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NOTE:

- 1) The text in **BOLD PRINT** must be included VERBATIM in Bylaws.
- 2) The text in *ITALICS* can be revised to suit the needs of individual Chapters but must be included in Bylaws.
- 3) The text in CAPS & **BOLD** has been added since last version.

BYLAWS
THE BOSTON AREA CHAPTER OF THE INTERNATIONAL SOCIETY
FOR PHARMACEUTICAL ENGINEERING, INC.

ARTICLE I: ORGANIZATION

Section 1. Name: The name of this organization shall be Boston Area Chapter of the International Society for Pharmaceutical Engineering, Inc. ("Chapter"). Its rules must be in accordance with all rules and regulations of ISPE and approved by the International Society for Pharmaceutical Engineering ("ISPE" OR "Society").

ARTICLE II: PURPOSES

Section 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. The Chapter will provide present and prospective ISPE members with local opportunities to discuss topics of related interest with their colleagues; to hold meetings and/or workshops on a regular basis; and to promote membership in ISPE. All applications for membership are subject to review by the International Board of Directors for qualification based on job functions. The Chapter will not solicit or promote for personal gain, products, services, or equipment.

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

Section 3. Industry Integrator. To foster and encourage favorable relations and provide opportunities for interaction among individual members, industry companies including suppliers, government and academia.

Section 4. Information. To collect and disseminate information for its members.

Section 5. Establish Profession. To enhance the image of pharmaceutical science, engineering, and technology as a profession and promote its importance within the industry.

Section 6. Not for Profit. The ISPE Boston Area Chapter is an incorporated organization operating on a not-for-profit basis.

ARTICLE III: MEMBERSHIP

There shall be eight classes of membership:

1. **Industry Member**
2. **Regulatory Authority/Government**
3. **Student**
4. **Academic Member**
5. **Emerging Economy**
6. **Honorary**
7. **Emeritus**
8. **Hardship**

Section 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 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 Chapter. Industry memberships are not transferable.

Section 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 and may 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.

Section 3. Student Members. Individuals enrolled full-time in 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 CHAPTERS, 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 of that Chapter. Student memberships are not transferable.

Section 4. 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 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 Chapter. Academic memberships are not transferable.

Section 5. 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 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.

Section 6. 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. They may become Honorary Members of the Chapter. Honorary memberships are not transferable.

Section 7. 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.

Section 8. Hardship Members. Any individual who is an active Member in the Society, 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.

ARTICLE IV: MEETINGS

Section 1. General. *The Board of Directors of the Chapter shall schedule the Chapter program year of events and Board meetings.*

Section 2. Notice. *The Secretary shall cause to be mailed, faxed or emailed to every member in good standing at his/her address as it appears in the membership records of the Chapter, a notice telling the time and place of Chapter meetings.*

Section 3. Quorum. *A majority of members present at any meeting of the Chapter shall constitute a quorum.*

ARTICLE V: VOTING

Section 1. Voice Vote. At all meetings of this Chapter, issues requiring a vote for resolution shall be referred to the eligible voting members there present for 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.

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

Section 3. Inspectors of Election. The Nominating Committee shall act as "Inspectors of Election" and shall at the conclusion of balloting certify the results in writing to the Chapter President. A copy of the results shall be physically affixed to the minutes of the Chapter Board meeting. The Chapter may also ask ISPE International to act as Inspectors of Election.

Section 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: BOARD OF DIRECTORS

Section 1. Board Membership. The Board of Directors shall consist of no fewer than three (3) members and shall include the Officers and Directors of the Chapter. The term of office for the Board of Directors shall be no more than two years and a director may not serve more than four (4) consecutive years unless that individual is elected an Officer. The elections of the Board of Directors shall be held no later than 1 August of each election year in order that the new Officers may attend the Society's Annual Meeting in the fall of each year.

Section 2. Function. The Board of Directors shall control and manage the affairs and business of the Chapter. Such Board of Directors shall only act in the name of the organization when it shall be convened or assigned by the Chapter President.

Section 3. Board Meetings. A simple majority of the members of the Board of Directors shall constitute a quorum. Meetings of the Board of Directors shall be held not less than three times during the Chapter year. Directors may attend a meeting by telephonic or similar equipment by means of which all persons participating can hear each other.

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

Section 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.

Section 6. Board Votes. Each Director shall have one vote, and voting shall not be done by proxy. Should a special vote of the Board of Directors be deemed necessary by the President, to occur between meetings of the Board, such a vote may be cast by telephone, fax, e-mail or by 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 Chapter, while advancing the science and art of pharmaceutical science, engineering, and technology. The Officers of the organization shall be as follows:

- 1. President*
- 2. Vice President*
- 3. Treasurer*
- 4. Secretary*

Section 1. President. The President shall preside at all Board and membership meetings. S/He shall preside over strategic planning for the chapter and will update a chapter business plan with input and approval from the board. The business plan is due the first board meeting of the new calendar year. S/He shall present 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 Board of Directors. S/He shall assure that all books, reports and certificates, 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 President of the Board of any organization.

Section 2. Vice President. The Vice President shall perform the duties of the President in his/her absence and shall succeed the President in the event that the President is unable to complete his tenure of office.

Section 3. Treasurer. The Treasurer shall have the responsibility to monitor the collection and disbursements of all monies belonging to the organization and shall be assisted by the staff of the Society with such monies or securities. S/He shall cause to be deposited in an insured financial institution the funds of the Chapter. S/He may be one of the Officers who shall sign checks or drafts of the Chapter. S/He shall render, at such stated periods to the Board of Directors, 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 Board of Directors approval an annual operating budget, said budget to cover the forthcoming Chapter year. The budget will be prepared in time for review and approval by the Board of Directors. S/He shall exercise all duties incident to the office of Treasurer.

Section 4. Secretary. The Secretary shall keep the minutes and records of the Board of Directors and of the Chapter. It shall be his/her duty to file any certificates required by 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 of the Chapter. S/He shall submit to the Board of Directors any communications that shall be addressed to him as Secretary of the organization. S/He shall attend to all correspondence of the organization and shall exercise all duties incident to the office of Secretary. They shall normally chair one of the chapter's committees.

Section 5. Officer/Director Compensation. No Officer/Director shall by reason of his office be entitled to receive any salary or compensation. Reasonable expenses incurred by an Officer/Director of the Chapter while conducting business for the Chapter will be reimbursed. Prior approval from the Board of Directors is necessary.

ARTICLE VIII: COMMITTEES

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

The permanent committees shall be as follows:

- **Nominating**
- *Program*
- *Membership*
- *Communications*
- *Bylaws and Policy*
- *Product Show and Vendor*
- *Young Professionals*
- *Past Presidents*
- *Advisory Board*
- *Chapter Excellence*
- *Social Committee*
- *Finance Committee*
- *Student Affairs*

Section 1. Rules for Committees. A majority of committee members shall constitute a quorum for transaction of committee business. Only ISPE members may serve on a committee or task team.

Section 2. Nominating. To the extent practicable, the Nominating Committee shall be composed of members with no personal involvement in the election and be comprised of the outgoing President *and active past presidents*. The committee will thoroughly review the active Chapter membership list in recommending a final slate. The committee will consider the natural progression of Officers and further, whenever possible, will recommend a current Director for consideration for an Officer position.

The proposed candidates will be contacted to determine their interest and have their responsibilities explained. The final list of nominees will then be presented to the Board of Directors for final approval prior to being voted on by the full membership. No change may be made to the slate once it has been approved by the Board without full consent of the Board.

Section 3. Program. This committee shall be responsible for the planning and execution of all Chapter educational meetings. It shall research and engage speakers for all programs. It shall work directly with the ISPE Education Committee on any Expanded Education Programs being considered. It shall be responsible for the setup, reception and signing of all participants at each function in conjunction with the Membership Committee.

Section 4. Membership. This committee shall be responsible for membership growth and retention. It shall work with ISPE International for membership verification and shall handle that aspect of the check-in process at all Chapter meetings. It shall work with the Chapter Officers and the International Membership Development Committee to develop annual methods for attracting and retaining local Chapter membership.

Section 5. Communications. This committee shall be responsible for transfer of all information to the Chapter membership and ISPE International, on all Chapter activities, ISPE national activities, and region industry facts. In concert with ISPE International and after review by the Vice President of Member Relations, it shall schedule and produce a regular series of publications for this purpose.

*Section 6. Bylaws and Policy. This committee shall be responsible for the development of long-range plans and policies for the Chapter and making recommendations for such to the Board of Directors. It shall review the Bylaws of the Chapter, recommending any changes, additions or deletions to ISPE International and the Chapter Board of Directors. **No changes to the Bylaws will be made before approval by the President of ISPE through the Vice President of Member Relations.***

*Section 7. Product Show and Vendor. This committee shall be responsible for recommending activities so that the interests of suppliers to the industry are properly represented. It shall also develop programs to increase financial support for the Chapter through advertising and exhibits. **It shall work to adopt and enforce all Society restrictions and guidelines in these areas.** Furthermore, it shall be responsible for planning and executing the activities required to hold an annual exhibits event known as the "Boston Product Show". The committee chair will normally serve a 2 year term. In their second year, the chair will train a successor, who will in turn serve a 2 year term.*

*Section 8. **Young Professionals.** This committee will oversee the activities and programs designed for young professionals and will coordinate its efforts with those of the Student Affairs Committee. The latter will retain responsibility for the formation of any Student Chapter and oversight of the annual student poster competition, and will work together with the Young Professionals Committee to coordinate activities at Chapter and international events. **A member of the committee will represent the Chapter on the International Young Professionals Committee or designated subcommittee.***

Section 9 Past Presidents. This committee will be responsible for advising and supporting the activities of the chapter. The intent of this committee is to leverage the experience of active past presidents to support and mentor the chapter's board of directors. Members of this committee shall be invited to participate in the activities of the chapter in a manner similar to that of board members. They shall not, however, routinely participate in board meetings nor vote as members of the board of directors. It

will be made of active past presidents, and normally chaired by the immediate past president. The committee chair will be elected by the committee members.

Section 10 Advisory Board. This committee will oversee the selection and formal interaction with the chapter's industry advisory board. This committee will recommend the members of the advisory board, and present them to the board of directors for approval on an annual basis. This committee will also determine the number and format of advisory board meetings held each year. The Immediate Past President will chair this committee. The committee, in conjunction with the appropriate officers, will help organize and execute advisory board meetings.

Section 11 Chapter Excellence. This committee reviews and compares the chapter's activities against the ISPE chapter excellence award criteria to identify areas where the chapter can improve. At the end of each chapter year, this committee is responsible to prepare the chapter excellence submittal to ISPE Head Quarters.

Section 12 Social Committee. This committee shall be responsible for the planning and execution of all chapter social functions. The primary goal of chapter social functions is to promote the networking and interaction of chapter members and guests. The social committee should actively find ways to encourage the participation of employees of operating companies at functions. Social functions may consist of the following: a ski trip, a golf tournament, an end of summer party, and a holiday party. The social functions should also provide a service to society by raising money that can be used for charitable purposes.

Section 13 Finance Committee. This committee shall be responsible for monitoring and managing the Chapter's finances. This committee shall be composed of the duly elected officers of the Chapter and Chapter Manager. Unless decided otherwise, the committee shall be chaired by the Treasurer who shall report to the Board of Directors. In the event one of the designated members is unable or unwilling to serve, the Board shall appoint a replacement from among the Board members for the remainder of the term.

Section 14 Student Affairs. This committee will oversee the formation of any Student Chapter and coordinate activities with the students and at Chapter and international events and the annual student poster competition.

ARTICLE IX: AMENDMENTS

Section 1. Bylaws. The bylaws may not be amended or repealed or new rules made for any reason without the consent of ISPE International.

The bylaws may be made, altered, or rescinded by a two-thirds vote by the Chapter Board of Directors present at any special or annual meeting duly called for said purpose. In addition, the bylaws may be amended pursuant to any

proposal by any member in good standing, and upon approval by two-thirds vote of the membership in attendance at meetings duly called for such purpose.

Section 2. Articles of Incorporation. The Chapter Articles of Incorporation may not be amended or repealed or new rules made for any reason without the consent of ISPE International.

Section 3. Chapter Charter. After initial issuance, ISPE annually reviews charters of each Chapter for compliance with all stated procedures. If the charter is not renewed, the Chapter will return all materials including its membership list to ISPE. The Chapter will make no further use of the ISPE name or logo and will take all necessary action to dissolve its legal entity.

ARTICLE X: INDEMNIFICATION

Section 1. Every Officer, Director, employee of the Chapter and such others as specified by the Board of Directors, may be indemnified by the Chapter 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 Chapter, 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.

Section 2. The Board of Directors shall have the power to purchase and maintain, at the Chapter's expense, insurance on behalf of the Chapter and on behalf of others insofar as power to do so had been or may be granted by statute, and give other indemnification to the extent not prohibited by law.

ARTICLE XI: GENDER

Section 1. Language. 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 XII: FISCAL YEAR

The fiscal year of the Chapter shall coincide with that of ISPE.

ARTICLE XIII: PROCEDURE

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