



Governance Structure

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ISPE GOVERNANCE STRUCTURE

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All inquiries should be addressed to:

John E. Bournas
CEO and President
International Society for Pharmaceutical Engineering, Inc.
600 North Westshore Blvd, Suite 900
Tampa, Florida USA 33609

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INTRODUCTION

OVERVIEW

ISPE, like many nonprofit organizations, accomplishes its mission with and through the energies of many contributors. To ensure that the experiences of each person are as positive and productive as possible as they work together, it is important that everyone be clear about the structure of the organization and the roles and responsibilities for each person or group.

Governance

The Board of Directors has ultimate governance authority over the organization. In simple terms, this means the Board has fiduciary responsibility and responsibility for the trust that is understood to exist between the mission of ISPE and the stakeholders ISPE serves.¹

Good governance means acting as stewards of the organization's interest and ensuring legal and ethical integrity, ongoing revenue generation and financial viability, board continuity, an effective oversight process, and compliance with the corporate charter and bylaws. The governance process should provide oversight, value-added guidance, and final decision making on strategy, program, and policy formulation; CEO selection; and oversight of strategic plan implementation.

Governance volunteers include Board Members. The Board Chair may also appoint individuals who are not Board Members to assist the Board with its responsibilities as described above. These volunteers typically work on committees or groups that report to the Board, and their role is consultative in nature.

Examples of governance committees include:

- Nominating Committee
- Finance and Audit Committee
- Governance Committee

The Chair of any governance group will always be a volunteer. Usually the volunteer will be a Member of the Board of Directors, although a non-Board volunteer chair may be appointed to lead a Board Working Group at the discretion of the Board Chair.

Operations

Most volunteer committees do not have governance functions. This distinction is important, because in governance the staff is essentially taking direction from the elected Board of Directors. The relationship in standing committee functions is different. To the extent that the CEO/President and staff are carrying out the Board-approved plans and budget, the volunteer role is to “collaborate” with other volunteers and staff to accomplish ISPE’s mission and business objectives, i.e., to produce deliverables as described in the annual Business Plan.

Functional (operations-supporting) volunteers assist the organization and staff in carrying out the aspects of the Society’s business that rely on subject matter expertise or access to key audiences. These volunteers typically serve as subject matter experts and technical advisors in the development and delivery of ISPE’s products, services, and Member benefits. They are accountable to the leader managing the project (typically staff), and the leader is the person ultimately responsible for successful project completion. Functional volunteers can serve in groups or as individuals.

Examples of operational groups that rely on functional volunteers include:

- Event Teams
- Document Teams

¹ Adapted from BoardSource’s definition in “The Handbook of Nonprofit Governance”

Facility of the Year Committee
CoP Steering Committees

The Chair of any operational group may be either a volunteer or a member of the professional staff. Chairs of operational groups are typically appointed based on expertise. If the Chair is a volunteer but the project leader is a member of the staff, accountability is shared. Staff leaders are, however, responsible for meeting project timelines and budget; they have the authority to do what is necessary to ensure the group is able to meet its commitments to ISPE.

Other Categories

ISPE's structure also accommodates additional categories of groups and volunteers that play important roles in the mission of the organization.

Advisory Volunteers/Groups

Advisory volunteers/groups assist the Society's leaders in improving ISPE's business by sharing their ideas, points of view or specialized expertise to inform decisions. These individuals/groups are not accountable for producing deliverables. Advisory individuals/groups can inform either governance or operational projects; they are accountable to the Board or staff leader who is responsible for successful project completion.

Examples of advisory volunteers/groups include:

- New Content Advisory Group
- Ad Hoc Focus Groups/Advisory Panels
- Pro bono experts (e.g., a financial advisor to the Finance and Audit Committee or a professor of adult education advising staff in the Training Department).

Independently Governed, Legally Affiliated Entities

Over its history ISPE has chosen to carry out important parts of its mission by facilitating the creation of groups that are governed independently but which are legally affiliated with ISPE by agreement. The rationale for doing this varies on a case by case basis.

On ISPE's organizational chart these groups are shown in their own shaded box. From that box there is a solid line to the Board of Directors, which ultimately sets the policies that govern these relationships, and a dotted line to the CEO/President, who is responsible for day-to-day operational interface.

Examples of Independently Governed, Legally Affiliated Entities include:

- Affiliates
- Chapters

Independently Governed, Legally Affiliated Entities may form Boards and Committees consistent with their own bylaws and contractual charter agreements with ISPE. Volunteers for these groups may have more than one role. For example, the Chair of an Affiliate Board has governance responsibilities at the Affiliate level, and at the International level may have operational or advisory responsibilities.

Partnering Organizations

From time-to-time ISPE chooses to partner with external independent organizations to fulfill its mission. The relationship of those partnerships are governed by the principles that have agreed upon by both parties, which may be a contract, memorandum of understanding, charter or other document that outlines the relationship.

Document Structure

The following pages reflect this best practice approach to organizational governance; a companion document exists and reflects best practices for structuring volunteer groups that support operations. The specific role, membership composition and responsibilities for the Board and all governance, operational, and advisory groups are captured in these two documents. This begins with the organizational chart at the front of each document, and it is followed by descriptions of each group that will play a part in delivering ISPE's mission, organized in sections according to their role. The Appendices contain policies and procedures that are relevant to volunteers who may serve in these roles.

A Note about Terms

ISPE attempts to be consistent in its use of terms. Unless noted:

Committees may be either governance or operational. Committees have specific charges and accountabilities on an ongoing basis.

Councils are representative bodies composed of the sitting leaders of peer groups within the Society. Councils have dual roles. They are simultaneously operational with respect to the goals of the groups they represent, and they are advisory with respect to ISPE's governance and operational functions.

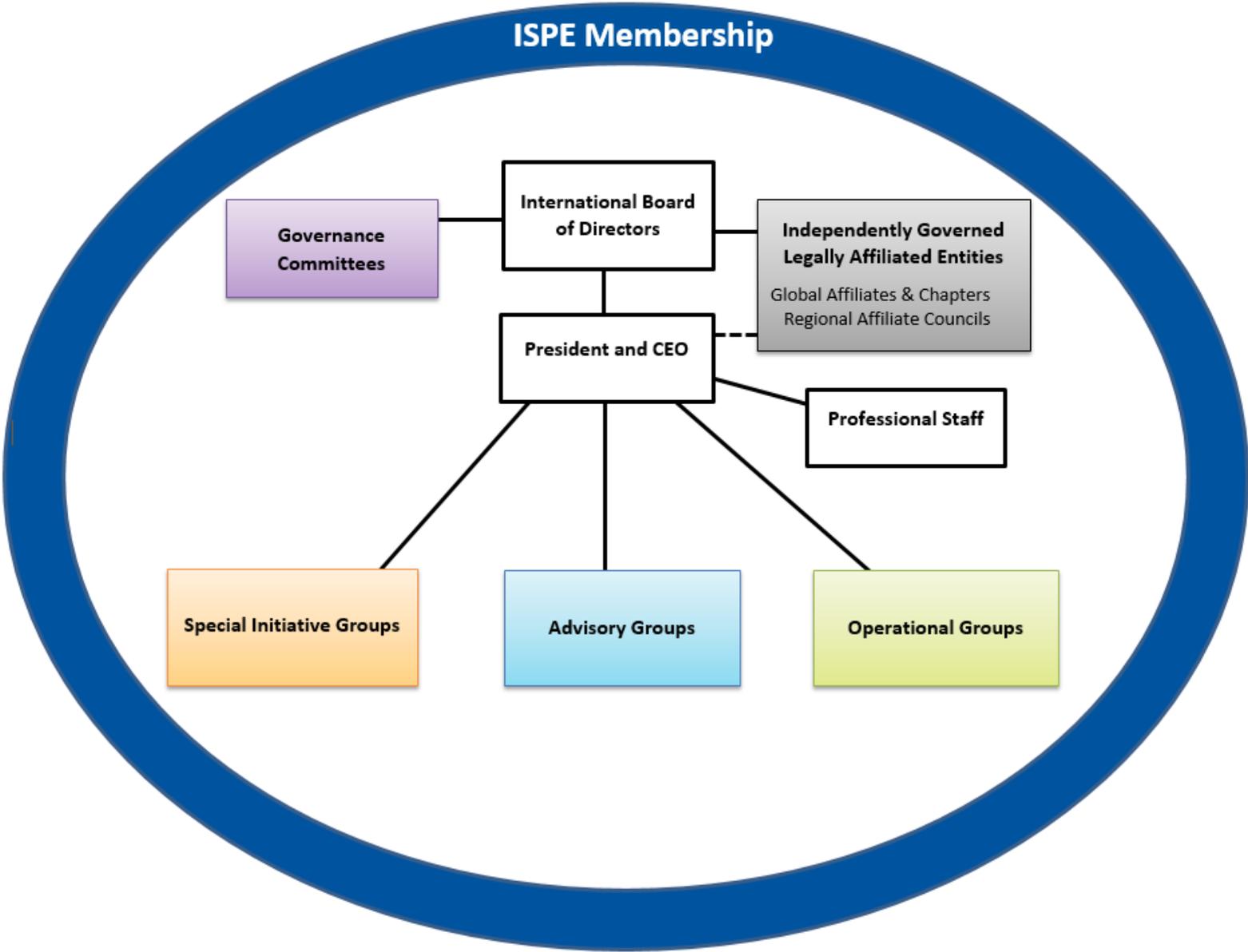
Teams may be either governance or operational. Teams have specific, time- or project-limited assignments, usually with specific deliverables.

Forums are advisory and ongoing.

Panels are advisory, time- or project-limited, and populated according to specific expertise.

Focus groups are advisory, time- or project-limited, and populated either randomly or according to broad demographic categories.

ISPE Organizational Chart



ORGANIZATIONAL GOVERNANCE

INTERNATIONAL BOARD OF DIRECTORS

COMMITTEE TYPE: Governance

ROLE: Create the Society's vision, establish its basic goals and policies, approve its financial direction and provide guidance to the Committees, Councils, Teams, Forums, and professional staff.

MEMBERSHIP COMPOSITION:

1. A maximum of 15 voting members who are currently active, dues-paying Members of ISPE shall comprise the Board of Directors. This number shall include the Officers (Chair, Vice Chair, Treasurer, Secretary) and 10 Directors. The immediate Past Chair will have an option to serve an additional term automatically as a voting member. The CEO/President, who also serves as an officer, shall serve as a regular, ex-Officio, non-voting member of the Board of Director, regardless of the total number of board members. The Secretary is responsible for recording minutes, however, a staff person may be assigned to take minutes on behalf of the Secretary.
2. Vice President-level staff may participate as key resources during the CEO/President updates or upon invitation by the Board of Directors.
3. Director Special Appointment. In order to insure appropriate skills and diversity within the Board to execute business strategies as defined in the 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 membership, (s)he is eligible to be considered as an officer candidate. This selection process shall be governed by the Nominating Committee.
4. Terms for all Officers will be for one year, two years for all Directors, commencing at the Annual Meeting. No Director will serve more than four consecutive years without having been nominated for an Officer position.
5. To the extent feasible, the Nominating Committee and the Board Officer Nominating Committee will seek a balance of all membership constituencies in selecting its candidates to meet the strategic governance needs of the organization. Contributions to the Society will be among the chief criteria in selection.
6. The Chair will establish Board Ad Hoc Teams and Panels, as needed, to work on special projects. Where appropriate to support strategic initiatives, the Chair, with support of the Executive Committee, may invite a team or committee representative to join the Board as an ex-officio non-voting liaison/guest.
7. Active participation is expected from all members. Absence from two consecutive meetings may subject members to dismissal from the Board in accordance with bylaws.

REPORTING REQUIREMENTS:

The International Board of Directors is the ultimate authority for the Society. Its policies and plans will be communicated to all Society groups as appropriate. The President will serve as the

Board's representative to Society groups, the official spokesperson on behalf of the Board, and will be the Society's Chief Executive Officer.

RESPONSIBILITIES:

1. Create the Society's vision, establish or approve all Society policies and control Society business.
2. Review and approve the annual operating budget submitted by the professional staff and Finance and Audit Committee. The approved budget will be managed by the CEO/President with "bottom line" deviations approved by the International Board.¹
3. On a quarterly basis, review actual-versus-budget financial reports, evaluate and take action on staff recommendations for operational adjustments, and where appropriate, undertake Board activity to improve the Society's fiscal health.
4. As part of the budget approval, authorize staff additions and total funding.
5. Authorize unbudgeted capital expenditures in excess of \$75,000.
6. Approve investment programs for revenue surpluses.
7. Annually review grants of authority to Society professional staff.
8. Approve the annual Business Plan. The approved plan will be managed by the CEO/President.
9. Annually approve the goals and priorities for the CEO/President.
10. Annually review Affiliate and Chapter charter compliance and recommend appropriate follow-up.

MEETING PROJECTIONS:

1. No less than four times per year as listed in the annual schedule.

STANDARDS OF CONDUCT FOR BOARD MEMBERS:²

Members of the Board of Directors shall:

1. Attend all Board meetings. Excessive absences from Board meetings or any assigned Committee/team meetings (typically defined as two consecutively missed meetings) may result in removal from the Board of Directors in accordance with the bylaws.
2. Submit reports and requests for action on or before stated deadlines.
3. Be prepared for all meetings, having carefully read all materials provided.
4. Form an informed opinion on the issues that will be presented at the meeting.
5. Participate in deliberations, making sure the important points related to diversified interests are raised in the discussion.
6. ALWAYS deliberate with courtesy and respect for the other members of the Board.
7. When casting votes, keep the best interest of the organization above any personal or special interests represented.
8. Accept decisions reached by the majority as the decisions of the entire Board.
9. Respect decisions reached by others as representing their best judgment.
10. Maintain confidentiality of closed proceedings.
11. Participate in Committee tasks and other tasks assigned.
12. Avoid situations where there is a possibility for a conflict of interest, and promptly disclose any conflicts of interest that arise.
13. Set an example of good leadership for the entire Society.
14. Maintain a high standard of ethical conduct in both volunteer and professional roles.

¹ See Appendix A for Board Grants of Authority

² See Appendices B, C, D and E for applicable policies.

EXECUTIVE COMMITTEE

COMMITTEE TYPE: Governance

ROLE: Provide strategic leadership for the Society, review issues for presentation to the International Board of Directors in summary form and act on behalf of the Board between meetings.

MEMBERSHIP COMPOSITION:

1. The full Committee will include the Past Chair, Chair, Vice Chair, Treasurer, Secretary, and the CEO/President as a non-voting member.
2. The Board Chair will serve as Chair of the Executive Committee.
3. The Staff Vice Presidents can participate in the meetings as non-voting members at the discretion of the Executive Committee. The Secretary is responsible for recording minutes.
4. Terms for all members will commence at the Annual Meeting.
5. Active participation is expected from all members. Excessive absences from Board meetings or any assigned Committee/team meetings (typically defined as two consecutively missed meetings) may result in removal from the Board of Directors in accordance with the bylaws.

REPORTING REQUIREMENTS:

1. Reports will be made to the International Board of Directors directly.

RESPONSIBILITIES:

1. Between meetings of the International Board of Directors authorize financial and operational decisions within the limit of its authority.
2. Develop the Strategic Planning Task Team for the Society, ensure the Board reviews the plan annually and enlists additional support for this project as required.
3. In conjunction with the professional staff, review and provide guidance on an annual Business Plan for approval by the International Board of Directors.
4. Develop recommendations for policies to be considered by the Board of Directors and develop consensus.
5. Provide orientation to the full International Board of Directors for their leadership positions and advise individual Officers or Directors of any unacceptable or inappropriate actions, reviewing such matters quarterly.
6. Review total staffing projections and proposed salary expenses with the President for inclusion in annual Business Plan and Budget.
7. Select a "CEO/President Search Committee" as outlined in Appendix I if needed.
8. Review operational reports from the President in detail for summary presentation to the International Board. Make recommendations to the President for adjustments as appropriate.
9. Approve unbudgeted capital expenditures between \$25,000 and \$75,000.
10. The Executive Committee will establish and carry out a process for the Board's evaluation of its own performance no less than annually.

MEETING PROJECTIONS:

1. No less than four times per year, as listed in the annual schedule.

EXECUTIVE COMPENSATION COMMITTEE

COMMITTEE TYPE: Governance

ROLE: Make recommendations to the full Board for the President's annual objectives and compensation and provide support for the President in legal – or otherwise sensitive matters -- related to personnel.

MEMBERSHIP COMPOSITION:

1. Officers of the Board of Directors
2. The Board Chair will serve as the Chair of the Committee
3. If needed, the Committee will seek support from the ISPE Director of HR

REPORTING REQUIREMENTS:

1. The Board Secretary will take confidential minutes.
2. Reports will be made to the International Board of Directors directly.

SPECIFIC RESPONSIBILITIES:

The Executive Compensation Committee is responsible for setting the compensation and conducting the annual performance evaluation of the CEO/President. The annual evaluation is intended to be a participatory process whereby the Committee and CEO/President work collaboratively in the development of long and short-term objectives, and a documented review.

1. Each year, the CEO/President will initiate the evaluation process by preparing for the Executive Compensation Committee a memorandum summarizing her performance against prior year objectives, describing areas for development and any matters of concern. This memorandum is to be reviewed by the Committee and included as input and also attached to the performance evaluation letter or document. A copy of the annual performance evaluation letter will be maintained in a secured file at the Headquarters office.
2. The Committee will solicit input from the Board regarding the performance of the CEO/President.
3. This Committee may also review the salary plan for the staff vice presidents.
4. The CEO/President will report to this Committee in any legal matters pertaining to employees or on sensitive member issues where confidentiality is required.
5. All actions of this Committee shall be in closed meeting and all deliberations treated as confidential matter. Each member of the Committee shall receive a confidential copy of the minutes of each meeting.

MEETING PROJECTIONS:

1. No less than annually; additional meetings as required

FINANCE AND AUDIT COMMITTEE

COMMITTEE TYPE: Governance

ROLE: Provide strategic financial oversight for the Society, review issues for presentation to the International Board of Directors in summary form.

MEMBERSHIP COMPOSITION:

1. The Finance and Audit Committee will include the Vice Chair, Treasurer, Secretary, Chief Financial Officer and CEO/President. The Chair and other relevant staff members will participate subject to need and availability. Additional members may be appointed by the Board.
2. The Treasurer will serve as the Chair of the Committee.
3. Terms for all members will commence at the Annual Meeting.
4. Active participation is expected from all members. Absence from two consecutive meetings may subject members to dismissal.

REPORTING REQUIREMENTS:

1. Reports will be made to the International Board of Directors directly.

SPECIFIC RESPONSIBILITIES:

1. Ensure integrity and financial accountability of ISPE and advise the Board on the direction and control of financial matters.
2. Monitor income and expenses against budget projections and present quarterly financial reports to the Board.
3. In conjunction with professional staff, prepare an annual international budget that accommodates the annual Business Plan, for approval by the International Board.
4. Develop procedures for professional staff, consultants, advisors, and volunteer leaders regarding expense reimbursements and reports.
5. Recommend investment strategies for approval by the International Board and monitor results.
6. Act as the Board's Audit Committee and serve as liaison with ISPE's auditor.
7. Prepare a financial risk analysis in the first quarter of the year and monitor that risk on an ongoing basis throughout the year, including potential mitigation factors and a call to action by the Board as necessary.

MEETING PROJECTIONS:

1. No less than four times per year; as listed in the annual schedule

NOMINATING COMMITTEE

COMMITTEE TYPE: Governance

ROLE: Select the best-qualified representatives from among the full, active international membership to serve as candidates for the International Board of Directors.

MEMBERSHIP COMPOSITION:

1. The Committee will be composed, at a minimum, of the Board Officers plus three past chairs, one young professional, one Chapter Chair, and one Affiliate Chair.
2. Additional appointments may be made by the ISPE Chair as needed to achieve proper input from all Society constituencies.
3. The ISPE Vice Chair will chair the Nominating Committee.
4. The CEO/President will serve as Staff Project Manager.

REPORTING REQUIREMENTS:

1. Reports will be made to the International Board of Directors directly.
2. The CEO will assign a staff member to take meeting minutes.

RESPONSIBILITIES:

1. The annual call for nominees will be issued by the CEO/President in Q1 each year.
2. The call should specify that the Committee is seeking nominees that properly represent the Society's constituencies and interests, for the International Board of Directors approval, then full membership vote.
3. The names of nominees will be sent to CEO/President, who prepares the package of nominees for review by the Nominating Committee.
4. The Nominating Committee performs a review/gap analysis on current Board makeup and capabilities to determine what qualifications are required to ensure the Board has the skills and experience required to operate effectively and implement the current Strategic Plan. The results will be reviewed and discussed with the Board for awareness and agreement. If agreed, the Board of Directors direct the Nominating Committee to provide recommendations for the appointed position.
5. If the list of prospective nominees does not address the needs identified in the gap analysis, the Committee, with and through the CEO/President, will initiate actions to reach out to potential nominees meeting those criteria.
6. Based on the abilities and qualifications of the suggested Members and on the results of the gap analysis, the Nominating Committee vets the recommendations and provides the slate of nominees for consideration and approval by the Board of Directors.
 - a. The abilities, qualifications and performance of current Directors completing their first term will be reviewed by the Nominating Committee for possible renomination.
 - b. New nominees may come from the entire active membership; any nominee who is not currently an ISPE Member will be required to join the Society before being placed on the ballot.
 - c. Contributions to the Society, ability to contribute to meeting the strategic objectives of the Society, industry experience, strategic business understanding and availability to serve should be the primary criteria utilized for analysis.
7. The Nominating Committee has exclusive authority to review, evaluate, and manage the overall election system to ensure it is the best possible for the membership, including a process for conducting and tabulating the voting.

8. The Committee will follow the election procedures outlined in Appendix F.

MEETING PROJECTIONS: No less than once annually; other meetings as needed to accomplish the Committee's responsibilities.

BOARD OFFICER NOMINATING COMMITTEE

COMMITTEE TYPE: Governance

ROLE: Present to the Board of Directors a slate of up to two candidates for election to the Office of Secretary of the Board of Directors. From time-to-time, this Committee may also be tasked with identifying and presenting a slate of candidates for other Society Offices should there be an unanticipated Board Officer vacancy(ies) due to unforeseen circumstances or removal.

MEMBERSHIP COMPOSITION:

1. Immediate Past Chair (serves as Committee Chair)
2. Chair of the Nominating Committee
3. Two members of the Board of Directors (who, by serving on this Committee are recused from consideration for the position(s) that are vacant)
4. Members of the Executive Committee

REPORTING REQUIREMENTS:

1. The CEO/President designates a staff member to take minutes of this meeting. Meeting minutes are confidential to the ISPE Board of Directors.
2. Reports are made to the ISPE Board of Directors and the final report to the Nominating Committee.

SPECIFIC RESPONSIBILITIES:

The Board Officer Nominating Committee nominates candidates for the Office of Society Secretary (and other Society Officer positions as required). It is responsible to:

1. Notify all members of the sitting Board to develop a list of potential Officer candidates.
2. Annually review the ISPE Secretary position description and determine potential candidates to stand for election.
3. Interview potential Secretary candidates to determine interest and to assess their level of personal and company commitment to entering the Officer succession.
4. Ensure the Committee Chair or designated Committee Member interviews the Vice Chair, Treasurer, and Secretary before making recommendation to advance in the Officer succession.
5. Recommend a final slate of no more than two candidates for the Secretary position. Make a recommendation on the advancement of the other Officer positions to the Board of Directors for election by the Board at their May-June meeting. Once elected by the Board of Directors, the positions of Chair, Vice Chair, Treasurer and Secretary of the Board will run unopposed in the general Society election.
6. Accomplish work within a timeline that coincides with the planning timelines and ballot deadlines established by the Nominating Committee.

MEETING PROJECTIONS:

No less than one time per year

GOVERNANCE COMMITTEE

COMMITTEE TYPE: Governance

ROLE: Make recommendations to the full Board regarding emerging issues and best practices pertaining to sound organizational governance.

MEMBERSHIP COMPOSITION:

1. At least three people appointed by the Chair, at least one of which is a Member of the Board of Directors
2. The Committee will be supported by the staff designated by the CEO/President.

REPORTING REQUIREMENTS:

1. Reports will be made directly to the International Board of Directors.

SPECIFIC RESPONSIBILITIES:

It is the responsibility of the Governance Committee to consider and report to the Board of Directors on all matters referred to it including:

1. Study proposed legislation and its effect on the existing governance documents and recommend ways to eliminate any apparent conflict.
2. Prepare the wording for all proposed amendments to the governance documents for the Board of Directors.
3. Give its opinion on all questions pertaining to the governance documents when such questions are submitted by the Chair, Board of Directors or the Executive Committee.
4. Bring to the attention of the Executive Committee and Board of Directors any violations of the governance documents, including recommendations for resolution of violations.
5. Review Board-approved governance documents on an annual basis.

The Governance Committee itself does not initiate any changes to the Society's governance; however, this Committee may forward recommendations for change to the Executive Committee for recommended action by the Board of Directors.

MEETING PROJECTIONS:

1. No less than annually; additional meetings as required

AWARDS COMMITTEE

COMMITTEE TYPE: Governance

ROLE: Select and administer all ISPE International Awards, review the existing Awards scheme to determine the need for modifications, eliminations, suspensions or additions of awards.

MEMBERSHIP COMPOSITION:

1. The Awards Committee shall minimally consist of the Awards Committee Chair, The Board Executive Committee and two Board Members at large. The Awards Committee Chair and two Board members at large shall be appointed by the Chair of the Board.
2. The ISPE CEO shall appoint a staff member to serve as Staff Project Manager.
3. The CEO and ISPE Staff Project Manager shall participate in the awards selection process, but shall not be a voting member.
4. When forming the Awards Committee the Awards Committee Chair shall consider diversification of the selection team including participant geography, background, and professional experience.
5. The Awards Committee Chair may recommend up to three more at large members (e.g. Chapter Presidents, Committee Leads, Young Professional Committee Leads, etc.) of ISPE to participate in the awards selection process if deemed appropriate to achieve the desired diversification of the awards selection team. The additional awards selection members shall be appointed by the Chair of the Board.

REPORTING REQUIREMENTS:

Report on progress will be made to the International Board of Directors; however, the committee has discretion on whether or not to keep the award recipient information confidential until the Annual Membership Meeting and Awards Ceremony.

RESPONSIBILITIES:

1. Annually review the existing Awards to determine the need for modifications, eliminations, suspensions or additions of awards.
2. Manage the selection of awardees as outlined in the Awards Policies.
3. Determine if there is a need for an ad hoc team to review nominations in a particular category. Oversee the ad hoc review team(s).
4. Interface with other ISPE award teams such as those for the Article of the Year and Facility of the Year to ensure consistency in award processes.

MEETING PROJECTIONS:

No less than once annually; other meetings as needed to accomplish the Committee's responsibilities.

ISPE AWARDS

Managed by the Awards Committee

- The Richard D. Purdy Distinguished Achievement Award
- The Joseph X. Phillips Professional Achievement Award
- Max Seales Yonker Member of the Year
- Committee of the Year
- Company of the Year
- Chapter and Affiliate Excellence Award

Managed by Other Committees

- Student Poster Competition – Graduate and Undergraduate (managed by the student initiatives staff liaison and Student Poster Competition Judging Team)
- Facility of the Year Award (Managed by the Facility of the Year Award Committee and FOYA Judging Team)
- Roger F. Sherwood Article of the Year (Managed by the Article of the Year Committee)

Definitions of the foregoing awards can be found on the ISPE website.

AWARDS POLICIES:

ISPE Award Authorization and Management

1. The Board of Directors shall sanction the development, requirements, nomination process, selection process and awarding of all international level awards.
2. In the case where Board of Directors sanctioned committee directly manages an approved award and its selection process, the committee may, at its discretion, change the award criteria, but may not change the intent and purpose of the award without the approval of the Board of Directors.

Nomination and Selection Process for Awards Managed by the Awards Committee

1. The awards selection process shall start well in advance of the Annual Meeting through a membership wide communication by the ISPE CEO announcing the opening of the award nominations and establishing the dates for award nomination submissions.
2. The Staff Project Manager shall collect all of the nominations, augment the nominations with ISPE International database information (committees, prior awards, speaker engagements, etc.) and populate a Nominations Worksheet for the purposes of numerically scoring each nomination for each of the awards.
3. The Nominations Worksheet along with the individual nominations and award criteria shall be issued to the Awards Committee for review and 'scoring.'
4. The Nominations Worksheets shall be completed independently by each Award team member. The Staff Project Manager shall collect and aggregate the data and submit a summary of the scores back to the Award Team.
5. The Award Team shall meet and deliberate the summary scores and determine final awardees.

General

1. The Purdy and Phillips Award are lifetime achievement awards. Someone can win both (in separate years) but cannot be awarded one more than once.
2. With exception of the “Member of the Year Award”, ISPE’s paid advisors are eligible for award recognition.
3. Board Members are not eligible to receive individual awards (Member of the Year, Purdy and Phillips) up to one year after their Board tenure ends and they are eligible for all awards after this time.
4. The Awards Committee reserves the right to present a nominee with an award other than the one for which the individual or group was nominated. It can also award multiple individuals/groups in any category and may choose not to award anyone in a particular category if there are no candidates who meet the criteria.
5. Before the list is sent to the committee for deliberation, staff should make the Awards Committee Chair aware of any noncompliance issues with Affiliates or Chapters to help ensure only those in compliance are considered for the award. Affiliate/Chapter leadership consistent with the Charter is part of the criteria for the Chapter/Affiliate of the Year Award. Additionally, staff should make the Awards Committee Chair aware of any violations of the Member or Volunteer Code of Conduct for individual award nominees. Awards Committee Chair and Staff Project Manager will meet to determine if nominees should be removed from consideration for the reasons noted above. Only those deemed eligible will be forwarded to committee for deliberation.
6. The ISPE international member database shall be leveraged for data mining on a particular individual’s contributions to ISPE.

Confidentiality of Awards Committee Decision

1. All discussions held by the Award Committee are confidential in nature. The Executive Project Manager shall ensure that all members of the Award Committee shall have on file a signed and current ISPE Volunteer Confidentiality form on file at ISPE.
2. Nominees and finalists will not be notified of any award committee consideration, deliberations, or decisions.

Affiliate/Chapter Excellence Award

1. Typically one Affiliate and one Chapter has received an award, but the committee has discretion on the number of awards.

INDEPENDENTLY GOVERNED LEGALLY AFFILIATED ENTITIES

AFFILIATE/CHAPTER¹ BOARDS OF DIRECTORS/ MANAGEMENT COMMITTEES

COMMITTEE TYPE: Independently Governed, Legally Affiliated Entities

ROLE: Manage operations of national/regional Affiliates/Chapters in a cost-efficient manner, consistent with the standards of the International ISPE as reflected in the Charter agreement, providing programs of particular interest to Members in that country or region. Interface effectively within the larger Society to ensure integration between local strategies and operations and those of ISPE as a whole.

MEMBERSHIP COMPOSITION:

1. Per the Charter agreement, Affiliate/Chapter bylaws must be consistent with International bylaws. In this way, all Members are eligible for election to Affiliate/Chapter Boards of Directors/Management Committees. Election procedures specified in Affiliate/Chapter bylaws must enable every Member to have a voice in the election.
2. A balance of industry professions should be achieved in the Board of Directors/Management Committee composition.
3. All Board and Committee Members must be Members in good standing of ISPE.

REPORTING REQUIREMENTS:

1. As specified in the Charter, Affiliates and Chapters are responsible to the International Board of Directors, which establishes policy pertaining to Affiliates and Chapters. Minutes of all Affiliate/Chapter Board of Director Meetings must be submitted to the Affiliate/Chapter Relations Department on behalf of the Board.
2. Any request for operating variance from what is contained in the Affiliate/Chapter Charter Agreement with the Society must be submitted to the International Board through the Affiliate/Chapter Relations Department.

RESPONSIBILITIES:

1. Develop and manage an annual operating plan and budget for the Affiliate/Chapter consistent with the standards and policies of ISPE International.
2. With input from the membership, develop an annual schedule of activities that best addresses their current needs in the Affiliate's/Chapter's geographic area.
3. With the approval of ISPE International, establish and manage Chapters (or regional sections) consistent with the standards and policies of ISPE International.
4. Participate in International committees to establish programs in the Affiliate's/Chapter's geographic area and to influence Society direction globally.
5. In conjunction with ISPE professional staff, establish efficient operating systems for marketing and processing payments for Affiliate and Chapter programs.
6. Inform the CEO/President of national or regional legal requirements affecting the Affiliate/Chapter.
7. Return the Charter Agreement signed by the Affiliate/Chapter President/Chair no later than the assigned deadline each year to the regional Affiliate/Chapter Relations departments and adhere to its provisions.
8. Send at least one official representative to all face-to-face Affiliate Council meetings and ensure that at least one official representative participates in all teleconferences/virtual meetings of the Affiliate Council. Active participation is expected from all Affiliate/Chapter members.

¹ See Appendix B for a list of Board-chartered Affiliates and Chapters as of December 2014.

REGIONAL AFFILIATE COUNCILS in ASIA-PACIFIC, EUROPE, and NORTH AMERICA-SOUTH AMERICA

COMMITTEE TYPE: Operational/Advisory

ROLE: Interface effectively with the International organization and local/regional peers to ensure maximum alignment and support for local success. Recommend policies and procedures to the CEO/President and International Board of Directors that will improve services to Members in the region.

MEMBERSHIP COMPOSITION:

1. Each local Board of a chartered Affiliate/Chapter must appoint the President/Chair and one other Affiliate officer to serve on the Council for a term of one year. If these representatives are unable to attend a particular meeting, each Board/Management Committee may designate an alternate leader (ideally an officer) from within the local Board leadership. The ISPE Staff Project Manager must be notified in advance of this designation.
2. The ISPE Staff Project Manager for the Council in each region will be the ranking staff Member on the Affiliate/Chapter Relations team.
3. The Council will designate its leadership annually no later than 30 September each year.
 - A. The Asia-Pacific Affiliate Council will designate a chair to a one-year term.
 - B. The Europe Council will elect one Member as Chair and one Member as Co-Chair, each to serve a one-year term. To ensure consistency, the Co-Chair will usually be nominated to the position of Chair after the first year. If for some reason the Co-Chair is unable to fill the position of Chair, one will be elected.
 - C. The North America-South America Council will elect a Co-Chair to a two-year term. The Co-Chair will progress to the position of Chair after the first year. If for some reason the Co-Chair is unable to fill the position of Chair, one will be elected.
 - D. The Chair and Co-Chair of the Council will represent the region's Affiliates and Chapters on the Regional Forum.

RESPONSIBILITIES:

1. Share best practices and lessons learned in delivering value to ISPE Members in the region.
2. Share programming and operational ideas with other Affiliates and Chapters as a means of improving procedures and reducing workload for volunteer leadership.
3. Inform the Council of relevant information and emerging trends from their local markets; investigate questions locally posed by the Council.
4. Receive, understand and communicate ISPE Society information to the local Board and take appropriate local action.
5. Make recommendations on how to improve Society tools and services, provide relevant data and assist the Society leaders to fully develop major strategic and business plan goals in the region.
6. Submit recommendations for operational changes, including changes to the annual charter.
7. Provide feedback regarding local reaction to ISPE products, services and benefits.

8. Where specified in ISPE's governance documents and annual business plan, suggest representatives from the region to serve on behalf of the Affiliate Council on other groups.
9. Work in close collaboration with the Knowledge Network Council to closely integrate the activities of CoPs and Affiliates/Chapters.

MEETING PROJECTIONS:

The Council will typically meet several times a year.

1. Virtual meetings will be held for the purpose of information exchange between the International and local groups to ensure alignment between local and global operations.
2. Face-to-face meetings typically occur once or twice a year. These meetings will usually occur in conjunction with an ISPE International meeting that is scheduled in the region.

APPENDICES

APPENDIX A: ISPE BOARD GRANTS OF AUTHORITY

Organizational Entity	Role	Business Plan	Budget	Line Budget Deviation	Authorized Signers on Accounts	Capital Expense Approval	General Expense Approval	Travel Expense Approval	Proposed Staff Training	Staff Training Expense Approval
Board	-Major Capital -Budget -Staff Numbers -Policy Approval -Financial -Operation -Investments	Approve	Approve	Review Quarterly	--	>\$75K	Approval of additional funds over total original budget	--	--	--
Executive Committee	-Strategic Plan -Compensation -Objectives -Policy Develop. --Capital	Develop; Review	Review			\$25-75K				
Finance and Audit Committee	-Auditing -Budget Review -Develop Grants -Exp. Procedures -Investment Oversight -Volunteer Reimbursement	--	Develop; Review	Review Monthly	--	--	--	Set Volunteer Policy	--	--
Chair	-Capital Approval		Review	--	Unlimited	<\$25K Unbudgeted	--	--	--	--
CEO/President	-Operation within Grants -Execute Contracts	Develop; Implement; Review	Develop; Implement; Review	Unlimited	Unlimited	Unlimited within budget	Unlimited within budget	All Staff >\$3K; Volunteers	Approve	Limited to Budget
Chief Financial Officer		--	Develop; Implement; Review	--	Unlimited within budget	< \$75,000 within budget	<\$75K within budget	All Pres; Staff <\$3K; Volunteers	Approve	Limited to Budget
Accounting Manager		--	Develop; Implement	--	10K within budget plus unlimited inter account transfers	--	\$1.5K within budget	--	--	--
Treasurer					Unlimited			Reviews President's travel reports		

APPENDIX B: VOLUNTEER and STAFF ROLES AND RESPONSIBILITIES

ISPE, like many nonprofit organizations, accomplishes its mission with and through the energies of many contributors. To ensure that the experiences of each person are as positive and productive as possible as they work together, it is important that everyone be clear about the roles and responsibilities for each person or group.

The Board of Directors has ultimate governance authority over the organization. In simple terms, this means the Board has fiduciary responsibility and responsibility for the trust that is understood to exist between the mission of ISPE and the stakeholders ISPE serves.¹

Board of Directors Responsibilities as a Body ²	
Volunteer Led Volunteer Responsibilities	Staff Driven Staff Responsibilities
<ol style="list-style-type: none"> 1. Determine the organization's mission and purpose 2. Select the executive 3. Support the executive, determine performance metrics and monitor her performance 4. Ensure effective organizational planning 5. Ensure adequate resources by identifying industry trends, business leads, and relationships that can enhance the organization's opportunities 6. Provide strategic financial oversight, ensuring the annual budget and financial controls are in place, the audit is completed, and risk is managed. 7. Determine, monitor, and strengthen the organization's programs and services 8. Enhance the organization's public standing 9. Ensure legal and ethical integrity and maintain accountability by establishing pertinent policies, adhering to provisions of the organization's bylaws and articles of incorporation, and clearly delegating hiring and managing employees to the executive 10. Recruit and orient new board members and assess board performance 	<ol style="list-style-type: none"> 1. Provide information and trends to inform Board decision-making 2. Support the hiring process as requested 3. Provide reports and data 4. Serve as the planning project facilitator, i.e., guide the process, provide timelines, generate/gather necessary information, and propose options for Board decisions 5. Work in partnership with the Board to identify business opportunities and funding leads 6. Provide information, make recommendations and implement procedures consistent with financial controls enacted by the Board 7. Provide trend information, analysis, and recommendations on programs and performance 8. Identify and recommend opportunities for Board participation or assistance in enhancing the organization's public standing 9. Research and recommend bylaw updates, policies, and procedures for Board action; keep the Board aware of any matters which may result in legal action or a negative impact on the organization's reputation 10. Assist the Board in assessing gaps; provide support for the recruitment, election and orientation processes

¹ Adapted from BoardSource's definition in "The Handbook of Nonprofit Governance"

² Adapted from BoardSource's "Ten Basic Responsibilities of a Nonprofit Board"

Board of Directors
Responsibilities as Individuals¹

Board Volunteer Responsibilities	Staff Responsibilities
<ol style="list-style-type: none"> 1. Attend all board and committee meetings and functions, such as special events 2. Be informed about the organization's mission, services, policies, and programs 3. Review agenda and supporting materials prior to board and committee meetings 4. Serve on committees and offer to take on special assignments 5. Make a personal or organizational financial commitment to the organization 6. Inform others about the organization 7. Suggest possible nominees to the board who can make significant contributions to the work of the board and the organization 8. Keep up-to-date on developments in the industry 9. Follow conflict of interest and confidentiality policies as well as the volunteer code of conduct 10. Refrain from making special requests of the staff 11. Assist the board in carrying out its fiduciary responsibilities, such as reviewing the organization's annual financial statements 	<ol style="list-style-type: none"> 1. Ensure Members are informed of event schedules 2. Provide up to date information resources and consultation 3. Ensure materials are prepared and made available prior to the meetings 4. Support committee work by providing information and logistical assistance 5. Assist Board Members in identifying opportunities that are in alignment with their personal or company goals 6. Ensure Board Members have access to current, accurate information 7. Assist the Board in assessing gaps; provide support and timeline for the recruitment, election and orientation processes 8. Provide information and trend data; ask leading questions 9. Provide the policies and consultation as to their interpretation as requested 10. Provide clear information as to staff roles; refer special requests to the appropriate person if they occur 11. Provide materials and information in a timely manner; provide consultation as needed

¹ Individual responsibilities adapted from BoardSource's "Six Keys to Recruiting, Orienting, and Involving Nonprofit Board Members"

Other Volunteers

ISPE’s structure provides for three main types of non-board volunteers. These are as follows:

Governance volunteers assist the Board with its responsibilities as described above. These volunteers typically work on committees or groups that report to the Board, and their role is consultative in nature. Some examples of governance groups include:

- Executive Committee
- Nominating Committee
- Finance and Audit Committee
- Governance Committee
- Ad Hoc Board Working Groups
- Others that may be added by the Board from time to time

Non-Board Governance Volunteers Responsibilities as a Body	
Volunteer Led Volunteer Responsibilities	Staff Driven Staff Responsibilities
<ol style="list-style-type: none"> 1. Clarify the group's charge and deliverables per ISPE’s governance documents, strategic/business plan, and/or specific direction from the Board 2. Develop and execute a plan for accomplishing the charge 3. Report as a body to the Board of Directors 	<ol style="list-style-type: none"> 1. Provide relevant information and materials in a timely manner; provide consultation including best practices as needed 2. Support the group’s work by providing data and other required information, logistical assistance, project planning/management and consultation <ol style="list-style-type: none"> a. Work with the Chair to create a project plan/timeline/milestones and ensure the group is aware of progress against the plan b. Inform the group concerning relevant data, trends, policies, procedures, resources and best practices c. Provide operational consultation as indicated d. Provide recommendations as indicated 3. Assist in the preparation of relevant reports to the Board

Non-Board Governance Volunteers
Responsibilities as Individuals

Volunteer Responsibilities	Staff Responsibilities
<ol style="list-style-type: none"> 1. Attend all group meetings (virtual and/or face to face) and functions, such as special events as disclosed and agreed prior to accepting the assignment 2. Be informed about the organization's mission, services, policies, and programs as well as the group's specific charge 3. Review agenda and supporting materials prior to meetings 4. Take on assignments and complete them by the due date 5. Communicate proactively regarding assignments, especially on matters that will impact the timeline or which could have budget implications 6. Follow conflict of interest and confidentiality policies as well as the volunteer code of conduct 7. Refrain from making special requests of the staff 	<ol style="list-style-type: none"> 1. Ensure group Members are informed of event schedules 2. Provide up to date information resources and consultation 3. Ensure materials are prepared and made available prior to the meetings 4. Support committee work by providing information, consultation and logistical assistance 5. Facilitate communication between group Members; consult on timeline adjustment options and implications 6. Ensure Committee Members have access to current, accurate information 7. Provide clear information as to staff roles; refer special requests to the appropriate person if they occur

Functional (operations-supporting) volunteers assist the staff in carrying out the operational aspects of the Society’s business that rely on subject matter expertise or access to key audiences. These volunteers typically serve as subject matter experts and technical advisors in the development and delivery of ISPE’s products, services, and Member benefits. They are accountable to the staff leader managing the project, and the staff leader is the person ultimately responsible for successful project completion.

Functional volunteers can serve in groups or as individuals.

- *Examples of operational groups assisted by functional volunteers include CoP Steering Committees, the FOYA Committee, the Young Professionals Committee, conference teams, and document teams*
- *Examples of functional (operations-supporting) volunteer roles for individuals include ad hoc speaking, reviewing a document draft, item writing for the certification exam, judging the student poster competition and serving as an ISPE Ambassador in your place of employment*

Functional Volunteers - Groups	
Volunteer Expertise Responsibilities as a Body	Staff Accountability Staff Responsibilities in Support of the Group
<ol style="list-style-type: none"> 1. Review the group’s charge and complete the assigned deliverables on an annual basis. The charge/ deliverables will be reflected the Society’s Strategic and Business Plans and annual agendas/directives. 2. Create a meeting schedule and format that supports achieving the assigned goals and is aligned with the needs of the group Members. 3. Work with assigned staff leaders to ensure ongoing alignment with the strategic and business plans. 4. Recommend criteria (needs/gaps) for recruiting new group members. 5. Recommend new members for appointment to the committee. 6. Adhere to ISPE’s policies, procedures and governance structure with respect to succession planning and term limits in groups where this applies. 	<ol style="list-style-type: none"> 1. Work with the Chair and group members to create project plans with timelines, milestones and completion dates consistent with the Board’s direction. Consistently manage the project so that timelines are met, and if obstacles are identified they are addressed in a timely manner so that the group’s charge and any deliverables are accomplished according to the plan. 2. Consult regarding the feasibility of the proposed schedule and facilitate meeting arrangements. 3. Provide consistent information and updates regarding emerging issues and alignment so that plans/activities can be adjusted proactively 4. Work with the volunteer development team to recruit prospective group members and assist the group in interviewing/screening these prospects as requested. 5. Ensure group recommendations are considered by the appropriate parties for approval. 6. Provide information and timelines to assist the group in succession planning.

Functional Volunteers - Individuals	
Volunteer Expertise Responsibilities as an Individual	Staff Accountability Staff Responsibilities in Support of the Volunteer
<ol style="list-style-type: none"> 1. Assess your knowledge and expertise; seek and accept only SME assignments for which you are qualified. 2. Review your charge and complete the assigned deliverables by the due dates. Communicate proactively if circumstances develop that will compromise completion by the due date. 3. Accept feedback from qualified peers and ISPE staff; make adjustments if requested. 4. Work with assigned staff leaders to ensure ongoing alignment with the strategic and business plans. 5. Adhere to ISPE's policies, procedures and volunteer code of conduct. 	<ol style="list-style-type: none"> 1. Clearly define the knowledge, skills, and expertise required for each volunteer assignment. 2. Work with the volunteer to create project plans with timelines, milestones and completion dates consistent with the ISPE Business plan. Consistently manage the project so that timelines are met, and if obstacles are identified they are addressed in a timely manner so that the group's charge and any deliverables are accomplished according to the plan. 3. Facilitate a content review process that ensures all material created for, and used by, ISPE is consistent with ISPE's brand as a leader in knowledge development. 4. Provide consistent information and updates regarding emerging issues and alignment so that plans/activities can be adjusted proactively. 5. Provide information regarding policies, procedures, and the code of conduct in a timely manner; consult as necessary with the volunteer regarding interpretation and application of these principles.

Advisory volunteers assist the staff in improving the Society's business by sharing information from the Member point of view and/or from their experience as a Member of a market segment ISPE wishes to serve. Advisory volunteers can serve in groups or as individuals. They are accountable to the staff leader managing the project, and the staff leader is the person ultimately responsible for successful project completion.

- *Examples of advisory volunteer groups include the New Content Advisory Group, Affiliate/Chapter regional councils and ad hoc focus groups formed from time to time*
- *Examples of advisory volunteer roles for individuals include participating in surveys and individual teleconferences concerning a subject of mutual interest*

Advisory Volunteers - Groups	
Volunteer Expertise Responsibilities as a Body	Staff Accountability Staff Responsibilities in Support of the Group
<ol style="list-style-type: none"> 1. Review the group's charge and provide SME advice on questions posed to the group as requested to support ISPE's strategic/business plans. 2. Work with assigned staff leaders to ensure the framework for considering the questions posed is in ongoing alignment with ISPE's strategic and business direction. 3. Recommend criteria (needs/gaps) for recruiting new group members as needed. 4. Recommend new members for appointment to the committee. 	<ol style="list-style-type: none"> 1. Pose questions and provide necessary background information to elicit informed ideas and opinions from volunteer advisors. 2. Provide consistent information and updates regarding emerging issues and alignment so that advice and recommendations can be adjusted proactively. 3. Work with the volunteer development team to recruit prospective group members. 4. Ensure group recommendations are considered by the appropriate parties for approval.

Advisory Volunteers - Individuals	
Volunteer Expertise Responsibilities as an Individual	Staff Accountability Staff Responsibilities in Support of the Volunteer
<ol style="list-style-type: none"> 1. Assess your knowledge and expertise; speak only to questions for which you are a qualified SME. 2. Complete the assigned deliverables by the due dates. Communicate proactively if circumstances develop that will compromise completion by the due date. 3. When applicable, consider input and questions from peers and ISPE staff; make adjustments to your own input if requested. 4. Adhere to ISPE's policies, procedures and volunteer code of conduct. 	<ol style="list-style-type: none"> 1. Clearly define the criteria (knowledge, skills, expertise or status) required for each volunteer assignment. 2. Communicate requirements and due dates effectively. Consistently manage the project so that timelines are met. 3. Facilitate a content review process that ensures the input of advisors is accurately represented. 4. Provide information regarding policies, procedures, and the code of conduct in a timely manner; consult as necessary with the volunteer regarding interpretation and application of these principles.

APPENDIX C: MEMBER AND VOLUNTEER CODES OF CONDUCT

Part I: MEMBER CODE of CONDUCT

As a Member of ISPE I will uphold the following values to the best of my ability:

Collaboration in the pursuit of ISPE's mission to be the leading technical organization for professionals engaged in producing quality medicines and pharmaceutical devices throughout the lifecycle.

Ethical behavior that is worthy of trust, respect, and admiration from others internally and externally.

Professionalism characterized by behaviors and communications that are honest, fact-based and politically neutral; demonstrating courtesy and consideration toward other people; adhering to high standards and integrity in all that I do; and engaging in constructive problem-solving.

Inclusiveness that allows for active and rewarding participation by other Members working throughout the global pharmaceutical supply chain.

I will at all times abide by and conform to the following Code of Conduct:

1. I will obey all applicable laws and regulations of the relevant government authorities while acting on behalf of ISPE or representing myself as a Member of ISPE.
2. I will only use ISPE's marks, insignia, name, logos, and trade dress (collectively, "ISPE Marks") in compliance with guidelines issued by ISPE from time-to-time.
3. While participating in ISPE events or representing myself as a Member of ISPE I will not engage in disruptive, inappropriate, verbally or sexually harassing behavior toward others, and I will observe the personal boundaries set by others.
4. I will comply with all applicable copyright and intellectual property laws, and I will adhere to any related guidelines issued by ISPE from time-to-time.
5. I will respect the data privacy of other Members. Therefore I will take no action to gather or "harvest" Member contact information in bulk from ISPE's Member database and distribute that information to others for any reason.
6. I will not represent myself or my company using ISPE's name in such a manner as to imply endorsement by ISPE in order to advance personal or company sales, leads or other gain.
7. If I choose to volunteer with ISPE, I will become familiar with and follow ISPE's policies, procedures, guidelines, and the Volunteer Code of Conduct while acting on behalf of the Society.

I understand that my acceptance of this Member Code of Conduct is applicable to the full duration of my membership regardless of whether my membership is maintained on a consistent or intermittent basis. I further understand that failure to comply with this Member Code of Conduct could result in sanctions up to and including loss of Membership and/or legal action depending upon the nature, severity, and material impact of the violation.

Part II: Volunteer Code of Conduct

It is the policy of ISPE that anyone who accepts a Volunteer role in this Society must affirm his or her understanding of the expectations in this Code of Conduct and agree to abide by the decisions of the CEO (or Board if applicable) in its interpretation and implementation.

ISPE is a Society of individual Members. Hence, this Code of Conduct applies to individuals and does not in any way imply or construe obligations upon Members' employers, regardless of the means by which membership dues are paid.

General Expectations

1. Volunteers will contribute to a collegial, inclusive, positive, and respectful work environment for fellow Volunteers, stakeholders, and staff, and they will model the best in professional behavior.
2. Volunteers will know, understand, and support ISPE's mission, core purpose, values, goals, strategies, and annual directives. They will also become familiar with and follow ISPE's policies, procedures, guidelines, and the Volunteer Code of Conduct while acting on behalf of ISPE.
3. Volunteers will not discriminate and will be respectful of ethnic, national, and cultural differences.
4. Volunteers will only use ISPE's marks, insignia, name, logos, and trade dress (collectively, "ISPE Marks") in compliance with guidelines issued by ISPE from time to time.
5. Volunteers will obey all applicable laws and regulations of the relevant government authorities, including all laws and provisions that govern appropriate conduct in the work place while acting on behalf of ISPE.
6. Volunteers will make or recommend decisions in the best interests of ISPE as a whole rather than focusing on any ISPE subpart or advocating options that advance a personal concern.

Meetings and Communication

1. While acting on behalf of ISPE, professional behavior and respectful discourse is required of Volunteers. Disruptive, inappropriate, or harassing behavior toward other Volunteers, stakeholders or staff is unacceptable.
2. Personal boundaries set by others must be observed. Sexual harassment including but not limited to unwelcome sexual advances, requests for sexual favors, and other verbal or physical harassment of a sexual nature will not be tolerated.
3. Only information deemed for public knowledge may be shared or discussed outside ISPE, unless specifically authorized to do so by the CEO/President and/or the Board Chair. No Volunteer will share, copy, reproduce, transmit, divulge or otherwise disclose any confidential information related to the affairs of the Society.
4. Volunteers will uphold strict confidentiality regarding any information discussed at meetings or in the course of any other deliberations and communications. Questions regarding the confidential nature of ISPE information or documents will be directed to the appropriate staff person or Board member.
5. Volunteers may not speak on behalf of ISPE or the Board to external parties such as the media or other interested individuals/entities unless specifically asked to do so by the CEO/President.
6. Volunteers may not speak as subject matter experts on behalf of ISPE internally or externally unless authorized to do so in accordance with ISPE procedures.
7. All contractual agreements are the responsibility of ISPE staff in accordance with established authority and procedures. Volunteers cannot make contractual commitments on behalf of ISPE with the exception of Board officers formally granted such authority by the Board's policies.
8. All ISPE correspondence, regardless of the medium, is a reflection on the Society. E-mail communications will follow the same professional standards as verbal communication. E-mails may be considered legal documents and, therefore, caution must be exercised when recording

written opinions and statements pertaining to the role of any ISPE Volunteer(s) or groups. The use of the “blind copy” function is strongly discouraged when conducting official ISPE business.

9. Volunteers will be supportive in communicating about ISPE to other Volunteers, Members, and stakeholders. Inappropriate communication by email or in any public forum about ISPE, its Volunteers, staff, stakeholders, policies, procedures or guidelines is not acceptable. Issues regarding ISPE will be taken up in private with the appropriate ISPE staff member.
10. Participation in committee meetings (in-person and/or teleconferences as determined by each committee) is typically required to fulfill a Volunteer’s duties.

Relationship with Other Volunteers, Stakeholders and Staff

1. Volunteers may not attempt to exercise individual authority over their respective volunteer groups, nor may they purport to represent the organization or their respective volunteer groups to other ISPE volunteers, stakeholders or staff, except as explicitly set forth in ISPE’s Governance and Volunteer Operations Manual.
2. Volunteers will understand the scope of their authority and exercise good judgment in their dealings with other Volunteers, stakeholders, staff, suppliers and the general public. Accordingly, volunteers will respond to all Members and stakeholders in a prompt, responsible, respectful and professional manner, and they will represent their role within ISPE clearly and accurately.
3. Volunteers will not request special/personal favors or confidential/embargoed information from other Volunteers, stakeholders, or staff without prior consultation and agreement of the CEO/President.
4. ISPE events are professional gatherings and therefore appropriate behaviors are expected. Volunteers will adhere to ISPE policies, procedures, guidelines, and the Volunteer Code of Conduct in all interactions with other Volunteers, stakeholders, staff, vendors, and other constituents.
5. Volunteers do not have direct authority over staff and do not have authority to delegate actions to staff without the approval of the appropriate ISPE manager.

Avoiding Conflict of Interest

1. No Volunteer will use any information provided by the Society or acquired as a consequence of the Volunteer’s service to the Society in any manner other than in furtherance of his or her volunteer duties. Furthermore, Volunteers will not misuse Society property or resources. They will at all times keep the Society’s property secure and will not allow any person access to such property unless authorized by ISPE.
2. Volunteers will not persuade or attempt to persuade any Member, exhibitor, sponsor, supplier, contractor, or any other person/entity with an actual or potential relationship with the Society to terminate, curtail or not enter into that relationship. Further, Volunteers will not take any action that would serve to reduce the monetary or other benefits to ISPE of such relationship(s).
3. Volunteers are expected to act at all times in the best interest of the Society and not for personal or third-party enrichment.
4. When encountering a potential conflict of interest, Volunteers will identify the conflict and report it to the staff member assigned to the committee or project. If an actual conflict of interest is determined to exist, the Volunteer may be asked to remove him- or herself from all discussions and voting on the matter.
5. Volunteers will not accept gifts, gratuities, free trips, honoraria, personal property, or any other item of value from any person or entity as a direct or indirect inducement to provide special treatment to such donor on matters pertaining to the Society without fully disclosing in advance such items to the staff member assigned to the committee or project.
6. Volunteers will not represent themselves as ambassadors, experts, or project leaders using ISPE’s name in such a manner so as to imply or advance personal or company sales, leads or other gain.

Volunteer Commitments

1. Volunteers will carry out volunteer duties in accordance with ISPE procedures and adhere to project timelines to which they have agreed.
2. In the event that a Volunteer realizes that s/he cannot fulfill a commitment, s/he will notify the responsible staff project manager or volunteer leader proactively.
3. Volunteers will recognize and be respectful of the fact that staff project managers have deadlines and may on occasion find it necessary to replace or augment volunteer resources.
4. Volunteers will relinquish project responsibilities promptly when requested if doing so is deemed to be in the best interests of the Society.

Confidential Materials and Work in Progress

Upon termination of service, Volunteers will promptly return to the Society all documents, electronic and hard files, reference materials, and other property not already on file in the ISPE office. Such return will not abrogate him or her from the continuing obligations of confidentiality with respect to the information acquired as a consequence of his or her tenure as a Volunteer.

Violations of the Code of Conduct

1. ISPE staff will resolve any issues with Volunteers in a professional manner.
2. If issues or violations of the Code of Conduct are persistent or egregious, Volunteers may be required to leave their volunteer position(s) and may be precluded from serving in volunteer roles in the future. Except in cases pertaining to the Board of Directors, the CEO/President will determine if this action is necessary and will notify the Volunteer. In cases pertaining to the Board of Directors, the Executive Council will determine if this action is necessary and will designate one of its Members to notify the Board Member.
3. Non-Board Volunteers who have been removed from a volunteer position have 30 days to appeal the decision to the Executive Council of the Board. The Executive Council will Review the situation and respond within 30 days of the request for appeal. All decisions of the Executive Council are final.
4. ISPE reserves the right to pursue additional measures up to and including legal action In extreme cases where the actions of a Volunteer may have compromised ISPE's mission, reputation, business prospects or legal stature.

APPENDIX D: VOLUNTEER POLICIES

MEMBERSHIP COMPOSITION:

1. Membership in volunteer groups is determined by the group type.
 - A. Members of the Board of Directors must be elected by the general membership or appointed by the Board of Directors as indicated in the bylaws.
 - B. Members of governance committees are appointed by the Chair of the ISPE Board of Directors or the Chair of the governance committee in consultation with the Chair of the Board and CEO.
 - C. Members of boards or committees serving ISPE's independently governed, legally affiliated entities take their seats based on the bylaws of those entities.
 - D. The Chairs of ISPE's operational committees, councils, teams, forums, panels and CoP steering committees (hereafter "operational groups" or "groups") are appointed by the CEO/President in consultation with the Chair of the ISPE Board of Directors and relevant stakeholders such as other Board Members, past leaders, etc. Thereafter, these appointed Chairs, working together with the professional staff, may appoint qualified "active participants" to serve on the group.
 - E. Ad hoc advisory or focus groups may be formed as needed at the discretion of the Board Chair (for governance assignments) or the professional staff (for operational assignments).
2. To the extent feasible given the charge of the group, a proper cross-section of the industry should be achieved on each committee, council, team, COP steering committee or advisory group. Members should have the appropriate background in the area of expertise or business required by the group's charter.
3. Any Member of the International Board of Directors may participate in any operational group, advisory team, or focus group as a non-voting member.
4. Terms for all participants will be for one year, commencing at the Annual Meeting. Normally participants will not serve on the same operational group for more than three, and in some cases up to five, successive terms.
5. Each operational group may recruit "corresponding members" as appropriate. Corresponding members are defined as those volunteers who participate as a member of the operational group but may only be able to do so in a limited manner. This may include not being able to attend Committee meetings in person and/or limiting participation to conference calls only.
5. A member of the professional staff will be appointed by the CEO/President as a Staff Project Manager for each operational group.
6. All "active participants" of operational groups must be Members in good standing of ISPE.
 - A. Contributing authors to ISPE's guidance documents and speakers who are not otherwise serving as an "active participant" on a committee are excluded from this requirement.
7. Each operational group will strive to integrate a minimum of 20% new Members into its roster annually. Concurrently, Members who have not been active or Members completing their final term may be removed from the roster. The Chair, in consultation with the Staff Project Manager, will perform an evaluation of the operational group's roster each year by 15 October.

ACTIVE PARTICIPATION:

1. All volunteers are required to review and agree to the combined Member and Volunteer Code of Conduct annually during the Membership renewal process. Participation by volunteers is governed by this Code, the Roles and Responsibilities that apply to the type of group on which they are serving, and the charter of the group as contained within the Governance Structure document which may be updated from time to time by the Board of Directors.

2. Each operational group is assigned critical responsibilities within the Society's mission. Hence, membership on an operational group requires dedication and a commitment to excellence. Duties and responsibilities cannot be taken lightly. Attendance at meetings, either in person, telephonically, or online, and a commitment to meeting ISPE's project timelines is crucial. Knowledge of the industry and ability to transfer that knowledge into products and services that advance the mission and financially support the Society is essential.
3. Active Participation is defined as follows.
 - A. The Volunteer is present either personally or virtually and contributes in the majority of face to face meetings and conference calls.
 - B. The Volunteer shows interest in committee activities and communicates regularly with the Chair, Co-Chair, and Staff Project Manager.
 - C. The Volunteer makes a tangible contribution to the work of the committee by taking on and following through with assigned tasks.
 - D. Volunteers are expected to expend efforts as necessary between meetings to complete operational group duties and responsibilities.
 - E. Volunteers who cannot meet the commitments and responsibilities outlined above should notify their Chair/Staff Project Manager and resign as an active Member of the group. Those who wish to contribute in a reduced capacity may be assigned to a special working group, if such a position is available, or as corresponding Members of the group.
4. Adding New Members
 - A. New Members are normally added at the beginning of the year (during or shortly following the ISPE Annual Meeting) or at the time the group is formed if it occurs at some other time.
 - B. When an opening exists in the middle of the year due to the departure of a Member or a skill set required by the group, an ISPE Member may be recruited or nominated to fill that void.
 - i. The position should generally be posted using ISPE's volunteer recruitment process
 - ii. All potential volunteers will generally be asked to complete a volunteer profile
 - C. The profiles of willing and qualified volunteers will be provided to the Chair and the Staff Project Manager who will evaluate the nominee's suitability. Suitability is based on factors including:
 - i. Current or previous job function, as having some relationship to the expertise the person is expected to provide to the operational group.
 - ii. Lack of commercial motivation.
 - iii. Ability to actively participate in the operational group's schedule, to commit to projects and meet deadlines for which the group is accountable per ISPE's Business Plan.
 - D. The ISPE Staff Project Manager is responsible for notifying new volunteer Members of their acceptance for service on the group and of the upcoming group meeting schedule.
5. Removing A Member
 - A. If a Member fails to participate in the minimum number of meetings, fails to meet critical deadlines, or is otherwise unable to contribute to the mission of the operational group, or breaches the Codes of Conduct, the Chair and/or the Staff Project Manager shall discuss the situation with the Member.
 - i. In all cases related to alleged breaches of the Codes of Conduct, the matter shall be handled as prescribed in the "Violations" section of the Volunteer Code.
 - ii. If the concern is related to performance as a group Member, the Chair and/or the Staff Project Manager shall request the Member's resignation unless there are circumstances that have been agreed to that have caused the lack of participation.
 - B. In the event the Member of an operational group does not resign when requested due to a performance concern, the Member may appeal the decision to the CEO/President. If the Member does not agree with the decision of the CEO/President, (s)he may appeal

the decision in writing, to the Executive Committee. The decision of the Executive Committee is final.

6. Requesting a Chair's Resignation
 - A. If a Chair fails to properly perform the functions of the position or violates the Code of Conduct (s) he shall be requested to resign.

REPORTING REQUIREMENTS:

1. Governance Groups: The Chair working in partnership with the Staff Project Manager will be directly responsible to the International Board of Directors.
2. Operational and Advisory Groups: The Chair working in partnership with the Staff Project Manager, will be directly responsible to the CEO/President.
3. All Staff Project Managers, with input from the Chairs, will contribute to quarterly written reports when requested by the Board concerning progress toward the Society's current Business Plan goals.

MEETING PROJECTIONS:

1. Each group will set a meeting schedule as required to accomplish its goals and assignments. All groups will leverage available technology, such as online meeting software, to conduct virtual meetings to maximize global participation.
2. The Chair will issue an agenda to all group Members in advance of each meeting through the Staff Project Manager.
3. In conjunction with the Board of Directors, the CEO/President will develop an annual schedule for face-to-face meetings for all groups based on input received from each group. The group Chairs should follow this schedule. Staff will make site arrangements for those meetings and notify all group Members. Chairs should check with staff for space availability before committing to any additional on-location meetings.

RESPONSIBILITIES:

1. In alignment with the objectives in the ISPE Strategic Plan, provide recommendations on the organization's annual Business Plan as requested.
2. Carry out assigned activities and create deliverables in the subject area within the group's charter as reflected in the final Business Plan as approved by the Board of Directors annually.
3. Create the deliverables in #2 above in the most cost-efficient manner possible and, where indicated in the Business Plan, in a manner designed to generate the revenue envisioned in the Plan.
4. As requested, review the plans for and consult on Affiliate and Chapter programs in the subject area within the group's charter.
5. Interact with other volunteer groups for program development and membership enhancement.

AD HOC GROUPS:

1. Governance Groups: The Chairman of the Board, in consultation with the Board or Executive Committee, may establish Ad Hoc Board Work Teams and Advisory Panels as deemed appropriate.
 - A. Ad Hoc Board Work Teams may be established to accomplish a specific assignment from the Board of Directors or for the purpose of providing governance-level oversight to cross-functional projects or initiatives that require coordination, communication, and – possibly – conflict resolution by the Board of Directors.
 - B. Ad Hoc Board Work Teams will be appointed by the Board Chair and will cease to exist when any of the following conditions is met: (a) The sitting Board Chair determines the Ad Hoc Board Work Team has achieved its mission. (b) The Chair-elect determines that the group is not needed for the year of his or her term, or (c) The Ad Hoc Board Work Team becomes a fully chartered Committee. Ad Hoc Board Work Teams will operate with the same procedures and policies as other governance groups.

- C. Advisory Panels will be established for the purpose of studying a specific question or developing expertise to guide and inform the Board's decision-making with respect to the area of assignment. The Panel will cease to exist when their report has been delivered to the Board.
- 2. Operational Groups: The CEO/President, in consultation with the professional staff and relevant volunteers as needed, may establish ad hoc focus groups, advisory groups or project teams to enhance market intelligence, strategic reach or to accomplish a specific task in the annual business plan. These groups will be created to accomplish key tasks that have a clear limited duration. They will operate under the supervision of the CEO/President and policies of the organization related to Volunteer conduct and roles will apply.

VOLUNTEER BENEFITS AND ELIGIBILITY

In general, associations and societies like ISPE rely on volunteers for many important functions. Some of the most important benefits that come from volunteering are intangible. These include significant learning experiences, career-enhancing relationships with other volunteers, and contributing to important work that drives the industry forward.

As a world-class not-for-profit organization, ISPE offers benefits to its volunteers that are comparable to, or better than, those offered to volunteers in similar organizations. These include:

- 1. Complimentary Registration at ISPE Global Conferences and the Annual Meeting. Select groups of Volunteers are offered complimentary registration to attend ISPE Conferences and the Annual Meeting including:
 - A. Past ISPE Presidents/Board Chairs
 - B. Current Members of the International Board of Directors
 - C. Richard B. Purdy Distinguished Achievement and Joseph X. Phillips Professional Achievement Award Winners through 2013 awardees.

Training courses, evening social events, and other optional events are not included in the complimentary registration.

Under normal circumstances any individual receiving complimentary registrations to ISPE Conferences or the Annual Meeting must be contributing as an active Volunteer at the time of the event. Exceptions may be made on a case by case basis depending on circumstances deemed relevant for consideration at the time of the request. The decision whether or not to grant complimentary registration will ultimately be made by the CEO/President.

- 2. Discounted Registration Fees at ISPE Global Conferences and the Annual Meeting. Volunteers who are ISPE Members in good standing, serving on one or more Committees, Councils, Teams, CoP Steering Committee, or Advisory Group, and who are conducting their activities in alignment with ISPE's Codes of Conduct, are eligible to receive a discount on registration for ISPE global Conferences and the Annual Meeting.
 - A. The amount of the discount will be determined annually as part of the ISPE business plan/budgeting process.
 - B. In order to receive the discounted rate, the ISPE Volunteer must be "active" as defined earlier in this document.
 - C. Discounted registration fees will only be offered at Global Conferences at which the committee(s) on which the volunteer serves is/are meeting during educational offerings.
 - D. Volunteers must register as a committee member and actually attend the committee meeting taking place if scheduled at the conference or Annual Meeting in order to be eligible for the discounted rate. Failure to do so may jeopardize future eligibility for discounts.

- E. Each volunteer's eligibility for the committee registration discounts at the Annual Meeting is reviewed once annually prior to the committee notice being sent for the Annual Meeting.
 - F. There is no cost associated with simply attending the committee meeting and not attending the conference.
3. Complimentary Copies of Good Practice Guides to Guide Team Members. Active Document Team Members who have contributed to developing and writing a new or revised Good Practice Guide receive a complimentary copy of the Good Practice Guide to which they have contributed.
4. Hotel and Travel Costs. ISPE does not cover hotel and travel costs for Volunteers. Exceptions to this policy include:
- A. International Board of Directors in cases where company or other support presents a challenge.

Past Presidents who are attending Annual Meeting and are an active member of a Committee. ISPE will cover hotel costs at Annual Meeting Sat-Tues if the Past President does not have company support for these costs.

APPENDIX E: CONFLICT OF INTEREST

INTERNATIONAL SOCIETY FOR PHARMACEUTICAL ENGINEERING, INC. Board Conflict of Interest Policy and Disclosure Form

In their capacity as directors, the members of the Board of Directors of the International Society for Pharmaceutical Engineering (ISPE) must act at all times in the best interests of ISPE. The purpose of this policy is to help inform the Board about what constitutes a conflict of interest, assist the Board in identifying and disclosing actual and potential conflicts, and help ensure the avoidance of conflicts of interest where necessary. This policy may be enforced against individual Board members as described below.

CONFLICT OF INTEREST POLICY

1. Board members have a fiduciary duty to conduct themselves with unconflicted loyalty to the interests of ISPE. In other words, in their capacity as Board members, they must subordinate personal, individual business, third-party, and other interests to the welfare and best interests of ISPE. This accountability to ISPE supersedes any conflicting loyalty, such as loyalty to other nonprofit organizations and membership on other boards. It also supersedes the personal interests of any Board member. Further, no Board member may use his/her position or knowledge gained from participation in a manner that conflicts with the interests of ISPE.
2. A conflict of interest generally is defined as a transaction or relationship in which, because the individual is (directly or indirectly) a party to the transaction or relationship or a possible beneficiary of it, there is or may be a conflict between the individual's obligations to ISPE and the individual's personal or business interests. The fiduciary duty of loyalty requires that Board members be faithful to the organization's best interests and not use their organizational position or knowledge to advance a personal or third-party agenda at the organization's expense.
3. All conflicts of interest are not necessarily prohibited or harmful to ISPE. However, full disclosure of all actual and potential conflicts, and a determination by the disinterested Executive Committee or Board members (as the case may be) – with the interested Executive Committee or Board member(s) recused from participating in debates and voting on the matter – that the best interests of ISPE are being served, are critical to resolving all conflicts of interest.
4. All actual and potential conflicts of interests shall be disclosed by all Board members to the Executive Committee, both through the annual disclosure form and whenever a conflict arises. The disinterested members of the Executive Committee shall make a determination as to whether a conflict exists and what subsequent action is appropriate (if any). The Executive Committee shall inform the Board of such determination and action. The Board shall retain the right to modify or reverse such determination and action, and shall retain the ultimate enforcement authority with respect to the interpretation and application of this policy to its individual Board members.
5. On an annual basis, all Board members shall be provided with a copy of this policy and required to complete and sign the acknowledgment and disclosure form below. All completed forms shall be provided to and reviewed by the Executive Committee.

ACKNOWLEDGMENT AND DISCLOSURE FORM

I acknowledge that I have read the Board Conflict of Interest Policy set forth above and agree to comply fully with its terms and conditions at all times during my service as an ISPE Board member. At present and during my service as an ISPE Board member since the completion of my last disclosure form (if any), I am not aware of any actual or potential conflicts of interest with my duties to ISPE except as fully disclosed below. In addition, if at any time following the submission of this form I become aware of any actual or potential conflicts of interest (as described above), or if the information provided below becomes inaccurate or incomplete, I agree to promptly and fully notify the ISPE CEO/President in writing, such information which shall be forwarded to ISPE Executive Committee for review.

Disclosure of Actual or Potential Conflicts of Interest:

Board Member Signature: _____

Board Member Printed Name: _____

Date: _____

APPENDIX F: INTERNATIONAL BOARD ELECTION PROCESS

ISPE will conduct its annual elections according to the following criteria and processes unless (1) a change to the Bylaws renders some portion of the process invalid or (2) the Board of Directors votes to amend this process outside of the annual Governance Structure update at each Annual Meeting.

Characteristics for Consideration of Board Candidates

- ISPE and professional contributions to the industry
- Ability to contribute to strategic and industry directional input relative to ISPE's strategic objectives
- Leadership and management skills
- Critical thinking skills
- Global perspective
- Commitment and support from company for time and resources
- Sufficient knowledge and understanding of ISPE

Criteria for Full Slate of Board Candidates

- All appropriate diversity will be achieved by proper categorical selection of candidates. In order to insure appropriate skills and diversity within the Board to execute business strategies as defined in the 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 membership, (s)he is eligible to be considered as an officer candidate. This selection process shall be governed by the Nominating Committee.
- Geographic and industry sector representation is essential
- Balance between suppliers and manufacturers should be evaluated
- Ideally, no more than one Board member from same company and in no case more than two Board members from the same company can serve at the same time

Criteria for Board Elections

- Ideally the Board will serve staggered two-year term with target of equal number of Directors elected each year. If the number of people rotating becomes out of balance due to resignations, the Nominating Committee should evaluate the situation and recommend a remedy for restoring balance to the full Board of Directors in a manner that is consistent with the Bylaws. The full Board then must vote to accept this remedy.
- The voting process should be as user-friendly as possible
- ISPE should strive to achieve industry benchmarks in voter participation
- The number of candidates should ideally exceed the openings by a minimum of 60%, but not if the Nominating Committee deems, and the Board affirms, that a sufficient number of candidates meeting the necessary criteria does not exist, i.e., quantity is not a goal irrespective of quality
- The order of the Director candidates on ballot should be alphabetized
- Candidates biographies appearing on the ballot will be limited to approximately 200 words in consistent, staff-written format
- Candidates are prohibited from organized "campaigning" in order to avoid "block votes"

Criteria for Officer Elections

- Ideally officers will succeed through each officer role in an orderly and predictable manner
- The term limit in each position is one year
- Generally officers will move forward, unless there is a catastrophic event or the officer is unable to continue serving
- Incoming officers below the Chair will be interviewed by the Board Officer Nominating Committee including the Society Chair to ensure there is a complete understanding and acceptance of the requirements of the office
- Each candidate for secretary must clearly understand that s/he is making a 5 year commitment to serve in the roles of Secretary through Past Chair
- The ballot will contain only one candidate for each officer position

ISPE Election Policies

Those individuals who have been recommended by the Nominating Committee and approved by the Board to stand for election as Directors of the International Society for Pharmaceutical Engineering shall be subject to the following campaign guidelines for election:

1. It is the intent of the Board to limit campaigning activities to only incidental and minor contacts with the membership. Nominees shall limit their electioneering to such promotions as normal business activities would determine. For example, communication that nominees are a candidate in the ISPE Board of Directors election as a matter of fact would be acceptable. Anything that attempts to influence people's decision - "You need to vote for this candidate in the ISPE election because..." would not be acceptable. Some companies produce internal communications about their employees. Posting on this type of communication is acceptable as long as it is stated as a matter of fact as described above and does not attempt to influence other ISPE Member votes.
2. In particular, the Board prohibits the following types of activities:
 - A. Mailings and other written solicitations on the part of the nominee to the ISPE membership at large.
 - B. Gifts, material or otherwise, sponsorships, entertainment or other activities conducted primarily for the purpose of influencing or announcing candidacy or other election-related interests on the part of the nominee to the membership.
 - C. Advertising of any sort in professional journals, newsletters or other communication vehicles for the purpose of announcing candidacy or promoting one's personal interest toward election. This would include endorsements in Affiliate/Chapter newsletters or similar publications. If Affiliates/Chapters have plans to promote the candidate, nominees are expected to notify appropriate Affiliate/Chapter leaders to discourage such promotion.
3. If, in the judgment of the Nominating Committee, a nominee violates these guidelines, the Nominating Committee may recommend to the Board that the nominee be disqualified from further consideration for the office of ISPE.
4. If candidates have questions about what is allowed and not allowed, they should contact the ISPE Board election staff project manager.

Election Timeline/Milestones

ACTIVITY

1. Call for nominations is conducted in Q1 and nominations are sent to CEO/President, who forwards to Nominating Committee
2. Board composition is evaluated against the Strategic Plan and determination is made if an appointed position is needed.
3. Additional recruitment of candidates (if needed)
4. Nominating Committee finalizes appointment recommendation (if applicable) and slate of director candidates for election. Officer Nominating Committee finalizes officer recommendation.
5. Board votes on the appointed position recommendation, slate of director candidates for election and officer recommendation.
6. Letters sent to nominees asking for commitment.
7. Candidates confirm commitment and send necessary materials.
8. Election commences at least 3 months prior to Annual Meeting.
9. Election closes at least 4 weeks after opening.
10. Board certifies final election results through vote to accept final election results.
11. Candidates are notified
12. Public announcement is sent.
13. Board is seated at Annual Meeting

Candidate Withdrawal

It is not uncommon that a candidate for the Board of Directors withdraws from the race after initially accepting the nomination. If this occurs, the procedure is as follows:

Before the Election Launches

1. Board Member Candidates
 - A. A Board candidate who needs to withdraw from the election should notify the Chair of the Nominating Committee. His/her reasons may be kept confidential from the Board at his/her request unless those reasons bear on the Governance responsibilities of the Board. (Example: if the person wishes to withdraw because of an impending job change that will make it impossible to serve but wants this kept confidential, the confidentiality can be maintained. If the person wishes to withdraw because s/he believes that ISPE is conducting illegal activity, this must be shared.)
 - B. Immediately upon learning of the candidate's withdrawal, the Chair of the Nominating Committee should notify the current Board Chair and the CEO, and should convene a meeting of the Nominating Committee.
 - C. Because ISPE typically nominates more candidates than there are slots to fill, the Nominating Committee should make a recommendation to the full Board regarding whether to hold the election with fewer candidates on the ballot or to nominate a new candidate. Relevant considerations include the proximity of the withdrawal to election launch, the availability of additional candidates and the likelihood of gaining a new candidate's commitment to serve in time to preserve the election timeline.
 - D. The Nominating Committee should offer a prepared motion which addresses all aspects of their full recommendation to the Board of Directors.

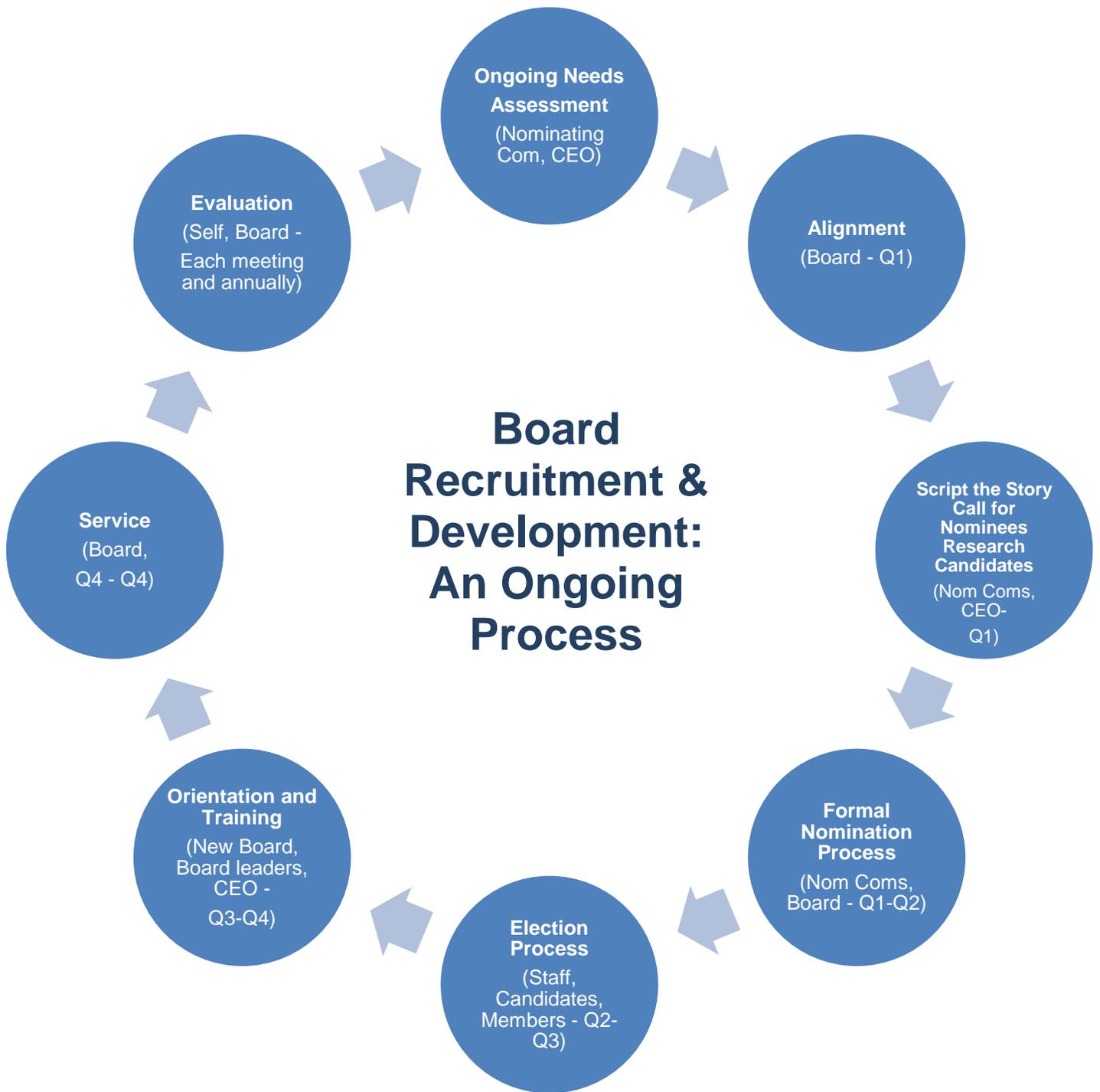
- E. The full Board must vote on the Nominating Committee's recommendation according to the Bylaws criteria for voting between Board meetings.
- F. Should the election proceed with fewer candidates than are needed to fill the open Board seats, the vacancy should be filled according to the procedure specified in the Bylaws.

2. Officer Candidates

- A. An Officer candidate who needs to withdraw from the election should notify the Chair of the Officer Nominating Committee. The same criteria for confidentiality applies to officers as to Board candidates as described in 1- A above.
- B. Immediately upon learning of the candidate's withdrawal, the Chair of the Officer Nominating Committee should notify the current Board Chair, the Chair of the Nominating Committee and the CEO, and should convene a meeting of the Officer Nominating Committee.
- C. The Officer Nominating Committee must:
 - i. Identify a new officer candidate
 - ii. Specify the officer role for which that candidate is being nominated
 - iii. Provide a clear recommendation to the Board regarding all affected nominations. (Example: Alpha, slated to become treasurer, withdraws. The Officer Nominating Committee decides to tap Beta but to serve as Secretary. Gamma, who was the original candidate for secretary will now be asked to run for treasurer.)
 - iv. If the Officer Nominating Committee decides to nominate a sitting Board Member to fill the open officer role, this will result in an opening on the Board of Directors. In that case, the Nominating Committee must also convene as described above and make a recommendation to the Board regarding that opening.
- D. The Officer Nominating Committee should offer a prepared motion which addresses all aspects of the full recommendation to the Board of Directors.
- E. The full Board must vote on the Officer Nominating Committee's recommendation according to the Bylaws criteria for voting between Board meetings.
- F. Should the election proceed with fewer candidates than are needed to fill the open Board seats, the vacancy should be filled according to the procedure specified in the Bylaws.

After the Election Launches

Should an Officer or Board candidate withdraw after the election has already launched, the election should proceed uninterrupted and the ballot should not be changed. After the election concludes, the Board should fill the vacancy according the procedure specified in the Bylaws.



APPENDIX G: CEO SUCCESSION

Policy for Replacement of the President/Chief Executive Officer

Purpose:

The purpose of this policy is to establish the process and general procedure necessary to recruit and replace the President/Chief Executive Officer (CEO) in the event of a vacancy.

Guiding Principles:

- To identify for the Board of Directors the key attributes and requirements for the CEO/President position.
- To execute all activities necessary to recruit and install a new CEO/President who meets the predetermined requirements, as outlined in the ISPE CEO/President job description.
- To recommend to the Board a slate of potential candidates.

Scope:

This policy applies to the Search Committee, the International Board of Directors, and others involved in the recruitment and selection of a new CEO/President of ISPE.

Procedure:

1. Upon formal resignation or removal of the CEO/President, or in the event that he/she is unable to act in this capacity, a Search Committee will be activated to recruit and select a replacement. The Search Committee is ordinarily comprised of the Executive Compensation Committee, two Past Chairs of the Society and the ISPE Director of Human Resources. Additional members of the leadership may also be asked to join the Search Committee.
2. The Search Committee will be responsible for reviewing the current job description, and employment contract for the CEO/President position and the ISPE succession plan, recommending a CEO profile, searching for and identifying a search firm, reviewing and presenting the firm and associated costs of the recruitment process, identifying potential candidates for selection, negotiating and approving the employment contract and compensation for the position, and presenting two to three successful candidates to the Board of Directors for selection.
3. A mentoring program for the new CEO/President with the current and past Chairs of ISPE may be established to facilitate initiation into the new role.

APPENDIX H: ISPE AFFILIATES WORLDWIDE

ASIA-PACIFIC AFFILIATES

- Australasia
 - Adelaide Chapter
 - Brisbane Chapter
 - Melbourne Chapter
 - New Zealand Chapter
 - Sydney Chapter
- China (under development)
- India
 - Ahmedabad Chapter
 - Bangalore Chapter
 - Hyderabad Chapter
- Indonesia
- Japan
- Korea
- Malaysia
- Philippines
- Singapore
- Thailand

EUROPEAN AFFILIATES

- Belgium
- Czech Republic/Slovakia
- France
- Germany/Austria/Switzerland
- Ireland
- Italy
- The Netherlands
- Nordic
- Poland
- Spain
- Turkey
- United Kingdom:
 - Central Region
 - Northeast Region
 - Northwest Region
 - Southern Region

NORTH AMERICAN AFFILIATES

- Canada (*previously the Central Canada Chapter*)
- United States
 - Boston Area Chapter
 - Carolina-South Atlantic Chapter
 - Chesapeake Bay Area Chapter
 - Delaware Valley Chapter
 - Great Lakes Chapter
 - Greater Los Angeles Area Chapter
 - Midwest Chapter
 - New Jersey Chapter
 - Pacific Northwest Chapter
 - Rocky Mountain Chapter
 - San Diego Chapter
 - San Francisco/Bay Area Chapter
 - South Central Chapter

SOUTH AMERICAN AFFILIATES

- Argentina
- Brazil

Rev 08/2014

APPENDIX I: ISPE AFFILIATE/CHAPTER CHARTER

THE INTERNATIONAL SOCIETY FOR PHARMACEUTICAL ENGINEERING, INC.
XXXX CHARTER
EFFECTIVE 1 FEBRUARY 2016

1. GRANT OF CHARTER

- 1.1. Charter. The International Society for Pharmaceutical Engineering (“ISPE”) hereby grants to the XXXX Chapter of ISPE, Inc. (“Chapter”), and the Chapter accepts a charter (“Charter”) to be an official chapter of ISPE. The Chapter shall use the aforementioned designation “XXXX Chapter of ISPE, Inc.” as set forth in the Articles of Organization on file with the Office of XXXX XXXX, which is acknowledged and agreed by the parties to this Charter to be an independent chapter of ISPE with authority to use such designation in connection with the activities of the Chapter in conformance with ISPE’s Corporate Identity Standards, subject to the following terms and conditions.
- 1.2. Territory. The Chapter is authorized to operate in the specific geographic area identified in Exhibit A, appended and incorporated by reference into this Charter.

2. OBLIGATIONS OF ISPE

ISPE’s obligations under this Charter shall include the following:

2.1. ISPE shall:

- a) Permit the Chapter to utilize the ISPE name in the name of the Chapter and permit additional uses of the ISPE name and logo in accordance with Section 4 hereof.
- b) Pay dues rebates to the Chapter in accordance with the ISPE dues rebate policy then in effect.
- c) Dedicate ISPE support staff to maintain and enhance the ISPE Chapter relationship.
- d) Provide education, training, information, tools, and consultation that enable the Chapter leaders to:
 - 1) plan and deliver Chapter education and networking events;
 - 2) communicate with Chapter Members;
 - 3) plan and provide career services;
 - 4) recruit, advance and retain Chapter Members; and
 - 5) manage the business of the Chapter.
- e) Provide the Chapter, periodically, with a statement of Chapter benefits that identifies the services to be provided by ISPE to the Chapter pursuant to section 2.1(d) of this Charter.
- f) Notify the Chapter of educational and other opportunities available to Chapter Members including those activities of ISPE that will take place within the territory of the Chapter.
- g) Promote the programs, products and services of the Chapter.

- h) Provide a means for the Chapter to maintain and use contact information for individuals who are not Chapter Members.

2.2 ISPE shall coordinate with and in a timely manner notify the Chapter regarding changes to the Charter criteria and changes to the dues rebate policy.

3. OBLIGATIONS OF THE CHAPTER

The Chapter's obligations under this Charter shall include the following:

3.1 The Chapter shall:

- a) Accept all ISPE Members residing in the Chapter territory as full Chapter Members without charging Chapter dues unless the charging of Chapter dues has been pre-approved by ISPE.
- b) Not accept any person who is not an ISPE Member as a Chapter Member.
- c) Promote membership in ISPE.
- d) Promote and encourage the use of ISPE programs, products and services.
- e) Comply with the criteria for Chapter status. (Current criteria are provided within Exhibit C, appended and incorporated by reference into this Charter.)

3.2 Access to Records of the Chapter. Upon written request by ISPE, the Chapter shall allow ISPE's auditors within thirty (30) days of such request to review the books and records of the Chapter, limited to what books and records and parts thereof could be reasonably necessary to establish whether the Chapter is acting in compliance with this Charter. It is understood that such audit will be made in a reasonable fashion so as not to disrupt the Chapter's activities and the cost of the audit shall be borne by ISPE.

3.3 Fiscal Year. The Chapter Treasurer is responsible for notifying the ISPE International Affiliate/Chapter Relations staff as to the Chapter's fiscal year and expected date for supplying the required annual reports. (Current criteria are set forth within Exhibit C.)

3.4 Compliance with Laws and Insurance. Each party warrants that it has and shall continue to comply with all applicable laws, regulations and other requirements that may affect its performance of this Charter. Each party warrants that it shall make all required filings, such as annual corporate filings and tax filings, as may affect its corporate or tax status. Each party shall maintain appropriate corporate insurance including Directors and Officers (D&O) insurance and general liability coverage. Each party, upon written request, will be provided immediately with copies of documents evidencing that party's compliance with laws and insurance that may affect the other party's performance under this Charter.

4. USE OF ISPE TRADEMARK AND COPYRIGHTED MATERIALS: CONFIDENTIAL INFORMATION

4.1 Limited License. Except as specified in Section 1.1, the Chapter shall not use, or cause to be used by any person, the logos, trademarks, service marks, trade names or copyrighted materials of ISPE (collectively "ISPE Intellectual Property") without ISPE's prior written consent, and the Chapter is to use such only in accordance with "ISPE's Corporate Identity Standards for Independent Chapters," as applicable. (Current ISPE Corporate Identity Standards for Independent Chapters are set forth within Exhibit B, appended and incorporated by reference into this Charter).

The Chapter shall not make or cause to be made any copies of ISPE's materials, including but not limited to guides, educational materials or publications (collectively "ISPE Materials"), resell any of the same or create derivative works of same without ISPE's prior written consent. Should the Chapter create any derivative works of ISPE Materials, it is acknowledged and agreed by the Chapter that all rights, title and interest in and to such works (including the copyrights) shall vest in and belong solely to ISPE. A "derivative work" would be any modification or revision of the ISPE Materials such as a translation, video, sound recording, abridgement, condensation or any other form in which the ISPE Materials may be recast or adapted. With respect to any permitted use of ISPE Intellectual Property, the Chapter shall ensure that the applicable copyright or trademark notice is made, pursuant to requirements of U.S. law and any other guidelines that ISPE shall prescribe. In any event, upon expiration or termination of this Charter, all use by the Chapter of ISPE Intellectual Property shall end immediately.

The Chapter acknowledges that ISPE is the lawful owner of the ISPE Intellectual Property and the Chapter agrees that it will not attempt to register the ISPE Intellectual Property in the Chapter's own or any other name or take any action (or aid others in taking any action) inconsistent with ISPE's ownership of the ISPE Intellectual Property. The aforementioned obligation shall indefinitely survive the expiration or termination of this Charter.

4.2 Confidential Information. Each party shall, during the term of this Charter and thereafter, maintain the confidentiality of any or all of the other party's confidential or proprietary information or data owned by it which is identified as "confidential" at the time it is disclosed (collectively, "Confidential Information"). Such Confidential Information shall at all times remain the property of its owner and shall be deemed to be furnished in confidence and solely in connection with the party's obligations under this Charter. Upon termination of this Charter for any reason, the party using the other party's Confidential Information shall immediately deliver to the owner all written documentation, including copies of or concerning such Confidential Information, and shall make no further use thereof, and shall make reasonable efforts to ensure that no further use is made by its employees, agents or

contractors. The confidentiality obligations under this Section 4.2 shall indefinitely survive the expiration or termination of this Charter.

5. SEPARATE ENTITIES; INDEMNIFICATION; ISPE ACTIVITIES

5.1 Separate Entities. ISPE and the Chapter expressly acknowledge and agree that they are, and shall remain, separate entities and that no partnership or agency is created by virtue of this Charter. As such, neither party shall be authorized to incur any liability, obligation or expense on behalf of the other. The Chapter is not liable or responsible for the debts or obligations of ISPE and ISPE is not liable for the debts or obligations of the Chapter. Likewise, in the event of any expiration or termination of this Charter, in addition to the other actions to be taken described in this Charter, the parties acknowledge and agree that the assets and the funds each party then holds, except for authorized charges pending and not yet paid by and to each other or otherwise reconciled by the parties, will remain the assets and funds of each party.

5.2 Indemnification. In furtherance of the above intention and agreement, ISPE hereby agrees to indemnify and hold harmless the Chapter, its officers, directors, agents, Members and employees from and against any action, suit, proceeding, claim, damages, liability, obligation, cost or expense which may arise, or may have arisen, by reason of any act or omission by ISPE, or any of its officers, directors, affiliates or employees thereof. Likewise, the Chapter hereby agrees to indemnify and hold harmless ISPE, its officers, directors, agents, Members, affiliates and employees, from and against any action, suit, proceeding, claim, damages, liability, obligation, cost or expense which may arise, or may have arisen, by reason of any act or omission by the Chapter, or any of its officers, directors, Members or employees thereof.

5.3 ISPE Activities. ISPE may, in its sole discretion, conduct its own activities within the specified geographic area identified in Exhibit A during the term of this Charter. Upon not less than 18 months prior written notice, ISPE reserves the right to modify or change the geographic areas described in Exhibit A, with the Chapter's active input and engagement. The changes will become effective on the expiration of the Chapter Charter immediately following the 18-month notification period.

6. TERMINATION OF CHARTER

Either party may terminate the Charter granted to the Chapter, with all of its attendant rights and obligations, (a) for any reason upon ninety (90) days written notice to the other party, and (b) upon ten (10) days' notice to the other party in the event of the other party's material breach of this Charter and such breach remains uncured during the notice period. Upon delivery of notice of termination, for any reason and by either party, the Chapter shall promptly deliver to ISPE a current roster of all Members of the Chapter, including all contact information, to enable ISPE to communicate with such Members. From and after the date of termination, the Chapter shall cease to identify itself as a Chapter of ISPE and the Chapter shall immediately cease use of any ISPE Intellectual Property for which it obtained ISPE's written permission to use. The Chapter may not utilize any ISPE Intellectual Property without ISPE's specific written permission for post-termination use. For a period of two years following termination of the Charter by ISPE with cause or by the Chapter without cause, the Chapter shall refrain from entering into an official relationship with another individual membership organization serving the pharmaceutical industry that is national or international in scope (including its local chapters and branches). Cause in this case refers

to breach of this signed Charter. Should the reason for termination be disputed, a formal review process would be required to establish the reason for the termination and both parties agree to the appeals process in Section 8.

7. WARRANT: LIMITATION OF LIABILITY

7.1 WARRANTY. ISPE MAKES NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED (INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE) CONCERNING ANY EDUCATIONAL MATERIALS, EDUCATIONAL PROGRAMS, MEMBERSHIP PUBLICATIONS OR ANY OTHER ARTICLE OR SERVICE PROVIDED HEREUNDER. ALL GUARANTEES, WARRANTIES, CONDITIONS AND REPRESENTATIONS, EITHER EXPRESSED OR IMPLIED, WHETHER ARISING UNDER ANY STATUTE, LAW, COMMERCIAL USAGE OR OTHERWISE ARE HEREBY EXCLUDED.

7.2 LIMITATION OF LIABILITY. THE CHAPTER ACKNOWLEDGES AND AGREES THAT ISPE SHALL NOT BE RESPONSIBLE FOR ANY DAMAGES WHICH THE CHAPTER MAY INCUR FROM ANY CAUSE, WHETHER LIABILITY IS ASSERTED IN CONTRACT OR TORT (INCLUDING NEGLIGENCE) ARISING FROM THE CHARTER OR ITS IMPLEMENTATION AGAINST THE CHAPTER. IN NO EVENT SHALL ISPE BE LIABLE TO THE CHAPTER OR ANY PERSON FOR LOSS OF PROFITS, LOSS OF USE, LOSS OF PRODUCTION, LOSS OF GOODWILL OR INCIDENTAL, INDIRECT, CONSEQUENTIAL OR SPECIAL DAMAGES OF ANY KIND EVEN IF ISPE HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. LIKEWISE, ISPE ACKNOWLEDGES AND AGREES THAT THE CHAPTER SHALL NOT BE RESPONSIBLE FOR ANY DAMAGES WHICH ISPE MAY INCUR FROM ANY CAUSE, WHETHER LIABILITY IS ASSERTED IN CONTRACT OR TORT (INCLUDING NEGLIGENCE) ARISING FROM THE CHARTER OR ITS IMPLEMENTATION AGAINST ISPE. IN NO EVENT SHALL THE CHAPTER BE LIABLE TO ISPE OR ANY PERSON FOR LOSS OF PROFITS, LOSS OF USE, LOSS OF PRODUCTION, LOSS OF GOODWILL OR INCIDENTAL, INDIRECT, CONSEQUENTIAL OR SPECIAL DAMAGES OF ANY KIND EVEN IF THE CHAPTER HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

8. APPEAL

The Chapter may request an opportunity to present an objection to a proposed modification of its geographic area under Section 5.3 or a proposed termination under Section 6 to the ISPE International Board of Directors, in which case the proposed action shall not become effective unless and until ratified by the ISPE International Board of Directors.

9. MISCELLANEOUS

9.1 Entire Charter. This Charter (together with any exhibits attached and incorporated by reference hereto) constitutes the entire Charter between ISPE and the Chapter with respect to the subject matter hereof. This Charter may be amended only in writing and executed by both parties.

- 9.2 Controlling Law. This Charter shall be governed by and construed in accordance with the laws of the State of Florida, USA, and venue for any litigation arising hereunder shall be Tampa, Florida, USA.
- 9.3 Waiver. Any waiver by either party to this Charter of any provision shall not be construed as a waiver of any other provision of this Charter, nor shall such waiver be construed as a waiver of such provision with respect to any other event or circumstance, whether past, present or future.
- 9.4 Severability. If any provision of this Charter is determined to be invalid or unenforceable in whole or in part, the remaining provisions shall be enforceable to the maximum extent possible.
- 9.5 Successors and Assigns. This Charter shall inure to the benefit of the parties and their successors and assigns. Neither party may sublicense or assign any of its rights or obligations under this Charter without the prior written consent of the other party.
- 9.6 Notices. Any notice contemplated by, or made pursuant to, this Charter shall be in writing and made by courier, facsimile, electronic mail or mail addressed or directed to ISPE, Affiliate/Chapter Relations at 600 North Westshore Blvd., Suite 900, Tampa, Florida, 33609, USA, or the Chapter at the home or business address of the Chair/President of the Chapter in office at the time the notice is sent. Either party may change the address for notice by 10 days advance written notice to the other party. Notice shall be deemed to have been sufficiently given or served as follows: (a) when received if delivered by mail; (b) one (1) business day after mailing if notice is given by reputable express courier; or (c) when sent, if by facsimile or electronic mail and a confirmation copy is sent by mail or express courier.
- 9.7 Termination of Prior Chapter Charter. This Charter supersedes and replaces any prior affiliate agreement or "Charter" between the parties and terminates any such agreement on the effective date of this Charter, 1 February 2016.

IN WITNESS WHEREOF, the parties have caused this Charter to be executed by their duly authorized representatives, effective as of 1 February 2016.

FOR THE:

XXXX Chapter
(Signature)

XXXX XXXX
Chapter President

Date

FOR THE:

INTERNATIONAL SOCIETY FOR PHARMACEUTICAL ENGINEERING, INC. (ISPE)

(Signature)

John E. Bournas
President and Chief Executive Officer

Date

EXHIBIT A

Geographic Territory of the Affiliate or Chapter

This Charter will be completed based on the designated area of each Affiliate or Chapter effective 1 February 2016.

The XXXX Chapter's geographic territory is [Description of geographic territory].

EXHIBIT B

Current “ISPE Corporate Identity Standards” applicable to all independent chapters



VISUAL
GUIDELINES
AFFILIATE/CHAPTER LOGO

TABLE OF CONTENT

This document is intended for all those who use the ISPE Affiliate/Chapter visual identity in communications and supporting documents. Instructions provided in this guide will ensure consistency in the use of the branding elements throughout ISPE's communication tools.

These guidelines must be followed at all times to convey a strong and consistent image across all communications, both internally and externally.

If you have any questions about our guidelines, please contact the Marketing/Communications Department.

OUR IDENTITY AND ITS COMPONENTS

Affiliate/Chapter Logo

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AFFILIATE/CHAPTER LOGO

USAGE POLICY

The ISPE reputation in the marketplace has been built over time by the quality and integrity of the activities of our Members, Affiliates and Chapters. ISPE's name and trademarks represent the organization and are collectively our greatest assets. We rely on all Members, Affiliates and Chapters to assist in maintaining the proper usage and thus protection of these trademarks. The ISPE "globe" logo and other ISPE logos are the property of ISPE and are trademarked internationally. ISPE staff, Members, Affiliates and Chapters are asked to use the appropriate version of the ISPE logo in accordance with the following usage rules and accompanying *Visual Guidelines* guide.

1. Affiliates and Chapters are encouraged to employ the appropriate ISPE logo version in developing their corporate identity.
 - ISPE's Affiliates and Chapters do not need approval or license to use the ISPE registered logo versions for official uses if used in accordance with the graphics standards set forth in this policy and in the ISPE *Visual Guidelines* guide.
2. ISPE logo(s) is not to be used to imply or suggest endorsement of any product, person, property, or service not provided by ISPE.
3. The logo(s) may not be used in a way that is confusing, misleading, or disparaging.
4. The logo versions cannot be altered or modified in any manner, including being combined with other elements or rearranged in any way.
5. Members are not permitted to use the ISPE logo on items such as, but not limited to, personal stationery, business cards, advertisements, or other property. If a Member wishes to indicate that he/she is a Member of ISPE on printed material, he/she must do so in wording only. For example, the piece would read "Member of ISPE" without a logo.
6. Organizations, unless licensed by ISPE, cannot use the ISPE logo(s) on any organization materials such as, but not limited to, brochures, stationery, business cards, equipment, giveaways, banners, and advertising materials.

AFFILIATE/CHAPTER LOGO

USAGE POLICY (CONT'D)

If an individual or company does not follow this policy and uses the ISPE logo without permission, the following actions will be taken by ISPE:

- A cease and desist letter will be issued to the member stating that he/she is not in compliance with the ISPE logo policy.
 - If a member does not follow the first cease and desist letter, the Society's attorney will issue a second letter.
 - If a member or company does not cease and desist, ISPE reserves the right to terminate membership and/or pursue legal action.
7. If an organization or individual has received special recognition from ISPE, they may note it by stating it in wording form only, without the use of the logo. In addition, the year in which the recognition was received must be included. For example, an organization that is recognized as ISPE Company of the Year in 2011 may only use the wording "2011 ISPE Company of the Year" on their materials. ISPE headquarters' approval is required for this type of use.
 8. Use of the ISPE logo(s) on company Web sites is restricted to links leading to www.ispe.org. Use of the logo(s) for this purpose is subject to ISPE review and approval. Web sites must be submitted for approval to ISPE. The use of ISPE logo(s) on a company's web site should NOT be positioned in a way that could be misconstrued as an endorsement of the company by ISPE.
 9. ISPE does not permit the use of the logo on any souvenir, or item for sale, unless the vendor is approved by ISPE.

All other requests for logo usage must have prior approval by ISPE's Marketing/Communications Department.

AFFILIATE/CHAPTER LOGO

OFFICIAL USAGE

The Affiliate/Chapter logo is used to represent the ISPE Affiliates and Chapters worldwide.

The logo formats to the right are the primary organizational identity elements for Affiliates and Chapters. They include the ISPE symbol, dividing line, country/region/city name, Affiliate or Chapter designation in definite order and definite proportions.

The arrangement order of the logo elements, as well as proportions, may never be altered.

Electronic files of these logos are provided to the leadership of each Affiliate and Chapter, and their Chapter Managers as appropriate.

One may choose to use the horizontal or block versions of the logo depending on the length and the available space. The block version should never have more than four lines of text under the blue dividing line.



AFFILIATE/CHAPTER LOGO

PROTECTION SPACE AND MINIMUM SIZE

PROTECTION SPACE

To protect the strength and integrity of the logo, a minimal clear space area, free of competing visual elements, should be maintained.

The  represents the minimum protection space around the logo.  is equal to 2/3 the height of the letter 'E' in the ISPE Affiliate Chapter logo.

MINIMUM SIZE

To ensure its impact and legibility, the logo should be no less than 1.5 inch wide.



HORIZONTAL VERSION



Minimum size: 1.5 in.

BLOCK VERSION



Minimum size: 1.5 in.



Minimum size: 1.5 in.

AFFILIATE/CHAPTER LOGO

TECHNICAL SPECIFICATIONS

At the minimum size, the font size should be 9.5 pt with a 10.5 pt leading to have a perfect alignment with the height of ISPE. A vertical line is needed when more than one country are placed on a same line. For a good alignment with the text, a 0.65 pt baseline shift must be applied to the vertical line. The blue dividing line between the ISPE logo and the text is a 0.5 pt stroke.

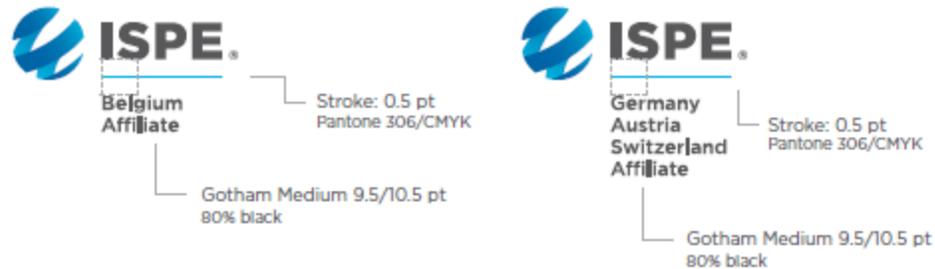
These specifications, which are valid when the logo is at its minimum size (1.5 in. width), must increase proportionally with the logo when used at larger sizes.

In the block version, depending on the length of text, there can be two to four lines under the blue dividing line.

HORIZONTAL VERSION EXAMPLE:



BLOCK VERSIONS EXAMPLES:



AFFILIATE/CHAPTER LOGO

IMPROPER USAGE

Any modification, even minor, of the logo's design, proportions, spacing, or colors can reduce its impact and diminish its authenticity.

Do not deform the logo, change its color, use shading, add a contour effect, modify the typeface, or apply any gradient effect other than the one presented in the official version.

Do not position it at an angle or vertically. The symbol and the acronym must always be used together, positioned and proportioned as presented in this guidelines manual.

The improper usage examples at right apply to the horizontal and block versions of the logo.

AN ELEMENT (CONTOUR EFFECT) HAS BEEN ADDED



THE GLOBE HAS BEEN FLIPPED AND THE TYPOGRAPHY MODIFIED



A DROP SHADOW OR FILTER EFFECT HAVE BEEN ADDED



A COLOR OTHER THAN THE OFFICIAL COLORS HAS BEEN APPLIED



ELEMENTS HAVE BEEN SCREENED OR MADE TRANSPARENT



DEFORMATION OF THE LOGO



USE OF THE GLOBE OR ISPE ALONE



OR



AFFILIATE/CHAPTER LOGO

IMPROPER USAGE (CONT'D)

If the logo is applied on a background, make sure there is sufficient contrast between the background and the logo.

You must respect the logo's protection space as presented on page 6.

The improper usage examples at right apply to the horizontal and block versions of the logo.

IMPROPER APPLICATION OF THE LOGO ON COLORED BACKGROUNDS



DISREGARD OF THE PROTECTION SPACE OF THE LOGO



DISREGARD OF THE GLOBE'S PROPORTIONS



COLOR

OFFICIAL COLORS

The official colors for the ISPE Affiliate/
Chapter logo are:

a dark blue (PMS 2945C)
a light blue (PMS 306C)
and a black 80% (PMS Black)

The blue gradient is a dynamic tone
that gives impact to the globe symbol.
The gray color creates a soft balance
in the logo.

The blue dividing line between the ISPE
logo and the text is in PMS 306C and
the text is in black 80%.



PMS 2945C	PMS 306C	PMS Black 80%
CMYK 100/52/2/12	CMYK 79/0/6/5	CMYK 0/0/0/80
RGB 0/84/159	RGB 0/185/228	RGB 89/89/91
HEX 00549f	HEX 00b9e4	HEX 59595b

COLOR

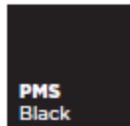
OTHER ACCEPTABLE COLOR USAGE

It is preferable that the logo(s) be reproduced in their official color palette.

However, if not possible, a black and gray version, and a reversed version of the logo are acceptable.

In the black and gray version, the text must be in 100% black and the dividing line between the ISPE logo and the text in 60% black.

BLACK AND GRAY



CMYK
0/0/0/100
RGB
0/0/0
HEX
000000



CMYK
0/0/0/60
RGB
105/105/105
HEX
696969

REVERSED LOGO



APPLICATIONS

LETTERHEAD

These are the required specifications to build your letterhead. It should always be printed on white smooth stock. The content should always be aligned with the "I" of the ISPE logo.

/ 8.5 in. x 11 in. Letter

Ideally: Gotham Book 10/12 pt, 100% black
 Otherwise: Arial Regular 10/12 pt, 100% black

Gotham Book 7.5/9 pt
 80% black

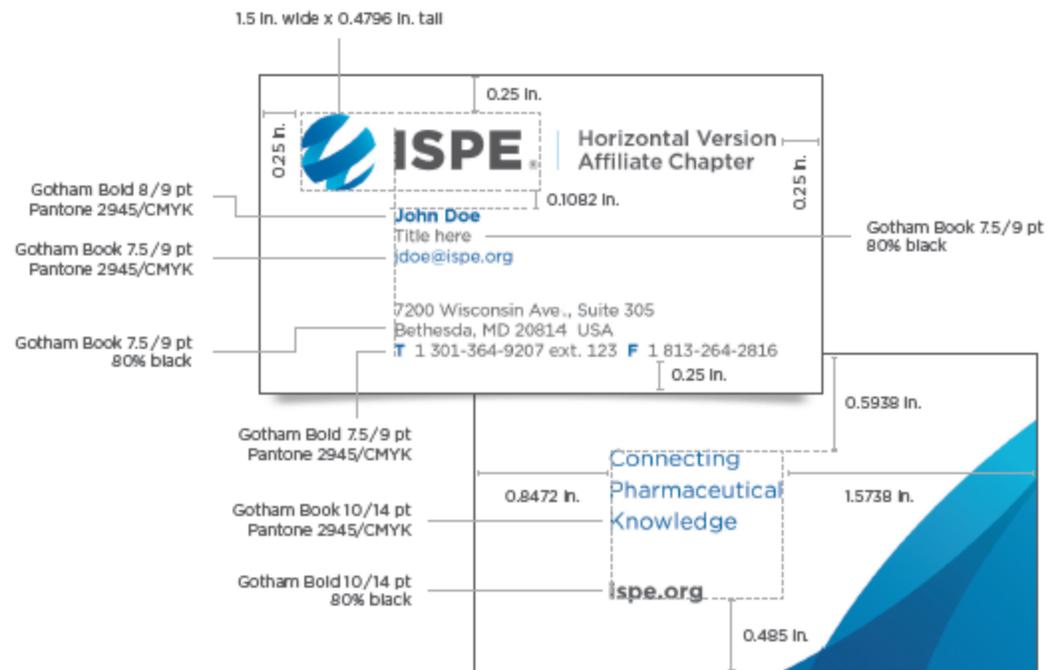


APPLICATIONS

BUSINESS CARD

Chapter and Affiliate business cards should conform to this template. Variation in title length may require a third line of text. The content of the cards should be aligned left with the "I" of the ISPE logo.

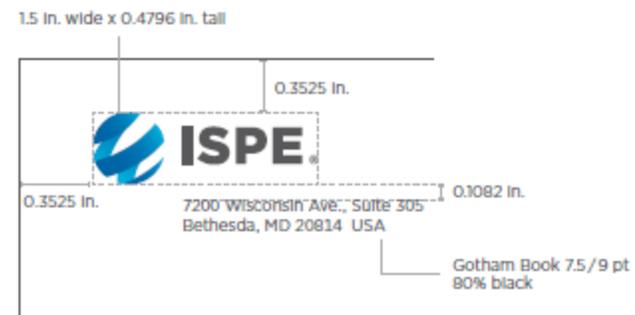
/ 3.5 in. x 2 in. Business card



APPLICATIONS

ENVELOPE

Chapter and Affiliate envelopes should conform to these specifications.



APPLICATIONS

POWERPOINT

The Affiliate/Chapter PowerPoint presentation is geared toward developing and delivering presentations with a consistent brand image.

This template allows flexibility in customizing presentations for ISPE audiences. This template is designed to be versatile, and can be used across multiple platforms like print, screen and projection.

Please secure permission from the author or publisher and properly credit all copyrighted photos, text and graphics used in ISPE print and online materials.



PARTNERING

PREFERRED USAGE

When partnering with another organization on a program or event, this is the preferred usage:

Follow the Affiliate/Chapter logo usage guidelines outlined in the guide and place the Affiliate/Chapter logo at the top left of the document.

The logo of the collaborating organization should be placed within the document below the Affiliate/Chapter logo and should never be larger than the Affiliate/Chapter logo.

The involvement of the other organization in the event should be clearly indicated. For example: "Co-Sponsored by:", "In Cooperation with:", "In Partnership with:", "In Conjunction with:", "Benefitting:", "Supported by:", etc.

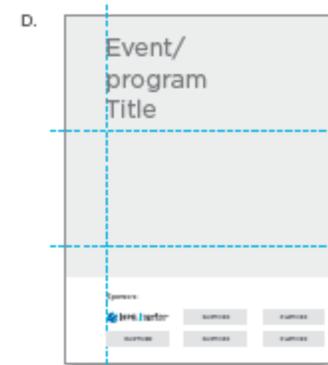
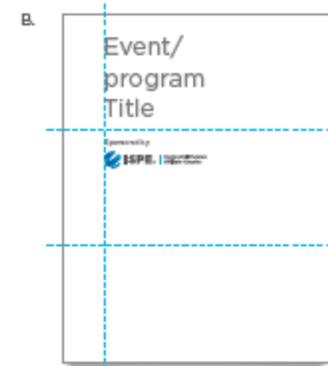
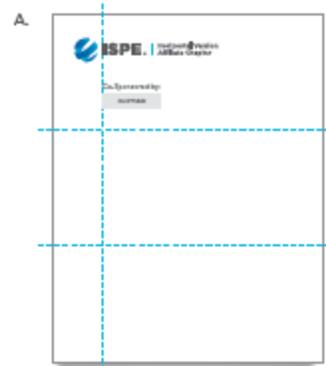


PARTNERING

PREFERRED USAGE (CONT'D)

Other possible options:

- A. The logo of the supporting or partnering organization should be placed below the Affiliate/Chapter logo within the document based on layout.
- B. Immediately following event/program title in body of document
- C. Immediately below event/program description at bottom of document
- D. Within a sidebar (best if there are multiple logos)



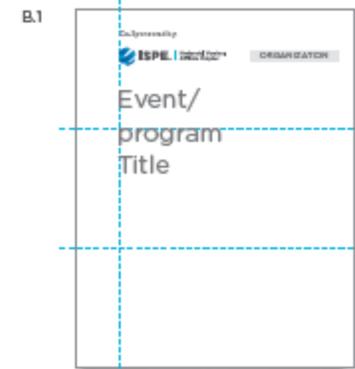
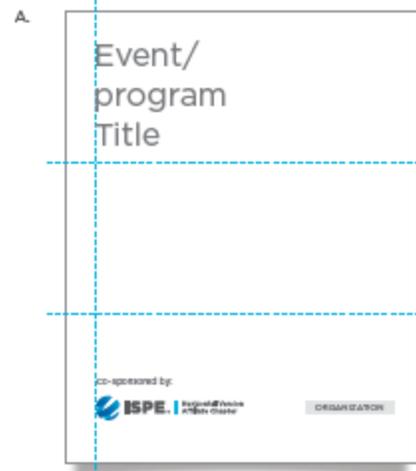
PARTNERING

SECONDARY USAGE

For a document promoting an ISPE Affiliate/Chapter program or event that is co-hosted or co-sponsored by another organization:

- A. Follow the Affiliate/Chapter logo usage guidelines outlined in this guide and place the Affiliate/Chapter logo at the bottom left of the document.
- B. The logo of the collaborating organization should be placed to the right of, or following, the Affiliate/Chapter logo and should never be larger than the Affiliate/Chapter logo.

The involvement of the organization(s) in the event should be clearly indicated. For example: "Co-Sponsored by:", "In Cooperation with:", "In Partnership with:", "In Conjunction with:", "Benefitting:", "Supported by:", etc.



PARTNERING

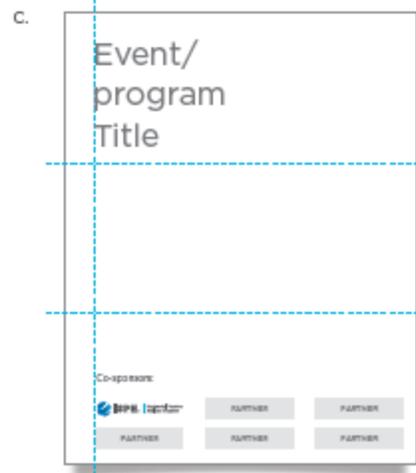
SECONDARY USAGE (CONT'D)

C. In the event there are multiple logos (more than one co-host or co-sponsor), they should be listed first by involvement (all co-sponsors together, etc.) and multiple logos within one category should be listed alphabetically.

D. For a document promoting a program or event hosted by another organization, where an ISPE Affiliate/Chapter is a supporting or partnering entity:

Follow Affiliate/Chapter logo usage guidelines outlined in this guide. Logo does not need to be top left, but should be appropriately placed within the document proportionate to other partnering logos.

Clearly indicate the involvement of the ISPE Affiliate/Chapter in the program or event. For example: "Co-Sponsored by:", "In Cooperation with:", "In Partnership with:", "In Conjunction with:", "Supported by:", etc.





For further information, please contact
ISPE's Marketing/Communications Department
at info@ispe.org

EXHIBIT C

Current Criteria for Chapter Policies and Guidelines

Effective 1 February 2016

All Chapters are required to define and address the local needs of technical professionals in the pharmaceutical industry in accordance with ISPE's objectives.

- 1 **Bylaws.** Chapter bylaws will be revised and amended as appropriate in accordance with annual changes in ISPE's bylaws that directly affect Chapter governance and operations. All amendments to the Chapter bylaws are to be forwarded to ISPE for review. ISPE will notify the Chapter if any amendments put the Chapter in breach of this Charter. The Chapter will have 30 days to cure the breach or be subject to termination per Article 6 of the Charter.
- 2 **Elections.** The Chapter will hold an election for its Board of Directors to include Officers and Directors at least every two (2) years. All ballots must be forwarded to ISPE for its review and comment before distribution to and voting by the Chapter Members. Election procedures should enable every Chapter Member to have a vote.
- 3 **Formation of Regional Branches.** The Chapter may request approval from ISPE to establish Regional Branches as appropriate in specific geographic locations within the Chapter's territory as identified in Exhibit A. The Chapter Board of Directors oversees all Regional Branch activities, includes activities in the Chapter budget and reports and ensures that the Regional Branches are compliant with all applicable ISPE policies and procedures.
- 4 **Organizational Alignment — Regional Affiliate Councils Structure & Chapter Attendance at Council Meetings.** The Chapter will appoint the President and one other Chapter officer to serve on the North America/South America Affiliate Council (NASAAC) for a term of one year. The Chapter Board may designate an alternate officer to attend a NASAAC meeting if the appointed representatives are unable to attend.
- 5 **Membership, Including Meeting and Event Pricing Recommendations.** ISPE collects all membership dues, which are billed throughout the year on an anniversary basis.
 - In order to become a Member of the Chapter, an individual must first join ISPE. All current ISPE Members are entitled to attend Chapter meetings at the Chapter Member rate.
 - The Chapter will charge nonmembers a significant premium, but no higher than the cost of an ISPE membership, to attend meetings and events.
 - Participating in local Communities of Practice ("CoPs") is restricted to Members only. Non-members may attend programs created by local CoPs and shall be charged the non-member fee premium, as outlined above.

- The Chapter will devote time at each meeting or event to brief the audience on ISPE membership benefits, and where possible, distribute membership marketing collateral and applications.
- Under no circumstances will the Chapter make its membership list available to another organization for any reason.

6 Organizational Promotion and Branding, Including ISPE Brand Standards. The Chapter will follow the ISPE Brand Standards. ISPE’s name and trademarks represent the organization and are collectively ISPE’s greatest assets. The ISPE “globe” logo, the ISPE acronym, the “INTERNATIONAL SOCIETY FOR PHARMACEUTICAL ENGINEERING” name and other ISPE logos are the property of ISPE and are trademarked internationally.

7 Electronic Communications and Presence on the Web. The Chapter will follow the policies and standard operating procedures which ensure ISPE’s electronic “face” is consistent in quality and use of brand standards and complies with all local, national and international laws. The policies and Standards of Practice (SOPs) include the Website Policy, Website Guidance and Email Procedures.

8 Meetings. The goal for all ISPE programming is a coordinated set of offerings that serve the needs and capabilities of the Membership both locally and internationally.

- The Chapter will not enter into any agreement to sponsor, endorse or help produce any seminar, conference or trade show with any for-profit organization without written approval from the ISPE International Board of Directors.
- With input and comments provided by ISPE, which will be considered by the Chapter, the Chapter may work with other local not-for-profit organizations to co-produce or co-promote seminars and conferences of mutual benefit.
- The Chapter will check the ISPE Global Calendar before it schedules any Chapter events. The Chapter will be aware of nearby chapters’ events and ISPE events when it plans Chapter meetings.
- The Chapter will provide ISPE the dates of proposed Chapter events at least 6 months in advance to help ensure that any conflicts with other ISPE events can be avoided. If there is a conflict, the two parties will work together to come up with a mutually acceptable solution.
- NASAAC representatives are invited to provide input for ISPE’s Continuing Education and Training schedule.

9 Sponsorships and Exhibits. The Chapter will present plans for advertising subsidies and vendor tabletop exhibits to ISPE Affiliate/Chapter Relations staff for review and finalizing at least six months prior to the event.

- For general guidance on planning local vendor nights, the Chapter should refer to the annual Affiliate/Chapter Event Planning Tool.
- Vendor nights with five (5) or fewer table top exhibits are exempt from prior authorization if they occur in conjunction with a local program.
- Vendor nights or trade shows with more than 75 tables may not be held 30 days before or after any global ISPE event held within a 400-mile radius.
- No Affiliate/Chapter event may exceed 375 table tops at any time of the year. Included in this total is up to 10 supplemental displays which may include booths that do not exceed 10' x 10' per exhibitor or truck displays contained within a single trailer.
- Table top displays are defined as consisting of the actual table top and a 3 foot border around the table top.
- The following types of displays are not permitted:
 - displays on anything other than tables (except as permitted in the 10 supplemental displays above)
 - displays on tables separated by partitions
 - displays by individual exhibitors that occupy more than one table, even if the individual exhibitor agrees to pay for more than one table. If an individual exhibitor has multiple divisions exhibiting, ISPE may provide one (1) table per exhibiting division so long as the total number of tables for such individual exhibitor does not exceed four (4) tables, and each table counts toward the total.

10 Contact with Regulatory Agencies. ISPE seeks the involvement of regulatory agency staff in all levels of ISPE.

- Regulators worldwide are offered membership at no cost; the Chapter is encouraged to invite professionals working for their national regulatory agency to join. ISPE Affiliate/Chapter Relations staff can provide boilerplate membership invitation letters and membership applications.
- The Chapter will follow ISPE's procedure for Regulator speaker requests by using the Regulator Request form.
- At least six months advance notice should be provided to obtain a Regulator as a speaker/presenter in order to get the request through the FDA's processes.
- The Chapter should not initiate contact with FDA headquarters; all formal requests for resources should be made through the ISPE Affiliate/Chapter Relations staff.

11 **Risk Management.** The Chapter is responsible for obtaining corporate insurance coverage, including Directors and Officers (D&O) insurance and general liability coverage.

12 **Reporting.** The Chapter must provide the following reports of its activities on the designated dates below:

- Signed copy of Chapter's 990 tax filing by May 31 (notify ISPE if extension is sought from the IRS)
- Insurance Declaration/Certificate by May 31
- Event flyers, email blasts, newsletters for review and approval by ISPE Affiliate/Chapter Relations staff *before launching to Members*
- Event rosters two (2) weeks after each event
- Board Meeting Minutes two (2) weeks after each meeting

13 **Organizational Initiatives, Reports and Guidance Documents.** All programming based on the Baseline® Pharmaceutical Engineering Guides, GAMP®, GAMP® Good Practice Guides and the ISPE Good Practice Guides (collectively, "ISPE Guides") is the property of ISPE.

- The Chapter shall not publish, revise or endorse professional guides, guidelines or standards without written permission of ISPE.
- The Chapter shall not copy, resell, translate or create any derivative works of the ISPE Guides.
- Suggestions for development or revision of existing ISPE Guides should be referred to Affiliate/Chapter Relations staff.
- The Chapter may hold programs to solicit industry comment on new initiatives, ISPE Guides or planned revisions to existing ISPE Guides during the official comment period and as long as a member of the Initiative/Document Team leads the presentation/discussion and gathers the comments. These programs should not conflict with other ISPE programs. All programming seeking local input ceases once the comment period ends.
- The Chapter may hold programs and invite but cannot guarantee that members of the Initiative/Document Team will present the program. Requests for speakers from the Initiative/Document Teams should be sent to the ISPE Affiliate/Chapter Relations staff.