



**ISPE
INTERNATIONAL AFFILIATE
START-UP GUIDE**

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EDITOR'S NOTES

The Affiliate Start-Up Guide is produced and designed as a guide to steering committees interested in forming new ISPE Affiliates.

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ISPE AFFILIATE HANDBOOK

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I. PURPOSE

Welcome!

This Start-Up Guide contains the information that is most important when a group comes together with interest in forming a new ISPE Affiliate. Access to the full Affiliate operational policies and procedures will be provided to the new Affiliate's Steering Committee when the group reaches the point of requiring that level of information. That information is not provided in the early stages to avoid overwhelming committees with a level of detail that is not yet important.

The formation of an ISPE Affiliate is a strategic decision for the organization. Individual Affiliates of ISPE are organized to provide a forum for transfer of information and technology on a more local/regional basis and to advance ISPE's global strategic objectives. These will be shared more fully when it is clear that sufficient interest exists in a country or region to move forward with planning. At a minimum, an Affiliate should expect to hold a series of meetings during a year, focusing on technologic and regulatory issues. In addition, vendor exhibits are often held and a newsletter is published to present new information, products and general industry news. Ultimately, the Affiliate might host expanded educational programs for industry representatives, regulators, and/or college students, contribute to the ISPE body of knowledge, and participate in community activities.

An ISPE local Affiliate can serve a specific country (e.g. the Argentina Affiliate), a geographic region (e.g., the Australasian Affiliate), or possibly a group of countries (e.g., the Germany-Austria-Switzerland Affiliate). The determinant of the Affiliate's reach might be the number of potential members in the area, the number of pharmaceutical firms, the level of interest of industry members, the availability and cost of travel services, and the existence of other ISPE Affiliates in or near the region. The name and geographical area covered by a new Affiliate are the decision of the International Board of Directors upon recommendation by the formation Steering Committee and the staff liaison.

The Start-Up Guide describes the Affiliate formation activities, ranging from contacting local industry members and forming a steering committee, to the ongoing maintenance and administrative responsibilities of the Affiliate once it has been organized and chartered. The tasks are described in detail and suggestions made how to accomplish them. Keep in mind that many of these are only suggestions. In addition, the amount of work required to both organize an Affiliate and perform the ongoing administrative requirements might seem extensive. As progress is made, and an understanding of each of the requirements is gained, the tasks effectively become easier. The activities also seem simpler, and the effort is both extremely worthwhile and rewarding.

II. ISPE INTERNATIONAL STRUCTURE

The concept of Chapters/Affiliates was certainly not originated by ISPE. However, at a very early stage in the Society's development, the International Board of Directors recognized the need for convenient, local activities to augment the more complex national (and eventually international) programs.

The Society was founded in July 1980. By 1984, with total membership approaching just 500, the Board began discussions on how a pilot Chapter program could be developed. With volunteer resources seriously strained at that time, it took two more years before a dedicated group of members who "shared the common vision" of a local extension of ISPE could be found. The first Chapter steering committee was formed in Northern New Jersey, USA, eventually establishing the first Chapter in 1986.

Today, the Society serves more than 21,000 members in 90 countries, 15 Chapters in the United States Affiliate, 1 Chapter in the Canada Affiliate and 23 additional International Affiliates. The emergence of Chapters and Affiliates around the world has had a profound effect on membership growth. In addition, there are more than 70 Student Chapters around the world. More than 96 percent of ISPE members belong to a North American Chapter or an International Affiliate.

As might be expected, such a rapid expansion in the number of individuals and groups has brought about significant changes in the Society's finances and structure.

Until 1987, the Society operated at a deficit. (Indeed, there was a year when one of the Chapters had more money in the bank at year's end than ISPE Headquarters.) Largely due to volume increase and growing customer acceptance of the seminar events, the Society was able to turn the financial corner that year. With the journal operating at a loss and membership dues less than annual cost of service, the educational programs continued to keep ISPE's "doors open." The success of these events enabled ISPE to expand into Europe in 1988 and to open a European office in 1992.

Structurally, ISPE has changed to reflect expansion and diversity. The Staff has been expanded significantly, operating out of offices in Tampa, Florida; Brussels, Belgium; Shanghai, China; and Singapore.

III. AFFILIATE ORGANIZATION/START-UP

The formation of a local ISPE begins by communicating with persons in the local industry and determining the overall level of interest and willingness to participate. Once that interest level is acknowledged, a series of activities must take place.

A. STEPS TO FORMATION

Following is a suggested path for establishing a new local Affiliate based upon the successful experiences of Affiliates that have gone before you. This list is only a general outline. **The sequence and timing of activities will vary with the formation of each new Affiliate and many of the activities can be performed concurrently.** ISPE's Vice President of Member Relations at ISPE Headquarters is available to assist all along the way and will notify you when you have formally achieved AFFILIATE status. It can be estimated that the path from beginning to end takes approximately two years.

All official documentation generated in the following process should be copied and the original documents forwarded to ISPE Headquarters for filing and permanent storage.

1. Determine Level of Interest (Survey) and Other Due Diligence Gain support from ISPE to Proceed
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2. Establish Steering Committee Define Responsibilities
--

3. Define Geographical Parameters of Prospective Affiliate Develop Affiliate Name
--

4. Open Bank Account if/when Needed

5. Plan Inaugural Interest Meeting to Gauge Broader Interest Establish Speaker and Location Establish Local Industry Mailing List, Mail Meeting Announcement via Regional ISPE Office

A. STEPS TO FORMATION (Continued)

6. Hold Inaugural Interest Meeting of Local Affiliate in Formation

Record Contact Information on all Member and Non-Member Attendees & report to ISPE regional office

Assess Results/Prospects; Gain Authorization from ISPE International to Proceed with Further Affiliate Development

7. Develop Working Committees

8. Seek Legal Consultation on Complying With Local Government Regulations

9. Work with ISPE International to Develop a Logo and Learn Relevant ISPE Operating Procedures

10. Develop Three-Year Business and Financial Plan

11. Develop Bylaws and File Documents with the Local Government to be Recognized as a Not-for-Profit (or Similar) Organization

12. Nominate and Elect Officers and Directors

13. Hire or Appoint an Accountant

14. Issue of Affiliate Charter from ISPE Board of Directors

THROUGHOUT THE PROCESS

Communicate with ISPE Through the Vice President of Member Relations (through Regional Affiliate Staff Where Applicable)

B. DESCRIPTION OF STEPS TO FORMATION

1. DETERMINE LEVEL OF INTEREST (SURVEY) AND OTHER DUE DILIGENCE

Discuss the formation of a local ISPE Affiliate and its benefits with persons in the local pharmaceutical manufacturing industry. Communicate this interest and solicit support from ISPE via the ISPE Vice President of Member Relations and regional Affiliate support staff.

Determine a geographical region for the prospective Affiliate. Determinants of this region might include local population of pharmaceutical firms, availability of cost and effective travel services.

Develop a mailing list from local resources (organizations, personal references), and augment them with regional contacts that may be available from ISPE.

Develop an interest survey (see example-Attachment 1) to assess actual level of interest and potential level of participation. The survey should be developed to collect the following information. Electronic survey tools are very helpful in this regard, and it is easy to give ISPE access to the survey results. If paper surveys are used, they must be tabulated and both original documents as well as the tabulation should be sent to ISPE.

The survey responses will be analyzed with help from ISPE. If the response is positive (more than ten percent of mailings and solid industry support), staff will report this to the ISPE Board of Directors. It is the Board's decision regarding whether to authorize proceeding to the next step which is to establish a Steering Committee. If the response does not indicate sufficient support for forming an Affiliate at this time, ISPE staff will discuss options for fully engaging the interested Members in the area without an Affiliate in place.

2. ESTABLISH STEERING COMMITTEE

Organize a Steering Committee of eight to ten local representatives with the commitment to support the Affiliate formation effort.

Elect a Steering Committee Chairman to lead the effort and maintain communications with ISPE. The responsibilities of the Steering Committee, as well as individual members of a Board of Directors, are outlined in the following section.

Establish objectives and preliminary goals dealing with Affiliate population and meetings.

Review the boilerplate Affiliate Charter document in place for existing Affiliates and ensure that all processes the steering committee undertakes occur in a manner that will ultimately be aligned with these requirements.

3. DEFINE GEOGRAPHICAL PARAMETERS OF PROSPECTIVE AFFILIATE

The geographical boundaries of the Affiliate should be finally defined based on the response from the survey and knowledge of the local industries. The parameters of any ISPE Affiliate will require approval from the ISPE Board of Directors through the ISPE Vice President of Member Relations. Future growth and expansion may require amendment of these boundaries. With the success and growth of an Affiliate it might become beneficial to organize Chapters in various locations within the area.

In addition, to avoid misrepresentation, duplication, and confusion each Affiliate must submit a proposed name to the ISPE Board for approval.

4. OPEN AN AFFILIATE BANK ACCOUNT (IF/WHEN NEEDED)

In order to deposit money from the attendees received for the first meeting and to pay for the respective services, you may be required to open a bank account. The steps necessary to do this will vary from country to country. Please advise ISPE's Vice President of Member Relations on the practices in your country and s/he will assist you in accomplishing what is required as easily as possible, drawing from the experiences of other Affiliate formation committees that have gone before you. In some cases, it may be beneficial to consult a local attorney/solicitor to assist you.

Establish a mailing address. A post office box is preferable to a business or home address because it provides continuity and eliminates corrections each year as the Affiliate leadership changes.

5. PLAN INAUGURAL AFFILIATE MEETING TO GAGUE BROADER INTEREST

To assist in the development of a new Affiliate, ISPE may provide financial support to defray the startup fees and to get the Affiliate up and running. This occurs only if the funds have been budgeted by ISPE International and/or otherwise approved by the Board of Directors. Generally it is best for the Affiliate in formation to garner the local support of industry for this first meeting. It is an important test of potential support for the organization.

If ISPE provides funds or a temporary loan of operating capital, ISPE attempts to pay expenses directly to suppliers. Experience has shown this approach works best for minimizing confusion and addressing local tax issues. Before the steering committee contracts with a venue, contact ISPE for discussion about procedures. If ISPE provides support or a loan for initial expenses, this support may include hotel deposits (which are repaid if the event is a financial success), incorporation fees and initial mailings. It is essential that the forming Affiliate demonstrate that it is capable of becoming financially self-sufficient through local activities as quickly as possible.

The planning and organization of the first meeting is critical to getting the local Affiliate off to the right start. Some caution should be exercised in the organization of the first meeting — keep it simple.

The location of the first meeting should be convenient for most of the audience. Typically, hotel conference rooms are used and a dinner is served. Fees for attendance depend on local custom, membership, type of meal, number of persons, quality of the facility and location.

An interesting speaker, covering a broad topic and attracting a wide audience is beneficial to exposing local industry personnel to the Affiliate. Recommended meeting formats and speakers are discussed in Section VII.

In order to effectively market the events/programs of the Affiliate, a local pharmaceutical industry mailing list of companies should be developed. This list should augment the one supplied by ISPE of members and subscribers in the Affiliate area.

The purpose of this meeting is twofold. First, it is a way to show the pharmaceutical manufacturing community in the Affiliate area what ISPE can offer in the way of programming and resources. Second, it is a way for the steering committee to determine whether there really is the amount of support needed from the broader community of manufacturers, suppliers, academics and regulators to justify moving forward to full formation status.

The meeting announcement should be developed and forwarded to ISPE regional staff and/or the Vice President of Member Relations for approval and distribution.

6. HOLD INAUGURAL MEETING OF LOCAL AFFILIATE

It's time! Hold that first meeting!

Keep detailed attendee list for this and all subsequent events.

Provide an analysis of attendees and support. This analysis should be discussed with regional Affiliate staff and/or the Vice President of Member Relations to determine alignment with expectations and the viability of moving forward to the next stage of formation.

7. DEVELOP WORKING COMMITTEES

It is critical to the future of the local Affiliate that committees are established to perform the number of tasks required to continue formation and growth of the organization. These committees can include Membership, Newsletter, Program (Seminar/Meeting), Industry/Vendor Relations and Special Projects. Other committees might be needed based on the membership and activities of specific Affiliates. The responsibilities of each of the committees are discussed in Section IV, Responsibilities. Local committees can also connect with International committees focused on similar disciplines, as well as with International staff, for assistance and best practices related to committee goals.

8. SEEK LEGAL CONSULTATION ON COMPLYING WITH LOCAL GOVERNMENT REGULATIONS

After a new Affiliate has proved itself to be viable, the required incorporation process may begin. Incorporation in the Affiliate's respective country is required.

The Affiliate should seek legal consultation on compliance with all governmental regulations. This advice should cover both how the group may function until it is legally recognized by the relevant government(s) and the steps that will be needed to obtain government recognition. This information should then be communicated to ISPE regional staff and/or the Vice President of Member Relations. They will assist in developing a plan for meeting these requirements as part of the larger planning process.

ISPE Headquarters will usually assist with funding the services of an attorney to file all the necessary documents for the local Affiliate if the Affiliate is experiencing early cash flow difficulties. The attorney will also review the proposed Bylaws of the Affiliate for compatibility with those of the Society. This information then supports the application to the federal government as a tax-exempt organization under the Society's US 501 (c) (6) tax designation (not-for-profit).

If possible and applicable, Affiliates should seek non-profit status in their respective countries to avoid taxes.

9. WORK WITH ISPE INTERNATIONAL TO DEVELOP A LOGO AND LEARN RELEVANT ISPE OPERATING PROCEDURES

Logo elements may be developed and submitted to ISPE at any time. Affiliates normally have the Steering Committee or local Members recommend local elements that the ISPE Marketing/Communications team can develop into a brand-compliant local logo. Affiliate logos normally incorporate the official ISPE logo; specific copyrights are attached to both the name and logo and any use must be approved. Please refer to the ISPE Branding Guidelines for general information on usage of ISPE brand marks.

It is also important at this time to begin acquainting committee volunteers with ISPE's policies and procedures for Affiliate operations. These are available in the Volunteer Resources section of ISPE's website in a secure area for Affiliate and Chapter leaders. General resources can be found here ISPE.org >> [ISPE Community](#) >> [Volunteers](#) >> [Volunteer Resources](#) >> Affiliate and Chapter Resources. Specific policies and procedures related to operating compliance can be found in this section under "Charters and Bylaws." Note: under the "Charters and Bylaws" section you will also find the Branding Guidelines mentioned above.

10. DEVELOP THREE-YEAR BUSINESS AND FINANCIAL PLANS

In order to keep both ISPE Headquarters and other local Affiliates informed of anticipated activities, a three-year schedule should be generated. While this schedule is not restricted from change, it should accurately reflect future plans to allow scheduling and coordination. Its purpose is to minimize conflicting activity dates within the Affiliate, with other Affiliates and with ISPE national programs.

Necessary changes in the proposed schedule must be brought to the attention of the Vice President of Member Relations and other Affiliates as soon as they are recognized.

In addition to meeting dates, a financial plan should be established. This should provide an estimate of the income and expenses of the Affiliate over a three-year

period. Further, all disbursement of funds should be submitted for approval, in concept, by ISPE Headquarters.

Other plans, including growth of membership, expansion of geographical base, and publication of newsletters should be identified to ISPE and discussed so that you may benefit from lessons learned by other Affiliates and find a smooth path forward.

11. DEVELOP BYLAWS AND FILE DOCUMENTS WITH THE LOCAL GOVERNMENT TO BE RECOGNIZED AS A NOT-FOR-PROFIT (OR SIMILAR) ORGANIZATION

A set of Bylaws must be developed and approved by ISPE to guide the Affiliate through its formation and continuation as a chartered organization. The Bylaws detail the operating mode of the Affiliate, including information concerning membership rights and priorities, the meeting attendance and collections and responsibilities to the Society. ISPE provides a bylaws template to assist you in creating this document. Please note that certain sections of the Affiliate Bylaws must appear verbatim as shown in the template (unless they are in conflict with local law) and other sections can be tailored to fit the needs of the particular Affiliate. ISPE Headquarters will provide an electronic version of the suggested Bylaws to your Affiliate Secretary upon request.

These Bylaws, along with the other supporting documents required by the local government (see #8 above) must be reviewed and approved by ISPE prior to filing them with the local authorities.

12. NOMINATE AND ELECT OFFICERS AND DIRECTORS

An Affiliate may function for the first year under the leadership of the Chairman of the Steering Committee. After that time, a Board of Directors (consisting of Officers and Directors) is officially elected by the Affiliate's full membership at least bi-annually.

Unless mandated otherwise by local laws, Affiliate elections should take place no later than August 1 of each election year to coincide with the ISPE election.

13. HIRE OR APPOINT AN ACCOUNTANT

It is imperative that each Affiliate have a person who is familiar with local tax laws and filing requirements and can prepare the annual tax and legal filings in a timely manner. In most cases, Affiliates hire or appoint an outside accountant to assist them. Sometimes a local company will provide the services of a staff member free of charge. The important things are (a) the person must be knowledgeable and his/her expertise recognized by the local government if necessary, and (b) there can be no real or perceived conflict of interest between the person and the rest of ISPE's members.

14. ISSUANCE OF AFFILIATE CHARTER BY ISPE

A charter is the bond between the Society and the Affiliate. It is the document that authorizes the Affiliate to operate as an official branch of ISPE. When a viable Affiliate has developed and the steps above have been fulfilled, the Chairman of the Society will issue the Affiliate Charter upon authorization of the Board of Directors. The Affiliate Charter recognizes the Affiliate as an official

entity, pending compliance with policy. This is renewed each year and subject to approval by the International Board of Directors.

THROUGHOUT THE PROCESS: COMMUNICATE WITH ISPE

Communication can be thought of as the lifeline of the organization. The role of the larger Society is to provide a vehicle for communication between Members, between the Affiliates and the International operation, and among the Affiliates. This communication is necessary not only to issues involving technology and regulatory concerns but also to the basic lessons learned on organizing and maintaining local Affiliates. It is the experience of the Society that the more often and substantively Affiliates communicate with the International and with one another, the easier the pathway to success.

ISPE's Vice President of Member Relations, with and through the regional Affiliate staff, has the responsibility of facilitating the formation of new Affiliates and to assisting established Affiliates in any way necessary. To guarantee this smooth flow of communication and simplify things for volunteers at the new Affiliate, all requests of the ISPE staff and departments should be sent to the Vice President (or his/her designee) for assessment and facilitation.

IV. RESPONSIBILITIES

A. ISPE LOCAL AFFILIATE

Local Affiliates are developed as the regional arms of the International Society. Their goals can be considered identical to those of the International Society and are defined, in brief, below. The Society's Mission Statement is the cornerstone of its Strategic Plan. The Strategic Plan is reviewed and revised annually.

1. **ISPE's Core Purpose** is to prepare technical professionals to lead global change and innovation in pharmaceutical manufacturing sciences and technology.
2. **ISPE's Core Principles** are to be
 - **COLLABORATIVE:** Members of the entire Society and staff will work together in the achievement of our shared vision and mission. We will strive to draw in and encourage those who wish to participate. In achieving desired results we will not fail to give credit where it is due. Collaboration also embraces working with other organizations to leverage the strengths of all in order to enhance offerings.
 - **ETHICAL:** We will use honesty in dealing with others and ourselves. We will adhere to individual principles that respect the views of others. We will foster a Society in which our behavior internally toward one another and externally toward the world at large is worthy of trust, respect and admiration.
 - **PROFESSIONAL:** Professionalism results from behaviors, actions, and communication that are honest, fact-based and politically neutral. ISPE will conduct business with the highest professional standards and with personal integrity. We will encourage all Members to be considerate, courteous, active listeners, and polite in their dealings with one another. When differences exist, we will work toward solutions and maintain mutual respect.

- **INCLUSIVE:** ISPE Members are the number one priority of the Society, and we will strive to see their needs are met. Volunteer participation will be a reflection of the diversity of our Membership (region, age, ethnic background, experience, etc.). The Society will exist to help Members reach their professional goals and, in so doing, help the industry achieve excellence.

The following committee descriptions and position responsibilities are, for the most part, simply suggested guidelines and many can be tailored to fit the individual needs of the respective Affiliates. However, some must be repeated verbatim in your Affiliate Bylaws.

B. STEERING COMMITTEE

The Steering Committee is the group of persons who initiate the formation of a local Affiliate. While there are no defined responsibilities, the Committee should maintain a concerted effort to ensure the continuation of the Affiliate formation once it has begun.

Typically, this group will perform the following:

- Solicit participation from local industry members
- Select a leader for communication with ISPE Headquarters and any regulatory bodies
- Develop the mailing list with the help of ISPE's Vice President of Member Relations
- Develop an interest survey with the help of ISPE's Vice President of Member Relations
- Develop an initial list, as part of a three-year plan, of:
 - Speakers
 - Meeting locations
 - Meeting formats

The Steering Committee normally becomes the first Board of Directors (Officers and Directors) of the formalized local Affiliate after an election by the general membership. The responsibilities of these officers are detailed below.

C. OFFICER/DIRECTOR RESPONSIBILITIES

The role of the Affiliate Board of Directors is to manage the operations of the local Affiliate in a cost-efficient manner, consistent with the standards of the Society, providing programs of particular interest to members in the local area. More specifically, these responsibilities include the following specific tasks.

1. President/Chairman will:

- Attend and preside over all Affiliate Board and General Membership meetings and functions.
- Chair the Board of Directors of the Affiliate and shall have powers as may be reasonably construed as those belonging to the chairman of any board.
- Coordinate overall Affiliate planning and activities.
- Serve on any ISPE's Task Teams that may pertain to activities of the Affiliate and attempt to attend at least one meeting. Every effort should be made to attend at least one ISPE international program per year.
- Appoint the Chairpersons of all Affiliate committees.
- Maintain on-going communication with and serve as liaison with ISPE's Headquarters through the Vice President of Member Relations.

- Assure that all documents, certificates and reports have been filed as required by local, state and federal laws.
- Be one of the officers who signs checks and drafts of the Affiliate.
- Be an elected and voting member of the Affiliate Board of Directors.
- Be an active ISPE member.

2. Vice President/Chairman will:

- Become acting President in the absence or inability of the President to exercise his/her duties and office until such time that a new President is officially named.
- Be an elected and voting member of the Affiliate Board of Directors.
- Same as President pertaining to Task Team meetings and attending ISPE events.
- Typically chair the Program/Meeting Arrangements Committee.
- Attend all Board and Affiliate meetings and functions.
- Be an elected and voting member of the Affiliate Board of Directors.
- Be an active ISPE member.

3. Treasurer will:

- Monitor the collection and disbursements of all monies of the Affiliate and be assisted by the ISPE staff with such monies or securities.
- Be an elected and voting member of the Affiliate Board of Directors.
- Deposit the funds of the Affiliate in an insured financial institution and maintain a checking account and an interest-bearing savings account in the Affiliate's name.
- Provide a financial report at each Board and Affiliate meeting and an annual report to ISPE Headquarters.
- Prepare an annual operating budget for the approval of the Affiliate's Board of Directors and to ISPE Headquarters.
- Attend all Board and Affiliate meetings and functions.
- Be primary liaison between the local bank and ISPE Accounting staff. Investigate questions or discrepancies xxx and report back to ISPE.
- Be an active ISPE member.

4. Secretary will:

- Record and distribute the Board and Affiliate meeting minutes.
- Forward all Board meeting minutes and newsletters to ISPE Headquarters through the Director of Chapter & Affiliate Relations.
- Be an elected and voting member of the Affiliate Board of Directors
- File any certificate required by local governments. Coordinate the distribution of meeting notices and Affiliate communications with the Newsletter Committee.
- Maintain a directory of all Officers, Board Members and Committee Chairpersons for each fiscal year.

- Attend all Board and Affiliate meetings and functions.
- Be an active ISPE member.

5. Directors will:

- Be elected and voting members of the Affiliate Board of Directors.
- Provide input concerning Affiliate planning and operations.
- Become Chairpersons of current Affiliate committees as directed by the President/Chairman.
- Perform service assignments as requested by the Board.
- Attend all Board and Affiliate meetings and functions.
- Be active ISPE members.

D. PAID AFFILIATE STAFF

Some Affiliates have never hired anyone, while others have had paid help almost from the beginning of their existence. There is no right or wrong way to proceed, and each Steering Committee will need to evaluate the local circumstances to decide what is best.

In ISPE's experience it is fair to say that those Affiliates which have hired a staff member to help organize and conduct administrative tasks often grow more quickly than those who do not. In addition, staffed Affiliates tend to have robust operations and volunteers who are able to focus on the topics that matter more to them. Hence, ISPE recommends careful consideration of the paid staff concept in the creation of the Affiliate's three year business plan. Several of ISPE's existing Affiliates have pioneered various ways of going about the hiring and paying of staff, and new Affiliates can learn from these experiences. The Vice President of Member Relations can assist the Steering Committee in exploring options based on local needs and regulations.

It is important to note that the Officers and Board of Directors will always be the people responsible for the Affiliate. Staff may be hired to assist in carrying out the Board's wishes at an operational level, but **the Board's duties cannot be delegated and are never negated by the hiring of paid staff to assist in the operation of the Affiliate.**

Attachment 1

(Usually set up as an electronic survey)

**ISPE _____ AFFILIATE
FORMATION SURVEY**

1. Are you currently a member of ISPE? YES NO
2. Do you think that an ISPE local Affiliate would be beneficial to the pharmaceutical/
biotechnology industry in _____? YES NO
3. Would you be interested in participating on the Steering Committee?
YES NO
4. If a local ISPE Affiliate is established in the area, would you join?
YES NO
5. If a local ISPE Affiliate is established in the area, would you attend monthly meetings?
YES NO
6. Are you, or have you been, involved in another ISPE local Affiliate?
YES NO
7. Which programs and services should a local ISPE Affiliate offer to its members?
A. Newsletter C. Educational Meetings
B. Vendor Night D. Other
8. Which of the following subjects are of interest to you (list others in addition to these that may
be of local interest)?
A. Plant Design G. Automation
B. Validation H. FDA Interaction
C. QA/QC I. SPC
D. CGMP J. Project Cost
E. WFI K. Other
F. HVAC
9. Would you consider being a:
A. Meeting Coordinator B. Speaker C. Other
10. In what type of business are you involved?
A. Pharmaceutical R&D/Manufacturing E. Consulting/Design
B. Biotechnology R&D/Manufacturing F. Construction
C. Medical Device R&D/Manufacturing G. Other
D. Contract Manufacturing
11. Is your supervisor and/or plant manager likely to be supportive of an Affiliate in
_____?
YES NO

12. If Yes to #11, may we contact him/her to seek involvement and support in the Affiliate? Please provide information if this is acceptable:

- Name/Title:
- Telephone:
- Email:

PLEASE PRINT

Name:	Title:
Company:	Street:
City, Mail Code:	Telephone:
Fax:	Email:

Please return to: Name/Company/Phone/Fax/Email