

# Affiliate/ Chapter Formation Guide

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# Program Overview

Thank you for your interest in starting a new ISPE Affiliate/Chapter in your local area! Affiliates/Chapters offer the opportunity to network with industry professionals in your region and local language. From training events and conferences to mentoring opportunities and social gatherings, ISPE's Affiliates/Chapters keep you connected to the industry at the local level. **Chapters** are defined as states, regions and/or territories within the United States. **Affiliates** are defined as countries or regions outside of the United States.

## ISPE Mission Statement

*ISPE is the global industry leader in connecting pharmaceutical knowledge to deliver manufacturing and supply chain innovation, operational excellence, and regulatory insights to enhance industry efforts to develop, manufacture and reliably deliver quality medicines to patients.*

## ISPE Vision Statement

*Provide solutions to complex pharmaceutical industry challenges through manufacturing innovation, member, and workforce development, technical, regulatory, and compliance collaboration.*





## ISPE Affiliate/Chapter Formation Background

ISPE 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 ISPE Chapter Steering Committee was formed in New Jersey, USA, eventually establishing the first Chapter in 1986.

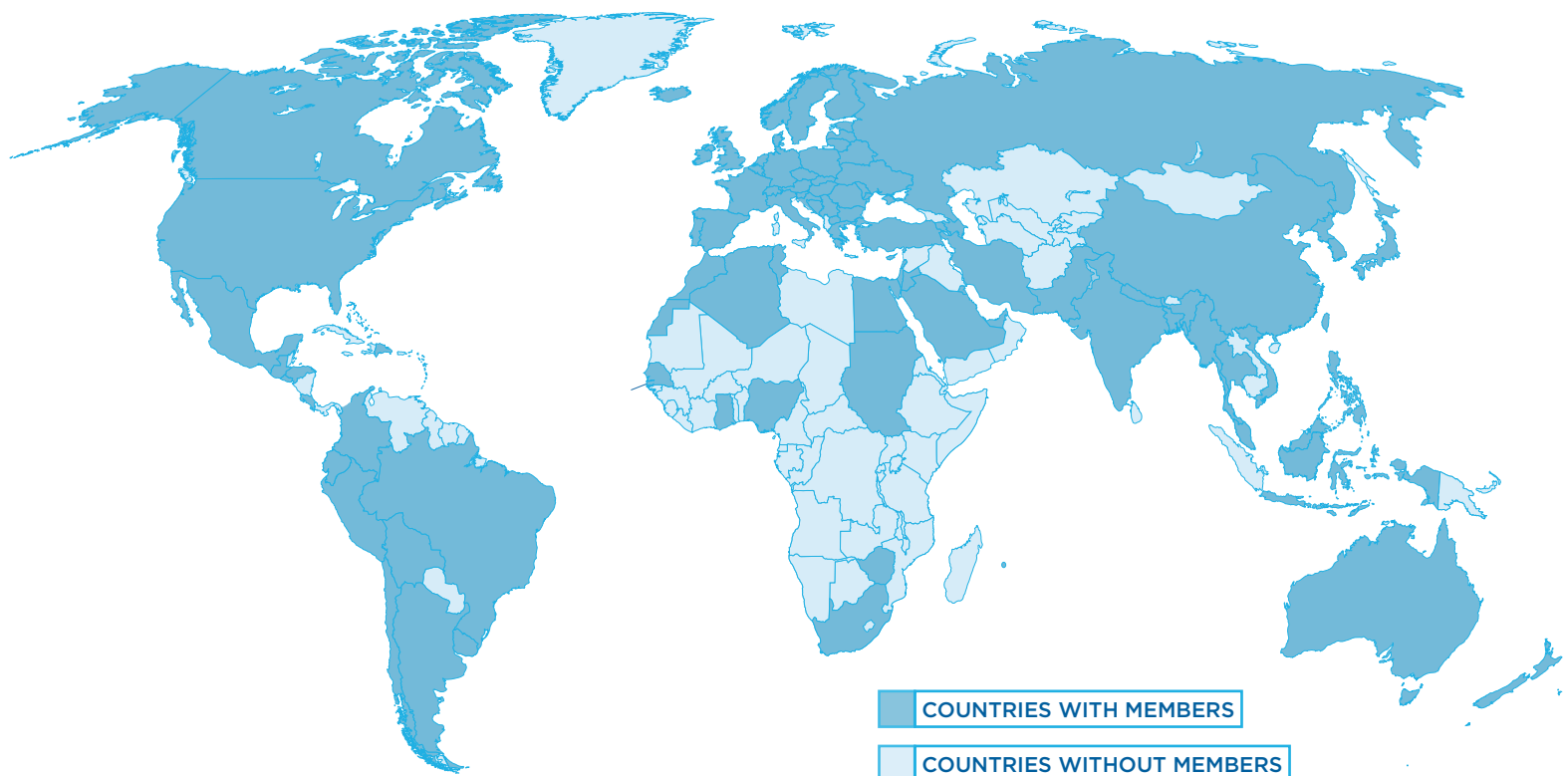
Today, ISPE serves more than 18,000 Members in 90 countries, 13 Chapters in the United States and 26 International Affiliates. The emergence of chapters and affiliates around the world has had a profound effect on membership growth. In addition, there are more than 65 student chapters around the world.

As may be expected, such a rapid expansion in the number of individuals and groups brought about significant changes in ISPE’s finances and structure. ISPE has evolved to reflect expansion and diversity. The staff has been expanded significantly, operating out of offices in Maryland, USA (Headquarters), Florida, USA (Operations), and Europe.

An ISPE Affiliate/Chapter can serve a specific country or state (e.g., the Argentina Affiliate), a geographic region (e.g., Great Lakes Chapter), or a group of countries (e.g., the Germany-Austria-Switzerland Affiliate). The determinant of the affiliate/chapter’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/Chapters in or near the region.

The name and geographical area covered by a new affiliate/chapter are the decision of the International Board of Directors (BoD) upon recommendation by the Formation Steering Committee and the staff liaison.

### ISPE Members Worldwide



## Affiliate/Chapter Program Goals

The ISPE Affiliate/Chapter Program goals are to:

- » Create a forum for pharmaceutical manufacturing professionals to collaborate and develop leadership skills
- » Educate and empower local communities
- » Encourage non-ISPE industry professional's participation to learn and contribute
- » Encourage open dialogue on issues that will ultimately benefit patients around the world
- » Enhance the ISPE member experience and improve value in membership
- » Mentor aspiring pharmaceutical manufacturing industry professionals
- » Provide current and timely educational opportunities and professional resources
- » Provide networking opportunities for local industry professionals
- » Strengthen connections among ISPE members







## Affiliate/Chapter Structure

ISPE members can establish an affiliate/chapter that will best serve members and professionals in the local area. Below is an overview of the formation process and structure of an ISPE Affiliate/Chapter:

### Getting Started

- » A minimum of **100 industry members** are required to form an affiliate/chapter
- » Affiliates/Chapters may recruit new members only within their designated geographical boundaries, but can accept membership from individuals outside this area
- » An ISPE member with a minimum of two years as an ISPE member in good standing can start an affiliate/chapter referred to as the petitioner
- » ISPE members with a minimum of one-year active ISPE membership may serve as an officer or steering committee member during the affiliate/chapter chartering process just not as the petitioner
- » Non-ISPE members are eligible to join the affiliate/chapter after it has been established
- » Regional, state/province and country affiliates/chapters must accommodate and serve all members within the proposed geographical boundaries
- » The affiliate/chapter geographic boundaries are determined upon request and availability

### Governance

- » Affiliates/Chapters may NOT bind ISPE or otherwise imply or infer agency on behalf of ISPE
- » Affiliates/Chapters must abide by ISPE trademark usage requirements and branding guidelines
- » Affiliates/Chapters must ensure compliance with all tax, privacy, and local/state or district/national laws applicable in their country
- » Changes to the affiliate's/chapter's territory should be reviewed and approved by the ISPE BoD
- » Affiliates/Chapters shall establish and maintain bylaws, that comply with the terms in the Charter Agreement. This document, as well as the other policies outlined within it, serve as the rules by which the chapter operates by
- » All official ISPE Affiliates/Chapters agree and abide to the ISPE Charter Agreement

### Leadership

- » There are four required officer positions: President/Chair, Vice President/Chair, Secretary, and Treasurer
- » An officer from another ISPE Affiliate/Chapter cannot concurrently serve as an officer at multiple affiliates/chapters
- » An officer must reside within the geographical boundaries of the affiliate/chapter
- » Additional positions, such as directors and committee chairs are optional yet recommended and only require an active ISPE membership
- » All positions may only be held by active ISPE members who do not hold a leadership position in a competing Pharmaceutical Association

## Minimum Activity Requirements

- » Affiliates/Chapters are to hold a minimum of three member activities (virtual and/or face-to-face) within the calendar year focusing on industry/regulatory issues, and local networking
- » Four officer meetings must be held throughout the year (virtual and/or face-to-face)
- » An annual meeting is required; however, can serve as one of the required member activities
- » Elections must be held, at a minimum, every two years
- » Affiliates/Chapters are required to submit an annual report reflecting on the previous year's activities
- » Affiliates/Chapters are required to follow all guidelines set forth by the ISPE Affiliate/Chapter Charter

In addition, vendor exhibits are often held, and a newsletter published to present new information, products, general and local industry news. Ultimately, the affiliate/chapter may host expanded educational programs for industry representatives, regulators, and/or college students, contribute to the ISPE body of knowledge and participate in online community activities.

## Benefits of Affiliate/Chapter Membership

There are several benefits to starting or joining an ISPE Affiliate/Chapter. Not only will you gain a sense of fellowship with colleagues in your profession, but you will be able to network and exchange knowledge with fellow ISPE members and other local pharmaceutical industry professionals. Other opportunities consist of:

- » Developing leadership skills by serving as an affiliate/chapter officer, speaking at chapter meetings or special events, and mentoring recent graduates and or students
- » Participating in co-sponsored events with other industry associations
- » Participating in local community outreach or public service projects to educate people about pharmaceutical industry related topics





# Eligibility Requirements

To be eligible to start an affiliate/chapter as the role of petitioner you will need to meet the following requirements:

- » Be an ISPE member in good standing for a minimum of two consecutive years
- » Be a resident of the area in which you plan to start an affiliate/chapter for at least one year
- » Have proven leadership experience in a professional setting
- » Not currently serving as an officer of another pharmaceutical industry organization

Below is a description of each:

- » **Membership Experience** - Starting an affiliate/chapter places a petitioner in a high-profile position in which they become an ambassador for carrying the reputation of ISPE. ISPE encourages members who understand the requirements for becoming a member, who can attest to what it's like to be a member, who abides by the ISPE Code of Ethics, and believes in the vision and mission of ISPE, to take on the charge of starting an affiliate/chapter in their local community. To truly understand the value of being an ISPE member, one should be a member for at least two consecutive years in good standing.
- » **Local Residency** - Petitioners must be a resident for at least one year in the proposed affiliate/chapter territory. It is important that the member is familiar with the area and understands the needs of pharmaceutical professionals in the community. Having connections in the area can also be very helpful in getting established. Members who have heavy travel schedules or live in the area part time should not apply due to the limited time available to commit to developing the foundation of the affiliate/chapter.
- » **Professional Leadership Experience** - Strong leadership skills are key in forming and running a successful affiliate/chapter. Petitioners should have previous leadership experience and/or knowledge in, but not limited to:
  - Starting an affiliate/chapter, user group or another organized network
  - Holding an officer or director-level position within a chapter or organization (recommended two years)
  - Serving in a leadership position in an affiliate/chapter, user group or other organized network (recommended two years)
  - Managing teams of people through employment or volunteer programs (consisting of five or more people)
  - Possess five years of experience working in a governance capacity
- » **Not currently serving as an officer of another affiliate/chapter organization** - ISPE requires members who are developing and managing an ISPE Affiliate/Chapter to focus their efforts on making the affiliate/chapter successful, and to avoid being distracted with the mission and objectives of leading another similar chapter organization. This also prevents the possibility of biases and preferences (NOTE: This applies to not only the petitioner, but the officer positions of President, Vice President, Secretary and Treasurer, this does not apply to directors and committee chairs).



# Affiliate/Chapter Formation

This Affiliate/Chapter Formation Guide describes the formation activities, ranging from contacting local industry members, forming a Steering Committee, ongoing maintenance, and administrative responsibilities of the affiliate/chapter once it has been organized and chartered. The tasks are described in detail and suggestions made how to accomplish them. In addition, the amount of work required to both organize an affiliate/chapter 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 formation 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. At start-up, for an affiliate/chapter to sustain itself, there must be at least **100 industry members** in the affiliate's or chapter's proposed geographic territory.





# Formation Process

There are three phases involved in the process of becoming an official ISPE Affiliate/Chapter which include: Establishment, Development and Launch Phase. The following checklist shows the path for establishing a new affiliate/chapter based upon the successful experiences of current affiliates/chapters. The sequence and timing of activities will vary with the formation of each new affiliate/chapter and many activities can be performed concurrently with an exception to those requiring pre-approval.

The Member Services staff liaison is available to assist along the way and will notify you when you have formally achieved ISPE Affiliate/Chapter status. It can be estimated that the path can take up to two years. All official documentation generated in the following process should be copied and the original documents forwarded to ISPE for filing and permanent storage.

## Formation Checklist

### Establishment Phase


- ☐ Receive petitioner eligibility clearance
- ☐ Submit Affiliate/Chapter Formation Petition
- ☐ Evaluation of Affiliate/Chapter Formation Petition
- ☐ Submit local industry mailing list to ISPE
- ☐ Determine Level of Interest
- ☐ Establish Steering Committee
- ☐ Define Geographical Parameters and Develop Affiliate/Chapter name

### Development Phase

- ☐ Plan Inaugural Interest Meeting
- ☐ Execute Inaugural Interest Meeting
- ☐ Develop Affiliate/Chapter Working Committees
- ☐ Seek legal consultation on complying with local government regulations
- ☐ Develop a logo and learn relevant ISPE operating procedures
- ☐ Develop Three-Year Business and Financial Plan
- ☐ Use ISPE templates to develop Charter and Bylaws and file with the local government to be recognized as a not-for-profit (or similar) organization

### Launch Phase

- ☐ Nominate and elect officers and directors
- ☐ Hire or appoint an accountant
- ☐ The Affiliate/Chapter Charter must be approved by the ISPE Board of Directors to officially recognize the Affiliate/Chapter as being in active status
- ☐ Open bank account if/when needed
- ☐ Develop Affiliate/Chapter launch marketing plan



Below are the detailed descriptions of each phase and activity throughout the formation process. Please stay in contact with the Member Services staff liaison should you have any questions during the process.

### 1. ELGIBILITY CLEARANCE

If you meet the eligibility requirements listed below please email [ACRelations@ispe.org](mailto:ACRelations@ispe.org) to receive eligibility clearance.

- Be an ISPE member in good standing for a minimum of two years
- Be a resident of the area in which you plan to start an affiliate/chapter for at least one year
- Proven leadership experience in a professional setting
- Not currently serving as an officer of another pharmaceutical industry organization

### 2. PETITION SUBMISSION


Before you submit a petition to start an ISPE Affiliate/Chapter, determine if the area where you are interested in is available. Refer to the [Affiliates and Chapters Page](#) to find out if one already exists. If one does exist, then contact the local affiliate/chapter directly for more information about membership and activities. If an affiliate/chapter does not exist, then consider working with a group of your professional colleagues in your region to submit a petition.

### 3. EVALUATION OF AFFILIATE CHAPTER PETITION

A. Once the petition has been pre-approved, it is evaluated by the Affiliate Chapter Relations Team, consisting of the ISPE Member Services Team and ISPE Board Members. The team will review and score petitions independently based on the following criteria:

- **Location** – Is the requested location a viable area to start an affiliate/chapter? Is the area too large to serve members? Does the proposed affiliate/chapter name encompass the territory they plan to serve? Are there at least 100 ISPE industry members in the area? Is this an area where ISPE should have a larger presence? Are there any existing ISPE Affiliates or Chapters nearby? If so, are there any concerns for conflict?
- **Leadership** – Does the applicant's leadership experience meet expectations for starting and managing an ISPE Affiliate/Chapter? Based on the applicant's experience reported, would this individual serve as a good leader for the affiliate/chapter? Are there any concerns?
- **Motivation** – Does the applicant appear to be interested in benefitting the greater good of the profession, or does he/she appear to be motivated to benefit his/herself? Does the petitioner have the time to commit and dedicate to starting the affiliate/chapter?
- **Vision** – Does the petitioner have a well-developed plan for the affiliate/chapter? Does he/she have a solid vision or mission statement? Is there a focus for the affiliate/chapter (i.e. education, networking, service, etc.)? Has the applicant investigated where, when, and how often to meet? How far into the future is the proposed plan?
- **Finances** – Based on the proposed affiliate chapter petition, does it appear that the affiliate/chapter will be able to financially support itself? Has the applicant proposed how the affiliate/chapter would be funded? Will it be able to raise the appropriate funds to support itself? Does it appear that it will have little to no expenses?





B. **Scoring:** Petitions will be scored on a “confidence” scale of 1 to 5, with 5 being the highest and 1 being the lowest. The total and average scores are then reviewed and evaluated by the ISPE Affiliate Chapter Relations Team.

C. **Final Decision:** Once scores are reviewed and evaluated; the team will make a final decision on the petitions. ISPE may approve or decline any application at its sole discretion. For petitions that have been declined, applicants will be notified via email. The applicant may be eligible to resubmit during the next enrollment period.

#### 4. **Submit Local Industry Mailing List**

Compile a mailing list from local resources (organizations, personal references), and submit to ISPE so it may be augmented with regional contacts available from ISPE.

#### 5. **Determine Level Of Interest**

Discuss the formation of a local ISPE Affiliate/Chapter and its benefits with persons in the local pharmaceutical manufacturing industry. The [Affiliate/Chapter Level of Interest Survey](#) will be sent to the mailing list to assess the actual level of interest and potential level of participation through an electronic survey tool by the Member Services staff liaison.

The survey responses of at least 100 industry members will be analyzed with help from ISPE. If the response is positive (more than twenty percent and solid industry support), staff will report this to the ISPE Board of Directors. It is the Board’s decision whether to authorize proceeding to the next step to establish a Steering Committee.

If the response does not indicate enough support for forming an Affiliate/Chapter at this time, the Member Services staff liaison will discuss options for fully engaging the interested members in the area without an affiliate/chapter in place.

#### 6. **Establish Steering Committee**

Organize a Steering Committee of at least five local representatives with the commitment to support the affiliate/chapter formation effort. Elect a Steering Committee Chairperson to lead the effort and maintain communications with ISPE. This person would also serve the role as petitioner for the affiliate/chapter. The responsibilities of the Steering Committee include:

- Establish objectives and preliminary goals for the affiliate/chapter activities and members
- Review the template Affiliate/Chapter Charter document in place for existing affiliates/chapters and ensure that all processes the Steering committee undertakes occur in a manner that will ultimately be aligned with these requirements

#### 7. **Define Geographic Parameters and Name Of Affiliate/Chapter**

Based off the results of the survey, determine a geographical region for the prospective affiliate/chapter. Determinants of this region might include local population of pharmaceutical firms, availability of cost and effective travel services. There must be at least 100 industry members in the proposed geographical area to move forward with formation.



## 8. Plan Inaugural Interest Meeting

The planning and organization of the first meeting is critical to getting the affiliate/chapter 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 virtual, or if in person convenient for most of the audience. Typically, hotel conference rooms are used, and food is served. Fees for attendance depend on local custom, membership, type of meal, number of persons and quality of the facility and location. **Virtual events are encouraged** to keep cost low and reach a greater geographic area. An interesting speaker, covering a broad topic and attracting a wide audience is beneficial to exposing local industry personnel to the affiliate/chapter. To effectively market the events/programs of the affiliate/chapter, a local pharmaceutical industry mailing list of companies should be developed. This list should augment the one supplied by ISPE.

The purpose of this meeting is two-fold.

- First, it is a way to show the pharmaceutical manufacturing community in the local 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 the Member Services staff liaison, for approval prior to distribution.

## 9. Execute Inaugural Interest Meeting

Hold the Inaugural meeting in person or virtual. Record contact information on all member and non-member attendees to the Inaugural Interest Meeting, and report to ISPE within two-weeks of the event. This analysis should be discussed with the Member Services staff liaison to determine alignment with expectations and the viability of moving forward to the next stage of formation.

Request authorization from the Member Services staff liaison to proceed with further affiliate/chapter development.

## 10. Develop Working Committees

It is critical to the future of the affiliate/chapter that committees are established to perform the number of tasks required to continue formation and growth of the organization. These committees can include Membership, Communications, Program (Seminar/Meeting), Industry/Vendor Relations and Special Projects. Other committees might be needed based on the membership and activities of specific affiliates or chapters. Local committees can also connect with International committees focused on similar disciplines, as well as with Headquarter staff, for assistance and best practices related to committee goals.



## **11. Seek Legal Consultation On Complying With Local Government Regulations**

After a new affiliate/chapter has proved itself to be viable, the required incorporation process may begin. Incorporation in the Affiliate/Chapter's respective country is required. The Steering Committee 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 the Member Services staff liaison. They will assist in developing a plan for meeting these requirements as part of the larger planning process.

The attorney will also review the proposed Bylaws of the new ISPE Affiliate/Chapter for compatibility with those of the ISPE, as well as appropriate legality within the local country for establishing a legal entity. If possible and applicable, affiliates/chapters should seek non-profit status in their respective countries.

## **12. Learn Relevant ISPE Operating Procedures**

It is also important currently to begin acquainting committee volunteers with ISPE's policies and procedures for affiliate/chapter operations. The ISPE Governance Structure (Attachment 2) provides details on chapter/affiliate structure.

## **13. Develop Three-Year Business And Financial Plans**

To keep the ISPE community informed of anticipated activities, a three-year schedule should be generated. While this schedule is not restricted from change, it should accurately reflect future to allow scheduling and coordination. Its purpose is to minimize conflicting activity dates with the affiliate, and with ISPE programs.

Necessary changes in the proposed schedule must be brought to the attention of the Member Services staff liaison, and other nearby affiliates or chapters 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/chapter over a three-year period. Further, all disbursement of funds should be submitted for approval, in concept, by ISPE. 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 chapter and find a smooth path forward.

## **14. 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/chapter through its formation and continuation as a chartered organization. The Bylaws detail the operating mode of the affiliate/chapter, including information concerning membership rights and priorities, the meeting attendance and collections and responsibilities to the ISPE. ISPE provides a Bylaws template to assist you in creating this document. Please note that certain sections of the ISPE Affiliate/Chapter Bylaws must appear verbatim as shown in the template (unless they conflict with local law) and other sections can be tailored to fit the needs of the affiliate/chapter. ISPE will provide an electronic version of the suggested Bylaws to your affiliate/chapter.

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





## **15. Nominate And Elect Officers And Directors**

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

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

## **16. Hire Or Appoint An Accountant**

It is imperative that each affiliate/chapter 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/chapters 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 their 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.

## **17. Issuance Of Affiliate/Chapter Charter By ISPE**

A charter is the bond between the ISPE and the affiliate/chapter. It is the document that authorizes the affiliate/chapter to operate as an official branch of ISPE. When a viable Affiliate/Chapter has developed and the steps above have been fulfilled, the Chairperson of the ISPE will issue the charter upon authorization of the Board of Directors. The ISPE Charter recognizes the affiliate/chapter as an official entity, pending compliance with policy. This is renewed each year and subject to approval by the International Board of Directors.

## **18. Open An Affiliate/Chapter Bank Account (If/When Needed)**

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 the Member Services staff liaison 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/chapter 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/chapter leadership changes.

## **19. Develop Affiliate/Chapter Launch Marketing Plan**

Please refer to the ISPE Branding Guidelines for general information on usage of ISPE brand marks. ISPE will create the affiliate/chapter logo. The Affiliate/Chapter Steering Committee will meet with the Member Services staff liaison, and the ISPE MARCOM (Marketing and Communications) team to develop the launch marketing plan.



## **20. Throughout The Process: Communicate With ISPE**

Communication can be thought of as the lifeline of the organization. The role of the larger ISPE is to provide a vehicle for communication between members, between the affiliates/chapters and ISPE. 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/chapters. It is the experience of the ISPE that the more often and substantively affiliates/chapters communicate with ISPE and with one another, the easier the pathway to success.

ISPE's Member Services staff liaison has the responsibility of facilitating the formation of new affiliates/chapters. To guarantee this smooth flow of communication and simplify things for volunteers at the new affiliate/chapter, all requests of the ISPE staff and departments should be sent to the Member Service staff liaison through this email: [ACRelations@ispe.org](mailto:ACRelations@ispe.org).



# Responsibilities

## ISPE Affiliate/Chapter

Affiliates/Chapters are developed as the local arms of ISPE International. Their goals can be considered identical to those of the ISPE International and are defined in the [ISPE International Strategic Plan](#). The Strategic Plan is reviewed and revised every 3-5 years. The following committee descriptions and positions can be tailored to fit the individual needs of the respective Affiliate/Chapter. However, the required duties must be repeated verbatim in your Affiliate/Chapter Bylaws.

## Steering Committee

The Steering Committee is the group of persons who initiate the formation of a local affiliate/chapter. While there are no defined responsibilities, the Steering Committee should maintain a concerted effort to ensure the continuation of the Affiliate/Chapter 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 and any regulatory bodies
- » Develop the mailing list with the help of ISPE's Manager, Volunteer Development and Engagement
- » Administer the survey of interest survey
- » 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/Chapter after an election by the general membership. The responsibilities of these officers are detailed below.





## Officer/Director Responsibilities

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

### President/Chair

- » Attend and preside over all Affiliate/Chapter Board and General Membership meetings and functions.
- » Chair the Board of Directors of the Affiliate/Chapter and shall have powers as may be reasonably construed as those belonging to the chairperson of any board.
- » Coordinate overall Affiliate/Chapter planning and activities.
- » Serve on any ISPE teams that may pertain to activities of the Affiliate/Chapter 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/Chapter committees.
- » Maintain ongoing communication with and serve as liaison with ISPE through the Member Services staff liaison.
- » 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/Chapter Board of Directors.
- » Required to ensure the Annual Report Survey is completed by the deadline set by the Senior Direct of Membership and Chapter Relations.
- » **Be an active ISPE Member in good standing for at least 2 years.**

### Vice President/Chair

- » Become acting President/Chair in the absence or inability of the President to exercise their duties and office until such time that a new President/Chair is officially named.
- » Be an elected and voting member of the Affiliate/Chapter Board of Directors.
- » Same as President/Chair pertaining to Team meetings and attending ISPE events.
- » Typically chair the Program/Meeting Arrangements Committee.
- » Attend all Board and Affiliate/Chapter meetings and functions.
- » **Be an active ISPE Member in good standing for at least 2 years.**

### Treasurer

- » Monitor the collection and disbursements of all monies of the Affiliate/Chapter and be assisted by the ISPE staff with such monies or securities.
- » Be an elected and voting member of the Affiliate/Chapter Board of Directors.
- » Deposit the funds of the Affiliate/Chapter 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/Chapter meeting and an annual report to ISPE.
- » Prepare an annual operating budget for the approval of the Affiliate's Board of Directors and to ISPE.
- » Attend all Board and Affiliate/Chapter meetings and functions.
- » Be primary liaison between the local bank and ISPE Accounting staff. Investigate questions or discrepancies and report back to ISPE.
- » **Be an active ISPE Member in good standing.**

### Secretary

- » Record and distribute the Board and Affiliate/Chapter meeting minutes.
- » Forward all Board meeting minutes and newsletters to ISPE through the Manager, Volunteer Development and Engagement.
- » Be an elected and voting member of the Affiliate/Chapter Board of Directors.
- » File any certificate required by local governments. Coordinate the distribution of meeting notices and Affiliate/Chapter 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/Chapter meetings and functions.
- » **Be an active ISPE Member in good standing.**

### Directors

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



## Paid Affiliate/Chapter Staff

Some affiliates/chapters have never hired staff, while others have had paid staff since 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/chapters which have hired a staff member to help organize and conduct administrative tasks often grow quicker than those which do not. In addition, staffed affiliates/chapters tend to have robust operations and volunteers who can focus on the topics that matter most to them.

Hence, ISPE recommends careful consideration of the paid staff concept in the creation of the affiliate/chapter's three-year business plan. Several of ISPE's existing affiliates/chapters have pioneered various ways of going about the hiring and paying of staff and new affiliates/chapters can learn from these experiences. The ISPE Member Service staff liaison can assist the Steering Committee in exploring options based on local needs and regulations. ISPE must be notified if a staff member has been hired.

It is important to note that the Officers and Board of Directors will always be the people responsible for the affiliate/chapter. 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/chapter.

# Affiliate/Chapter Level of Interest Survey

<b>Name</b>		<b>ISPE Member ID (if applicable)</b>	
<b>Title</b>			
<b>Company</b>			
<b>Street</b>			
<b>City</b>			
<b>Country</b>			
<b>Postal Code</b>			
<b>Email</b>			
<b>Telephone</b>			
<b>Affiliate/Chapter Name</b>			

- Are you currently a member of ISPE?  
☐ Yes      ☐ No
- Do you think that an ISPE local Affiliate/Chapter would be beneficial to the pharmaceutical/biotechnology industry in \_\_\_\_\_?  
☐ Yes      ☐ No
- Would you be interested in participating on the Steering Committee?  
☐ Yes      ☐ No
- If a local ISPE Affiliate/Chapter is established in the area would you join?  
☐ Yes      ☐ No
- If a local ISPE Affiliate/Chapter is established in the area, would you attend the following events (select all that apply):  
☐ Meetings      ☐ Educational  
☐ Training      ☐ Networking  
☐ Webinar      ☐ Virtual Events
- Are you, or have you been, involved in another ISPE local Affiliate/Chapter?  
☐ Yes \_\_\_\_\_  
☐ No
- Which of the following subjects are of interest to you (select all that apply)?
 

<input type="checkbox"/> Active Pharmaceutical Ingredients	<input type="checkbox"/> Biotechnology
<input type="checkbox"/> Commissioning and Qualification	<input type="checkbox"/> Containment
<input type="checkbox"/> Critical Utilities	<input type="checkbox"/> Disposable
<input type="checkbox"/> GAMP Blockchain	<input type="checkbox"/> GAMP Data Integrity
<input type="checkbox"/> GAMP MES	<input type="checkbox"/> Good Automated Manufacturing
<input type="checkbox"/> HVAC/Sustainable Facilities	<input type="checkbox"/> Investigational Products
<input type="checkbox"/> Oral Solid Dosage	<input type="checkbox"/> Pharma 4.0
<input type="checkbox"/> Process Analytical Technology and Lifecycle Control Strategy	<input type="checkbox"/> Process/Product Development
<input type="checkbox"/> Regulatory and Quality Networking	<input type="checkbox"/> Project Management
<input type="checkbox"/> Student	<input type="checkbox"/> Sterile Products Processing
<input type="checkbox"/> Women in Pharma (WIP)	<input type="checkbox"/> Supply Chain, Operations and Packing (SCOPE)
	<input type="checkbox"/> Emerging Leaderst



8. Would you consider volunteering in one of the following areas?

- ☐ Affiliate/Chapter Leader
- ☐ Board Member
- ☐ COP Leader
- ☐ Meeting Coordinator
- ☐ Speaker
- ☐ Not interested at this time

- ☐ Author/Editor/Blogger
- ☐ COP Contributor
- ☐ Guidance Documents
- ☐ Social Media
- ☐ Steering Committee Member
- ☐ Other \_\_\_\_\_

10. How much time would you commit to volunteering?

- ☐ 0 hrs/week
- ☐ 1 - 5 hrs/week
- ☐ 6 - 10 hrs/week
- ☐ 11 - 20 hrs/week
- ☐ 21+ hrs/week

11. What type of business are you involved with?

- ☐ API/Excipient Supplier/Distributor
- ☐ Contract Manufacturer
- ☐ Cosmetics, Nutraceuticals, Food Manufacturer
- ☐ CROs/Clinical Materials/Investigational Products
- ☐ Educational or Government Entity/Libraries
- ☐ Equipment/Material Supplier
- ☐ Generics Manufacturer
- ☐ Laboratory Services
- ☐ Medical Devices/Diagnostic
- ☐ Pharmaceutical/Biotech Manufacturer (Not CMO)
- ☐ Service Provider/Consulting
- ☐ Other \_\_\_\_\_

12. Is your supervisor and/or plant manager likely to be supportive of your participation with a local ISPE Affiliate/Chapter?

- ☐ Yes
- ☐ No



# ISPE Governance Structure Excerpt

## Affiliate/Chapter Board 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:**

- » 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.
- » A balance of industry professions should be achieved in the Board of Directors/Management Committee composition.
- » All Board and Committee Members must be Members in good standing of ISPE.

**Reporting Requirements:**

- » 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.
- » 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:**

- » Develop and manage an annual operating plan and budget for the Affiliate/Chapter consistent with the standards and policies of ISPE International.
- » 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.
- » With the approval of ISPE International, establish and manage Chapters (or regional sections) consistent with the standards and policies of ISPE International.
- » Participate in International committees to establish programs in the Affiliate's/Chapter's geographic area and to influence Society direction globally.
- » In conjunction with ISPE professional staff, establish efficient operating systems for marketing and processing payments for Affiliate and Chapter programs.
- » Inform the CEO/President of national or regional legal requirements affecting the Affiliate/Chapter.
- » 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.
- » 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.

# Affiliate/Chapter Petition Form

## Petitioner Contact Information

Name		ISPE ID	
Title			
Company			
Email			
Telephone			
Affiliate/Chapter Name			

## Eligibility

- ☐ Have you been an active ISPE Member for at least 2 years?
- ☐ Are you a resident in the area which you plan to start the affiliate or chapter?
- ☐ Describe your previous leadership experience in a professional setting.
- ☐ Are you currently serving as an officer of another pharmaceutical industry organization?

## Affiliate/Chapter Concept Plan

- ☐ What is your vision and goals for establishing a new affiliate or chapter?
- ☐ Who will be working with you to establish the affiliate or chapter? Please include their names and titles in the description.
- ☐ What is the requested geographic territory of the affiliate or chapter? (Country of Spain & Portugal)
- ☐ What is the proposed affiliate or chapter name? (i.e. Iberia Affiliate or Boston Chapter)
- ☐ What is the purpose and mission of the affiliate or chapter?
- ☐ What will the areas of focus?
- ☐ What is the proposed structure?
- ☐ How will your affiliate or chapter be financed?

## Declaration

This section requires that you, as a representative of your group, acknowledge that you've read and agreed to the terms and requirements of the [ISPE Member & Volunteer Code of Conduct](#), and affirm to the information you submitted in your petition.

## Electronic Signature

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