any individual who is an active member, upon becoming unemployed may request a suspension of 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 on committees 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 Chairman when 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 Chairman 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. TEN (10) members present at any meeting of the Society 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 act as "Inspectors of Election" and shall at the conclusion of balloting certify in writing to the Chairman 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. The Board of Directors shall be composed of not less than three (3) and not more than sixteen (16) members including the Officers of this organization and the Past Chairman. 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 President shall serve as a non-voting member of the Board of Directors.

Sec. 2. Function. The Board of Directors shall control and manage 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 Chairman.

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 the Directors, unless the act of a greater number is required by law or by 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 Chairman or the 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 Chairman 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

The primary responsibility of each Officer shall be to manage the affairs, funds, and property of the Society, while advancing the science and art of pharmaceutical science, engineering, and technology. The Officers of the organization shall be as follows:

1. Chairman
2. President
3. Vice Chairman
4. Treasurer
5. Secretary

Sec. 1. Chairman. The ISPE Chairman shall preside at all Board and membership meetings. He shall present at each Annual Meeting of the organization an annual report of the work of the organization. He shall appoint chairpersons of all committees, temporary or permanent, with the approval of the Executive Council. He shall assure that all

books, reports and certificates as required by law are properly kept or filed. He shall be one of the Officers who may sign the checks and drafts of the organization. He shall have powers as may be reasonably construed as belonging to the Chairman of the Board of any organization.

Sec. 2. President. The 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 President. The Executive Council shall fix the compensation of the President and conduct an annual performance review. The President shall be responsible for hiring and supervising all members of the International Staff and shall serve as Chief Executive Officer of the Society. He shall be one of the Officers who may sign the checks and drafts of the organization and shall be the official spokesman for the Society.

Sec. 3. Vice Chairman. He shall perform the duties of the ISPE Chairman in his absence and shall succeed the ISPE Chairman in the event that the Chairman is unable to complete his 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. He shall cause to be deposited in an insured financial institution the funds of the Society. He may be one of the Officers who may sign checks or drafts of the organization. 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. 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 his duty to file any certificate required by any statute, federal or state. He shall give and serve all notices to members of this organization. He shall be the official custodian of the records and seal of this organization. He may be one of the Officers authorized to sign checks and drafts of the organization. He shall attend to all correspondence of the organization and shall exercise all duties incident to the office of Secretary.

Sec. 6. Director Compensation. No elected Director shall by reason of his 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 Chairman 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

The committee chairpersons of this organization shall be appointed by the ISPE Chairman, with approval by the Executive Council, and their term of office shall be for a period of one (1) Society year or until their successors are appointed. Committees, Councils, Task Teams, and Communities of Practice may be established as deemed necessary by the ISPE Chairman or International Board of Directors.

Sec. 1. Rules for 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 Chairman.

Sec. 2. Nominating Committee. This committee will consist of three Past Chairmen, one of whom shall be the immediate Past Chairman, Executive Council, the President, and any appropriate additional representatives as determined by the ISPE Chairman. 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.

Sec. 3. Executive Council. This council will consist of all elected Officers, the immediate Past Chairman, and the President, who shall not have a vote. The Council 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.

Sec. 4. Certification Commission. The Certification Commission shall develop, manage, and administer any professional certification programs conducted by the Society. The Commission shall consist of a minimum of 12 individuals appointed by the ISPE Chairman, with approval by the Executive Council, and not all such individuals need to be Society members. The Commissioners shall serve terms of three years each on a staggered basis, with vacancies filled by the ISPE Chairman.

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. Sixty dollars of the membership dues 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 a 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.

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.