

ENGINEERING PHARMACEUTICAL INNOVATION



**ISPE COMMUNITIES OF PRACTICE
START UP AND OPERATIONS
HANDBOOK**

JANUARY 2007

EDITOR'S NOTES

The ISPE Communities of Practice Start Up and Operations Handbook is produced jointly by the ISPE Community of Practice Council (COPC) and ISPE staff members and is a living document updated annually.

It is designed as a guide to steer committees forming new ISPE Communities of Practice and those that are already established.

Additionally, it is used by Communities of Practice in everyday business.

Scott Ludlum, Director of Business Initiatives

Assisted by:

Lauren Bingham, Business Initiatives Coordinator

ISPE COMMUNITY OF PRACTICE START UP AND OPERATIONS HANDBOOK

TABLE OF CONTENTS

	<u>PAGE</u>
I. Purpose of Handbook	4
II. About ISPE	4
III. About COPs	4
IV. Expectations	5
V. Structure	5
VI. Essential Components	6
A. Support from ISPE and Staff Liaisons	6
B. Community of Practice Council	7
C. Mode of Operation for COPs	8
D. COP Steering Committee	10
E. COP Membership	12
F. COP Software	13
VII. Global COP Structure	14
A. Global, Regional, and Local COPs	15
B. COP Development	16
C. Communication and Interaction	17
VIII. Interaction with Affiliate and Chapters	19
IX. COP Activities	20
A. Steering Committee Meetings	20
B. COP Forums	21
C. COP Networking Events	21
X. Contributions to ISPE Body of Knowledge	22
A. Technical Documents	22
B. Education	23
C. How the Educational Process Works	24
XI. Getting Started: Forming New COPs	26
XII. Growing and Sustaining COPs	28
A. Sustain and Evolve Checklist	29
XIII. Characteristics of Successful COPs	30
A. Ten Characteristics Identified by APQC	30
XIV. Benefits of COPs	31
 APPENDICES	
A. NAEC/EEC Chart	32
B. COP Roadmap for Success	33
C. ISPE Technical Document Proposal	38
D. COP Education Topic Submission Form	40
E. COP Networking Event Template	42

I. Purpose of Handbook

The purpose of this Handbook is to provide guidance toward the formation and operation of ISPE Communities of Practice. It is intended to serve as a model for developing new ISPE Communities of Practice and maintaining and growing existing COPs. Among numerous things, this Handbook describes the purpose, role, organization, start-up, operational guide, expectations, and keys to success for developing and implementing ISPE Communities of Practice. Similar to actual communities that will change and evolve at different stages of their life cycles, this handbook is designed to be a living document that will evolve and expand in conjunction with the communities.

II. About ISPE

ISPE's Core Purpose

To lead global change and innovation in pharmaceutical technology and process

ISPE's Core Values

Leadership
Innovation
Collaboration
Integrity

ISPE's Audacious Goal

The Society will revitalize global public health through support of scientific innovation in the development and manufacture of affordable medicines..

ISPE's Tag Line

Engineering Pharmaceutical Innovation

III. About Communities of Practice (COPs)

By definition, a Community of Practice (COP) is a group of people that share a concern, a set of problems, or a passion about a topic, and who deepen their knowledge and expertise by interacting on an ongoing basis. As ISPE has grown, the need has arisen for the society to develop new and innovative ways to disseminate relevant and timely information to both Members and non-members alike. Forming ISPE Communities of Practice is an effective means for accomplishing exactly that.

ISPE recognizes that the pharmaceutical industry is challenged by the need to increase efficiency and productivity while being afforded fewer resources by which to accomplish this. ISPE members and constituents require relevant, timely information that is more easily accessible to address their

needs and help them do their jobs better. As a result, ISPE is supporting new and diverse communities of practice that allow for like-minded professionals to collaborate on and address issues in an open and efficient manner on a global, regional, and local level.

It has been determined that using technology as an enabler is essential to the success of ISPE COPs. This determination is being taken very seriously by ISPE and as a result, ISPE is implementing COP software that will facilitate the ability for community members to connect with one another and collect the data they are sharing. More specifically, the new COP software offers the ability for community members to:

- a. Become a member of ISPE communities easily with one click and access the communities members belong to in one convenient location
- b. Receive a welcome message confirming a member has joined the community
- c. Identify other community members with similar interests
- d. Share information about themselves while controlling the amount of information members wish to share
- e. Engage in electronic discussions about topics relevant to the job community members are doing on a daily basis
- f. Access current news and hot topic items about the discipline represented by the community
- g. Schedule an online chat with an unlimited number of other community members
- h. Collaborate on documents with a check-in and check-out features

IV. Expectations of ISPE Communities of Practice

The primary business intent of ISPE Communities of Practice is:

- a. To provide a forum for community members to help each other solve everyday work problems and engage in active networking.
- b. To develop and disseminate best practices, guidelines, and procedures for use by community members
- c. To organize, manage, and steward a body of knowledge from which community members can draw
- d. To innovate and create breakthrough ideas, knowledge, and practices.¹

V. Structure

All communities of practice share a general structure that consists of three basic elements including a *domain* of knowledge that defines a set of issues, a *community* of people who care about and are connected in some way to the

¹ Ibid

domain, and the shared *practice* that is being developed to be effective in the domain.² The domain, community, and practice are specifically defined as:

- a. Domain – the area of knowledge that brings the community together and defines the key issues that members need to address.
- b. Community – the group of people for whom the domain is relevant and the quality of the relationship among members.
- c. Practice – the body of knowledge, methods, tools, stories, cases, and documents which members share and develop together.³

Successful communities of practice require a focus on the social structure which is the actual community component; as well as developing the practice.

VI. Essential Components of the Community

For the community to develop and evolve there must be a strong pull from practitioners that are passionate about forming a community around a particular discipline within the industry. Likewise, ISPE will provide basic administrative support that enables community members to focus on the practical aspects of forming and developing the community.

A. Support from ISPE and Staff Liaisons

ISPE's role is to provide COPs with basic administrative support with the understanding that the success of the community is ultimately determined by the passion and effective leadership of the steering committee, as well as the drive by community members to "Connect and Collect." ISPE assigns a primary staff liaison to each COP and there is generally an ISPE Advisor assigned to a COP as well. In some cases with the larger, more globally established COPs, ISPE may assign more than one staff liaison to better serve the community. In the example of COPs such as GAMP and Investigational Products, multiple staff liaisons are assigned to the global COP with the expectation that the Global Council of the COP will determine how best to utilize available resources of the staff liaison.

Responsibilities of the staff liaison include:

1. COP liaisons and volunteers work together to implement COP Roadmap for Success
2. Assist volunteers develop new COPs and grow existing ones through adherence to COP Operations Handbook
3. As requested, participate in staff liaison meetings to discuss COP initiatives and make recommendations for improving COP structure

² McDermot, Richard, Snyder, William M., Wenger, Etienne. *A Guide to Managing Knowledge: Cultivating Communities of Practice*. Harvard Business School Press. 2002. Boston, Massachusetts. Pg. 27

³ Kahan, Seth. *Engagement, Identity, and Innovation: Etienne Wenger on Communities of Practice*. *Journal of Association Leadership*. Winter 2004. Pg. 28.

4. Attend COPC meetings (when available) and review minutes
5. Regularly review COP Web sites and ensure content is kept current
 - a) Assist volunteers as requested to edit existing and post new content
6. Participate on COP Council E-Discussion and COP Staff Liaison E-Discussion and disseminate information to individual COP leadership as needed
7. Communicate regularly with COP Chairs and organize conference calls as needed between personal meetings of steering committees
8. E-Discussions responsibilities include:
 - a) Use and encourage the use of E-Discussions by steering committee members
 - b) Ensure we have moderators for each public E-Discussion
 - c) Communicate with moderators on a regular basis and address any misuse of public E-Discussions
 - d) Keep steering committee member information up to date
 - e) Monitor error messages and address as appropriate
 - f) Notify COP steering committees when E-Discussions are not functioning properly
 - g) Manage one-way communication process with COP members to keep updated on COP events, what is being accomplished, and what upcoming activities are
9. Take minutes during conference calls and in-person meetings and make documents and presentations available on COP E-Community
10. Work internally with ISPE departments to assist COPs with marketing and communications, technical documents, E-Letters, training and education events, write and review articles, member benefits – both ISPE and COP
11. Assist COPs develop recognition plan for participation by COP members
12. Keep COP member roster updated (assuming this is made available)
13. Assist with COP networking events such as COP night at the Annual Meeting
14. Develop metrics for success and monitor progress of COPs

B. Community of Practice Council

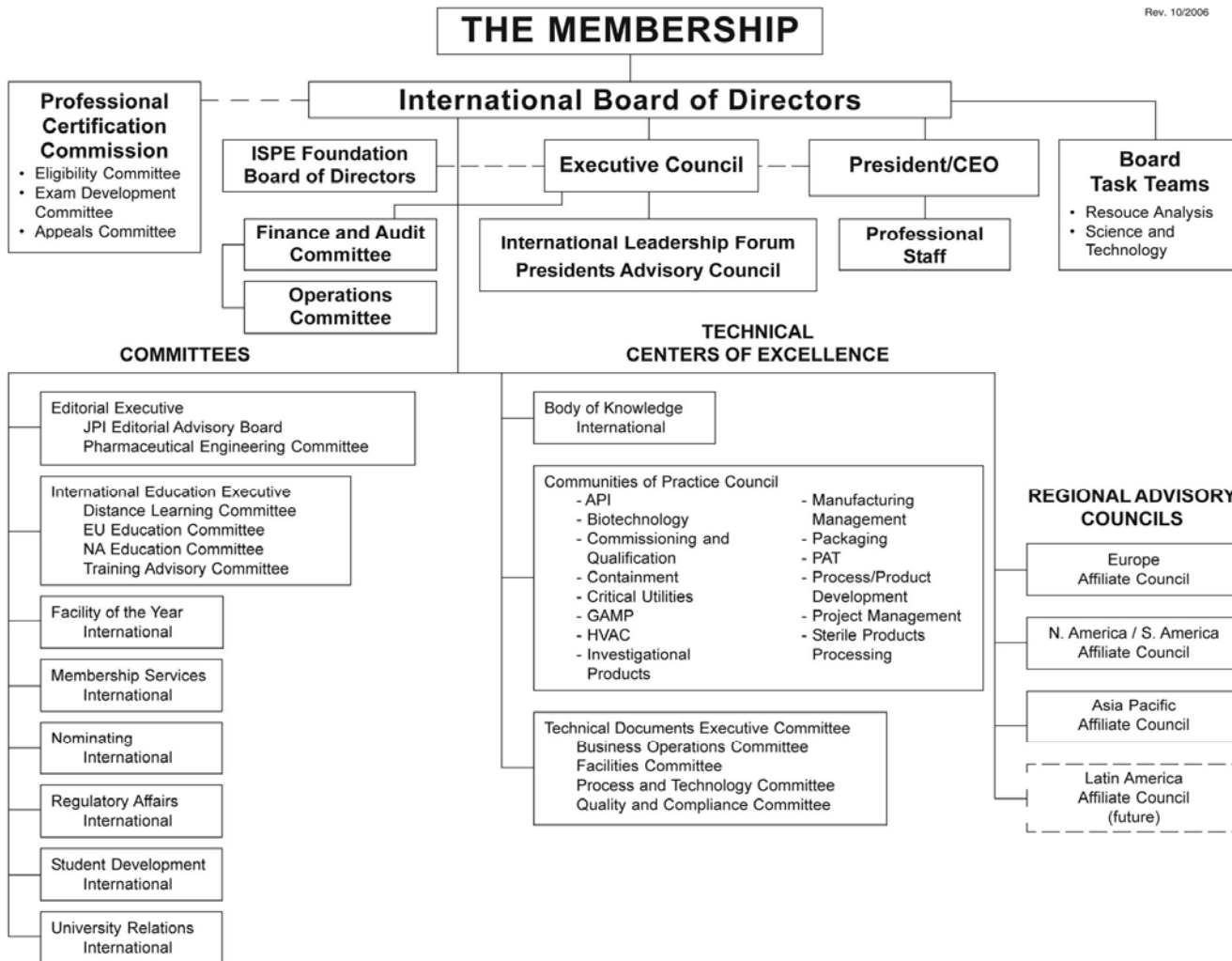
The role of the Community of Practice Council (COPC) is to provide oversight and strategic leadership in the development of ISPE Communities of Practice. The COPC serves as the “community” for the communities and is tasked with identifying strategic opportunities to develop new ISPE COPs and addressing challenges and opportunities in developing new and existing COPs. Composition of the COPC includes Chairs, co-Chairs, and vice-Chairs of all ISPE COPs, as well as ad hoc members as determined by ISPE and the COPC.

1. Responsibilities of the COPC:

- a) Determine which industry disciplines should be represented by Communities of Practice and provide advice and guidance in developing new COPs and growing existing COPs
- b) Serve as a liaison among individual COPs to provide guidance and share best practices for the consistent development of each COP.
- c) Review data and make recommendations to ISPE on issues of strategic development including:
 - Launching and promoting COPs
 - Identifying subject categories to be included as topics for E-Discussions
 - Assisting and making recommendations for the effective implementation and use of COP software
 - Recommend potential solutions to help slower developing COPs evolve more effectively
 - Determining whether a new COP should be formed or not as well as whether it should be a new COP or a sub-COP under and existing COP
- d) Identify areas of overlap among COPs and develop a strategy for the joint development of technical content.
- e) Develop a short-term and long-term plan for ensuring the effective integration of COPs within all aspects of the Society, especially Affiliates and Chapters

C. Mode of Operation for COPs

ISPE Communities of Practice are an important component within the overall governance structure of the Society as communities are considered “Technical Centers of Excellence” and are overseen by the Community of Practice Council and governed by ISPE’s International Board of Directors. COPs operate in a manner similar to ISPE committees, councils, and task teams. As such, COPs are not a legal entity and they do not maintain fiscal or budgetary authority. This is represented in ISPE’s Organizational Chart below.



It is important to stipulate how communities interact with internal ISPE constituents and external organizations not associated with ISPE.

1. Interaction with internal ISPE Constituents

- North America South America Affiliate Council (NASAAC) – The role of the NASAAC is Recommend policies and procedures to the International Board of Directors that will improve Affiliate and Chapter services to Members.
- International Education Executive Committee (IEEC) - The role of the IEEC is to act as an advisory board for the North American and European Education Committees, the Asia Pacific Affiliate Council, and the Training Advisory and Distance Learning Committees to develop and produce a full curriculum of high quality, cost efficient education programs within the Society's Body of Knowledge.
- North American Education Committee (NAEC) – The role of the NAEC is to develop and produce a full curriculum of high quality, cost efficient Continuing Education programs for North America and South America that meet ISPE's Strategic Plan goals and the needs of the industry.
- European Education Committee (EEC) – The role of the EEC is to develop and produce a full curriculum of high quality, cost efficient

Continuing Education programs for Europe that meet ISPE's Strategic Plan and the needs of the industry.

- Distance Learning Committee (DLC) – The role of the DLC is to develop a full curriculum of high quality, cost efficient distance learning education programs to meet the ISPE Strategic Plan goals and support the Society's Body of Knowledge while identifying the appropriate technology-based media for delivery.
- Technical Documents Committee (TDC) – The role of the TDC is to oversee the development of all Society guidance for Industry, utilizing personnel from industry, regulators, and suppliers. When the COPs have an idea for creating a technical document, they must work with the TDC and the respective subcommittee that will assist the COP the process for creating the technical document.
- Body of Knowledge Committee (BOKC) – there needs to be a direct link between the BOKC and the COPC. Staff liaisons from each are responsible for keeping each group updated and scheduling meetings if needed.
- Facility of the Year Committee (FOYC) – The Director of Business Initiatives will distribute a spreadsheet containing a summary of the technical merits of submissions to staff liaisons for each community.

2. **Collaborating with External Organizations**

Once communities begin to thrive, requests may come from organizations not associated with ISPE seeking sponsorship or collaboration opportunities with the COPs. Steering Committee Chairs are to forward these requests to the primary staff liaison and discuss the potential opportunity for collaboration. All negotiations must be conducted by ISPE and the final decision will be communicated by ISPE to the proposing organization.

D. COP Steering Committee

The Steering Committee of each COP is vital to the initial start up and evolution of the COP. The Steering Committee must first develop short term and long term goals for the COP and create a mission that aligns with ISPE's overall direction and objectives. The main short term goal is, of course, identifying the domain, community, and practice of the community. Once this has been specifically stated, the next step is to develop a critical mass of members that want to belong to the COP and help it grow. For this to happen the steering committee must be dedicated and committed to facilitating the creation of an environment where the exchange of ideas and knowledge is created. Additionally, it should foster an environment where active participation from community members results in valued added educational programs, technical documents and

publications, hot topic seminars and discussions, and other products and services that are created for and by community members.

The critical mass of community members and the level of participation they engage in ultimately determine the success or failure of the community. If sufficient value is perceived, the community will flourish as a result. If the community is not well organized or governed, members will choose not to participate. The role of the steering committee is to facilitate the activities of the community based on the needs of members. Subcommittees or teams are to be developed based on the interests and needs of the community to get the work done and create value.

1. Composition of the Steering Committee:

- a) All steering committee members must be ISPE members
- b) Global representation from North America, Asia, Europe, and Latin America
- c) Equal representation of members from industry manufacturer and supplier organizations
- d) Two co-Chairs from different geographic regions. One should be from an industry manufacturer.
- e) No less than 10 steering committee members, with the ideal number being about 12 to 15 members.

As the community develops and the steering committee evolves from managing activities to facilitating the creation of an entirely new body of knowledge and social structure, the role and composition of the steering committee will change as well. It is therefore up to the discretion of the individual community to determine the overall composition of the steering committee and the method of interchanging new steering committee members, including how long the tenure should be.

2. Responsibilities of the Steering Committee:

- a) Respond to and address requests from ISPE as well as from the COP Council
- b) Engage in active participation by attending meetings, participating on conference calls, providing suggestions and input, contributing to the development of the community's body of knowledge, and encouraging participation of community members
- c) Ensure there are moderators for E-Discussions and facilitators for communities once the COP software is implemented
- d) Create sub-teams and recruit members to address the needs of the community. Sub teams may include but are not necessarily limited to:
 - Educational programs team
 - Technical documents team

- COP software implementation team
 - Marketing and communications team
 - Article Review team
 - Member recruitment and activities team
 - E-Discussions
- e) Set the strategic direction and develop tangible deliverables for the community through feedback from community members and regular meetings and conference calls of the steering committee.
 - f) Align the community with relevant ISPE committees, councils, task teams, affiliates, chapters and Special Interest Groups (SIGs).
 - g) Represent the community at ISPE conferences and other relevant industry events
 - h) Submit proposals for educational programs and the creation of technical documents on behalf of the community
 - i) Communicate regularly and collaborate closely with ISPE staff and advisor liaisons to accomplish the mutual goals of ISPE and the community
 - j) Participate on E-Discussions for the steering committee and on public E-Discussions of the community
 - k) Consider and discuss how specific activities and the body of knowledge of the community may overlap with and affect other communities

E. COP Membership

Membership in ISPE COPs is open to anyone, including ISPE members and non-members alike. There will be a two-tiered structure that restricts full access to the entire COP body of knowledge to ISPE members only. Additionally, individuals may participate in as many communities as they like. Once the COP Software is implemented and there are tangible benefits to participating in COPs, this added value provided by COP participation is expected to result in more ISPE members and a higher percentage of renewing ISPE members.

1. Non-Member Participation

Ways for non-ISPE members to participate in communities include:

- a) Gain limited access to the global ISPE community
- b) Participate in E-discussions by posting questions and receiving responses
- c) Write and review articles for ISPE journal, magazine, and other publications
- d) Contribute to development of educational and training programs
- e) Contribute content and receive E-Letters (although not all content will be accessible to non-ISPE members)
- f) Be included in COP directory (non-members will not have access)
- g) Attend COP networking functions

- h) Attend general COP meetings and work on small focus groups to help determine the direction in which the COP evolves
- i) Attend educational sessions at ISPE conferences

In addition to those referenced above, ISPE members can participate by:

- Gain full access to:
 - All functionalities of COP software
 - ISPE Web site
 - Documents and minutes from COP meetings
 - White papers and content developed by COPs
 - Journal and magazine articles
- Serve as members of COP steering committees and subcommittees
- Serve as facilitators for communities and moderators for E-Discussions
- Assist in writing technical documents and guides
- Provide comment on draft documents when available

A successful COP encourages active participation, although “active” can only be defined by the participants themselves. The key to success is finding a way to provide value to each and every type of participant. Several categories of participants may include:

- The coordinators or co-Chairs of the steering committee
- The core group or steering committee
- Leaders (of sub teams or subcommittees)
- Experts
- Beginners
- Occasional
- Peripheral
- Lurkers
- Alumni
- Outsiders
- Transactional
- Sponsors

F. COP Software

In order to facilitate active participation by COP members, ISPE is implementing a COP software package that will greatly enhance opportunities for COP members to connect with one another and collect and share experiences and information to help them be more effective at their jobs. The COP software will provide COP members with a friendly and welcoming online environment where COP members can identify others with the same or similar interests.

Although not all functionalities will be accessible to non-ISPE members, a summary of some of the most interactive COP software functionalities includes:

- Single log-on to ISPE Web site and COP sites
- Easy and convenient access to join and visit communities
- Member profile
- Different types of communities including public and private
- Member search
- Discussions
- News

ISPE will work with the COP Software provider to effectively integrate relevant information contained on COP Web sites within the COP software.

Privacy: ISPE is firmly committed to protecting the privacy of its web site users. ISPE collects unique identifiers (such as membership numbers, user name and password) to verify the user's identity, provide customized web pages and customized information. This information is never disclosed nor sold to third parties. The ISPE Communities of Practice web site also provides member profile data such as name, city, state, job title, and workplace to other members through its online directory. Other identifying information is not available. Users of this site agree to use directory information for individual, personal, and confidential reference purposes only and agree not to use this directory, in whole or in part, for mailing lists, solicitations, or other commercial purposes.

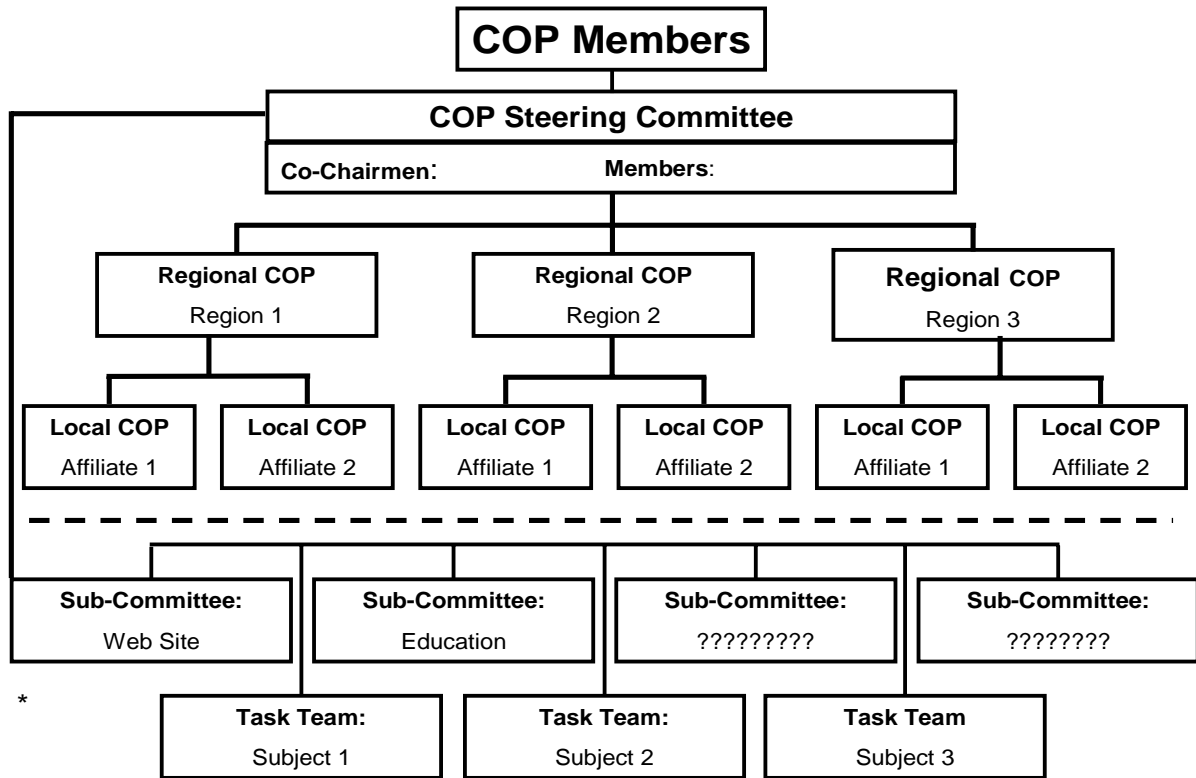
Users of this site further understand and agree that their names and contact information may be posted on this site in a membership database for access by members only. Such users agree to indemnify and hold ISPE harmless from any and all claims arising out of or relating to the publication or display of their names and/or contact information.

VII. Global COP Structure

As more ISPE Communities of Practice are realizing the need to become fully global and interest continues to grow to start local COPs, there is a need to formalize the structure among the various groups. Developing a formal COP structure is to be accomplished by identifying the relationships between Global ISPE COPs, COP Regional Groups and local COPs representing specific countries and/or languages.

While the need exists for different COPs to adapt variations of the recommended structure, the global structure to follow should be used as a model.

Generic Organizational Structure for COP



A. Global, Regional, and Local COPs

The evolution of ISPE COPs worldwide has taken place sporadically with no consistent process to describe and document how and when this should happen. In some cases, local COPs have or are developing before there is a Global COP in place. In other cases, a global COP may exist but there is no formal tie between local groups and the global COP. For clarification, global, regional, and local COPs are defined below:

1. **Global COP** – a global COP is intended to be the foundation for a community that will be represented globally in different geographic regions of the world. The Global COP may have regions and local COPs reporting to it and is to follow the requirements for development and operation as outlined in ISPE’s COP Operations Manual. Global COPs are comprised of the various Regional COPs whose Chairs sit on the Global COP Council. It should be noted that Regional and Local COPs will only develop with the buy-in of the local ISPE Affiliate(s) and the relevant Global COP.
2. **Regional COP** – a regional COP is administrative in nature and serves a governance purpose for specific geographic regions such as the Americas, Europe, or Asia-Pacific.

3. **Local COP** – a local COP may be formed when there is interest in engaging in activities related to the COP at a local (country) and/or language based level. Local COPs should develop through communication and interaction with ISPE Affiliates and Chapters. A local COP needs buy in from the Regional COP (if it exists) and approval from the global COP before it can formally develop.

B. COP Development

1. Global COP

The process to form a global COP must be followed as outlined in this manual.

2. Regional COP

Regional Steering Committees have one seat on the Global COP Steering Committee. Consistent with the specifications contained in the COP Operations Manual, each Regional COP must have:

- a) A Steering Committee composed of members from manufacturing industry, suppliers, consultants, and at least one academic and one regulator if possible. All steering committee members must be an ISPE member in good standing.
- b) Manufacturing industry professionals should be in the majority and drive activities of the Steering Committee. In the event that this is not possible, the Steering Committee must accommodate the consensus of all manufacturing industry representatives in decisions involving the activities of the group.
- c) Members of the Steering Committee should rotate every few years once the group is well established.
- d) Regional COPs should take advantage of opportunities to share what is going on globally through membership of the Global COP and at events made available by ISPE.
- e) One of the responsibilities of Steering Committee members will be to manage the operational behavior of Task Teams formed at the local level.

3. Local COP Development

If the local COP being proposed covers a discipline for which no Global ISPE COP already exists, the individual(s) proposing the COP are to follow the requirements for starting a new ISPE COP as detailed in ISPE's COP Operations Manual.

New local COPs are requested to develop a draft charter that clearly identifies the scope and focus of the new local COP. A member of the prospective local COP may be asked to outline the intent of the local COP and solicit members by whatever means available, including from

Affiliates and Chapters. The one or two-page charter requirements must be consistent with those included in ISPE's COP Operations Manual for the proposal of a new global Community of Practice. The charter should include:

- COP Name
- COP Steering Committee Members and company affiliation
- Sponsor (COP Regional Group Steering Committee Member)
- Statement of Purpose
- Description of scope, focus, and any deliverables that will be generated by the local COP
- List of anticipated activities to involve COP members
- List of existing or potential members and company affiliation
- Demonstrate that the proposed domain, community, and practice are consistent with those of the Regional COP Group
- Links to other Regional COPs and the Global COP

Proposed Local COP charters must be submitted for review to the Global COP for approval. Local COPs should not begin activities or attempt to develop a Web site prior to being approved by the Global COP Steering Committee.

Similar to the relationship between the Global COP and the Regional COP group, the local COP is accountable to the Regional COP. Thus, the Chair of the Local COP Steering Committee will sit on the Regional COP Steering Committee and should make every attempt to personally attend meetings. Membership in a local COP must be prefaced by joining the global COP.

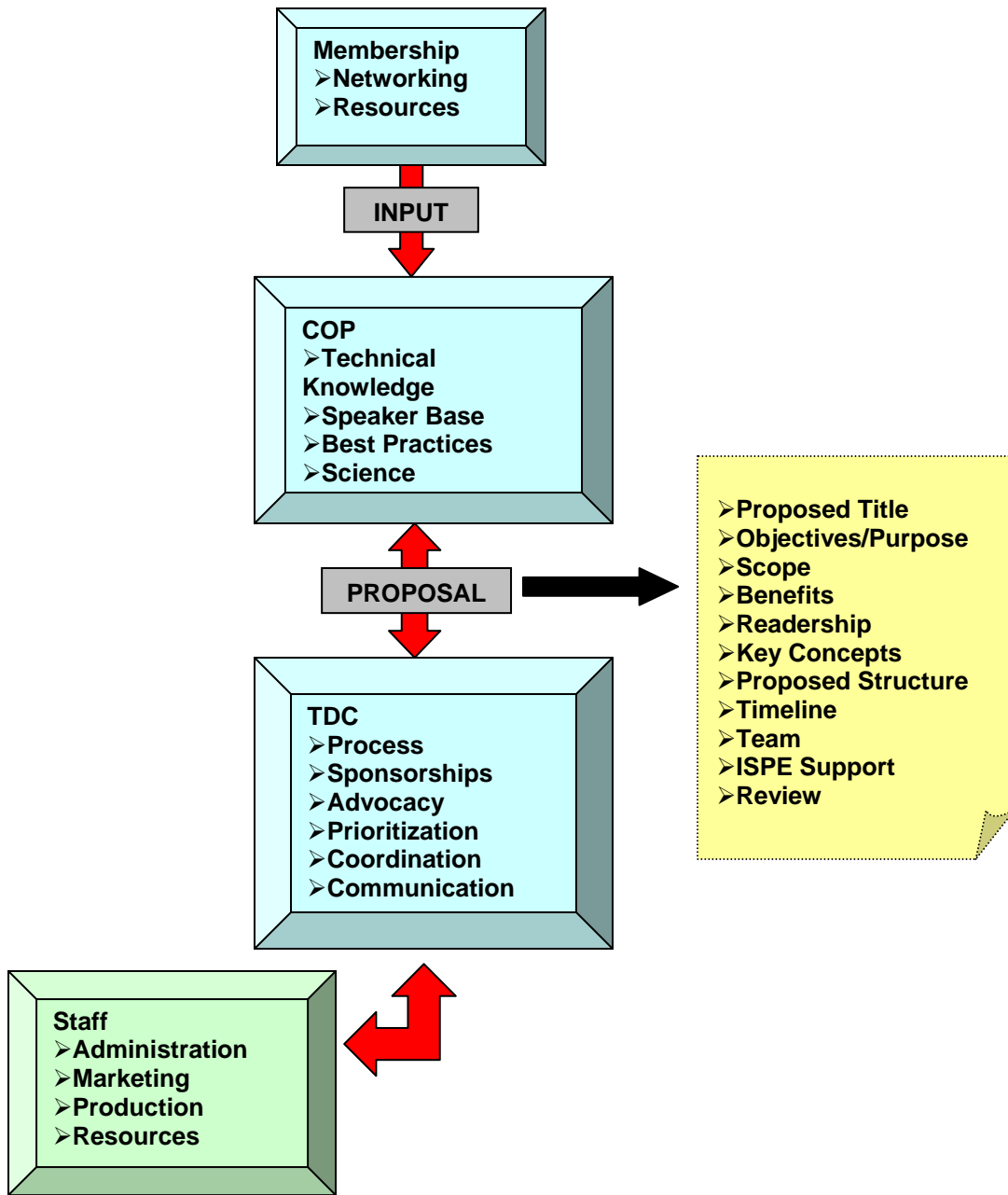
C. Communication and Interaction among COP Groups

Although it is not the intention of the Global COP Steering Committee to dictate or otherwise interfere in regional and local issues, regular communication and interaction among the COP groups should occur to ensure:

- COP members anywhere in the world have access to global information and knowledge about the discipline of the COP as well as information about other members of the COP
- Regional COP Steering Committees need to exchange ideas and experiences about how members can become more involved.
- Local Task Team activities can be shared with other interested COP groups

- All relevant policies, procedures, guidance, or other information coming from ISPE, ISPE's COP Council, or the Council of the specific global COP should be shared and communicated
- ISPE's Global COP Council as well as the Global Council of the specific COP are to function as a conduit of advice and communication to the Regional Steering Committees

TDC Flow Chart



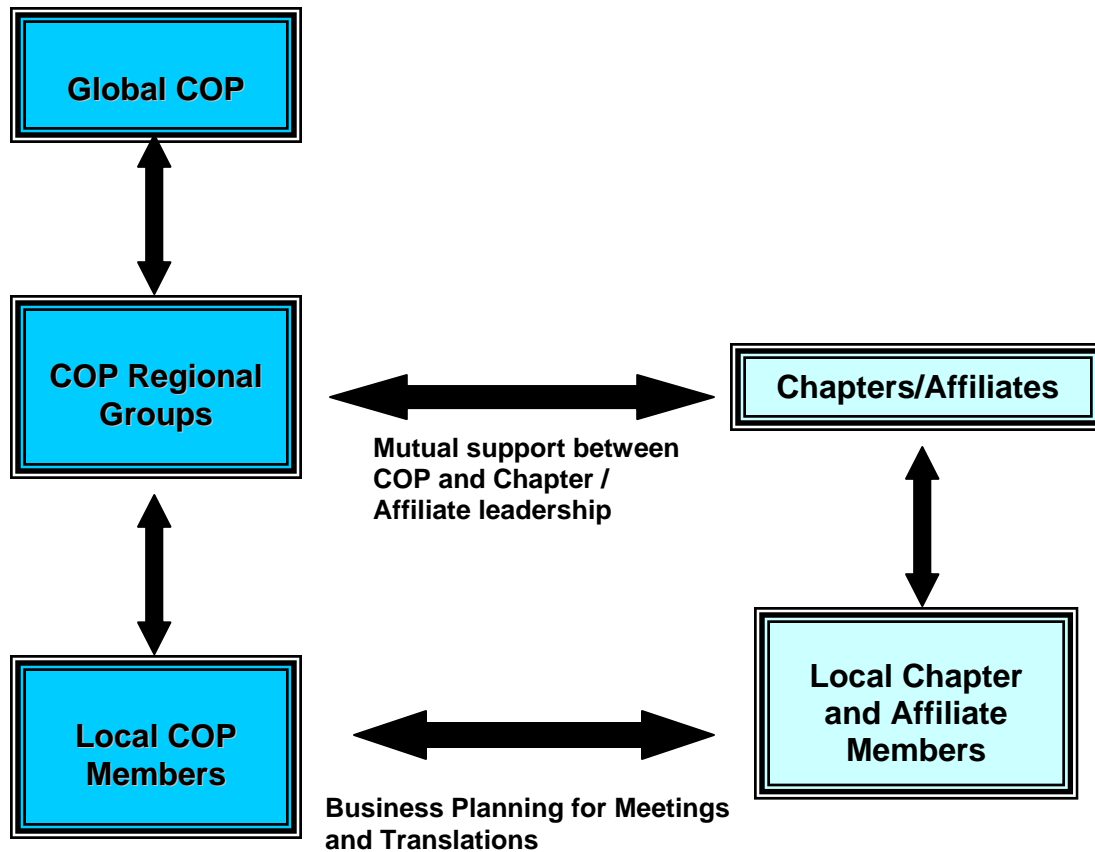
VIII. Interaction with Affiliates and Chapters

The success of COPs is directly linked to close interaction with ISPE Affiliates and Chapters. The activities of local COPs are to be fully integrated with Affiliates, Chapters, and Global COPs.

The relationship between COPs and Affiliates/Chapters is mutually beneficial as Affiliates/Chapters benefit from access to subject matter experts in disciplines covered by the COPs. COPs benefit from access to a larger audience from which to recruit COP members. Paramount to the success of this relationship is the need to disseminate current information about COPs and their activities to the Affiliates and Chapters. This will be facilitated by doing the following:

- Focus on COPs at local Affiliate/Chapter events including:
 - COP roundtables
 - Introduction and overview of COPs
 - Identification of and access to local “COP Champions”
 - Annual COP meetings
- COPs provide regular briefings to Affiliates and Chapters and include the names and contact information of the Steering Committee Chairs and members
- ISPE to provide relevant COP information to Affiliate/Chapter leadership including:
 - Updated promotional materials detailing what COPs are and the benefits of membership
 - Access to COP Operations Manual
 - Document on global governance structure of COPs
 - Overview of COP software and progress updates on implementation
 - COP applications
- Invite representatives from all COP steering committees to APAC, EAC, NASAAC meetings
- Identify COP leaders willing to give presentations at local Affiliate/Chapter events (COP speaker database)
- ISPE to provide Affiliates and Chapters with regular updates on progress made with implementation of COP software

Desired State COP-Affiliate/Chapter Model



IX. COP Activities

A. **Steering Committee Meetings**

Meetings of the COP Steering Committees should take place as needed and are generally scheduled to take place during all North American Conferences and during at least one European Conference. Steering Committees are encouraged to use conference calls and WebEx meetings as needed. Similar to meetings of committees, councils, and task teams, expenses for COP Steering Committee members to attend meetings are not reimbursed by ISPE.

The schedule for COP Steering Committee meetings is approved by the ISPE International Board of Directors. COP Steering Committees are expected to provide their staff liaison with suggested dates. Once the schedule is approved by the BOD, Steering Committees should follow the approved schedule. If this is not possible, Steering Committees should contact their primary staff liaison. ISPE cannot guarantee, however, that

requested changes to committee meeting dates can be accommodated due to potential limitations on meeting room space and other logistical considerations.

B. COP Forums

Will be conducted virtually and in-person as a means for COP members to exchange ideas and set best practices; brainstorm ideas for potential deliverables such as articles, technical documents, or educational programs; provide updates on work being done by Global COPs and the local COPs; and providing regulatory updates.

Costs for COP Forums must be kept to a minimum so venue options different from traditional ISPE venues must be considered. Examples of these include: colleges or universities, company conference rooms, conference centers or catering halls, lower star hotels, etc. Amenity packages may be less than those offered by Society programs and could include: the absence of proceedings, more simplified and cost effective means for marketing the programs, and more cost effective catering options.

COPs desiring to schedule a forum for their members should propose their ideas and collaborate with ISPE. Please contact Scott Ludlum, ISPE Director of Business Initiatives, at sludlum@ispe.org

C. COP Networking Events

COP networking events may take place in an effort to enable COP members to “connect and collect” with one another in a less formal and social atmosphere. Any COP can propose having a COP networking event as long as the following guidelines are adhered to:

1. The proposed networking event should benefit multiple COPs and should not be unique only to the particular COP that is proposing the event. Any resources allocated by ISPE in support of COP networking events will be done to benefit multiple COPs.
2. The proposed event should not conflict with the timing of ISPE educational events, networking events, or any other global ISPE event
3. The proposed event must be paid for by sponsorships or other approved types of fundraising initiatives in order to be financially self-sufficient. ISPE does not have a budget for COP networking events
4. It is important to note that COP networking events are ISPE events. This means these networking events are managed consistently with the way ISPE networking events are managed and ISPE always maintains sole fiscal responsibility for the events. COPs may be asked for ideas about planning the event and recommendations for sponsors, but ISPE will be responsible for managing all business aspects of the event.

Generally COP networking events will be free of charge to ISPE members but participants must be existing COP members. COP networking events are open to non-ISPE members; however, they will be required to pay a minimal administrative fee of US \$30.00. The only exception to this will be speakers and designated guests.

X. Contributions to ISPE Body of Knowledge

A. Technical Documents

One of the primary benefits shared by ISPE and community members is the creation of a community-specific body of knowledge. At one point or another most communities will desire to create some sort of technical document to benefit community members. Details of the procedure to follow are provided below and a blank template is included as an appendix to this manual. The following information is to be provided to ISPE's Technical Documents Executive Committee:

- Proposed title of document
- Objectives and purpose – what is the document/paper attempting to achieve?
- Scope – what will it cover?
- Benefits – what will the benefits to the industry be?
- Readership – who is the target readership?
- Key Concepts – are any new concepts defined? Are any established concepts central to the document?
- Proposed structure
 - Main headings?
 - Target length?
 - Any Appendices
- Timeline – when is it required by and why?
- Team – who will write the document
 - Leader?
 - Team?
- ISPE Support – what support is needed from ISPE?
 - Authoring?
 - Editing?
 - Facilitating?
 - Other?
- Review – who needs to review it?
 - ILF?
 - Board?
 - COP (which)?
 - TDEC?
 - Other?
- Approval – who needs to approve it?
 - ILF representative?
 - Board representative?

- COP representative?
- Technical expert?
- Regulator?
- Other?
- Distribution – who should receive the final version?
 - Regulatory agency?
 - ISPE Web site?
 - Other?

B. Education

Ideally COPs are the perfect means for recommending and producing educational sessions for ISPE conferences and training events since COP members should be the subject matter experts and are in tune with what topics are most relevant and timely. The COPs will play an active role in making significant contributions to the educational process but are not responsible for developing educational programming themselves. The distinction between conferences, training, and on-line educational events follows, although the process for contributing to all is nearly identical.

1. ISPE Continuing Education Conferences (Coordinated by NAEC and EEC)

Help professionals keep current with emerging global industry trends and practices. Through interactive seminars, sessions, workshops, ideally each with case studies, participants can stay on the cutting edge by learning about regulatory updates and new technology. Additionally, Continuing Education conferences allow for peers to share common problems and co-develop solutions through a variety of networking activities and interaction with each other and in many cases regulatory officials. Components associated with conferences include:

- a.) Seminars - Within CE Conference or the Annual Meeting are seminars focused on one-topic area. The length is one-day or longer and in-depth materials are supplied
- b.) Sessions – Within the CE Conferences or Annual Meeting are sessions but they are shorter than a seminar (less than one day) and are typically focused on a more specific topic area
- c.) Workshops – Workshops are also within the CE Conferences or Annual Meeting but are short in duration (usually one to five hours) and they are highly interactive with limited amount of lecture

2. Classroom Training Courses (Coordinated by TAC)

Taught and developed by globally recognized faculty, ISPE classroom training offers individuals smaller class sizes that provide one-on-one interaction with instructors. The professionals teaching the courses are experts in their fields bringing valuable, practical industry experience to each session. Classroom training is offered publicly at ISPE

Training events worldwide. Select training courses are available as a blended learning experience - a combination of Web-based and classroom learning.

3. **On-Line Education (Coordinated by DLC)**

These sessions can be of various lengths (mostly one to three hours) depending upon topic. It may also have one to a few presenters. (IEEC = International Executive Education Committee; NAEC = North American Education Committee; EEC = European Education Committee; TAC = Training Advisory Committee; DLC = Distance Learning Committee)

All COPs are asked to actively participate in ISPE's educational process by recommending relevant and "hot" topics.

COPs may:

- a) present various concepts for consideration
- b) may recommend potential speakers
- c) function as conference leaders and speakers

Although COPs should recommend topics to be presented, this does not automatically ensure COPs will be chosen to present or as leaders, instructors or speakers. The call for submissions is an extremely competitive process and will become increasingly more competitive as more COPs emerge and develop. Even if topics are recommended by COPs, the COPs still must participate in the proposal review process. Any educational proposals put forth by the COPs will be reviewed and evaluated the same as all other proposal submissions.

The COP Steering Committee should consider ideas for educational sessions that emanate from discussions and meetings as well as ideas proposed by the COP members. The Education Committees (IEEC, NAEC, EEC, TAC, DLC) will coordinate efforts with the Steering Committee to evaluate proposed topics. The educational committees can then solicit conference leaders or speakers and participation from COP members. However, individual members of the COP can propose a topic for a session(s), classroom training course(s) or on-line education without coordinating efforts with the COP Steering Committee.

The International Executive Education Committee has outlined a specific educational process that follows. The complete flow chart is included as an Appendix.

C. How the Educational Process Works

1. Call for educational suggestions, including a form to complete, is sent by ISPE directly to COPs and is also posted on ISPE's Web site

2. COPs send suggestions for conference, training or distance learning topics; or communicate they have none to IEEC
3. The education committees receive other suggestions from the general membership or industry and not only those submitted by COPs
4. All suggested topics are reviewed and analyzed by the specific educational committee
5. If the education committees believe there a topic related to a COP discipline that has not been submitted from the COP, to make the suggestion directly to that COP
6. The education committees notify those COPs and other external sources submitting suggestions that are not accepted and states specific reason
7. The education committees notify those COPs and other external sources submitting proposed topics of acceptance and provides process procedures
8. COPs selected as leaders identify speakers from COP membership and other external sources, possibly including non-selected leaders. The process to be followed includes:
 - a) The leader submits a leader application, provided from the ISPE Office specific to the type education they are using (conference, training, on-line)
 - b) Select the speakers: conduct a specific call for speakers to the entire COP membership using the forms provided by the ISPE Office specific to the type education they are using
 - b) Speaker logistics and organization – the leader is responsible for being the “project manager” of their education offering and works closely with the ISPE Education Staff
9. The education committees may match leaders not associated with COPs to liaise with COPs to potentially assist in identifying speakers

There are several ways for the COPs to participate in the educational process and to contribute to the development of ISPE’s Body of Knowledge that include:

- Recommending Hot Topic Webinars and Identifying Appropriate Speakers – COPs should make recommendations for “hot topic” Webinars based on what is of interest and relevance within the discipline as determined by COP members. The recommendation comes from the COP

Steering Committee and it is then responsible for identifying speakers from the community. Suggestions for topics suggested to ISPE must be substantiated by community feedback as being a viable subject that would attract attendees.

- Articles for PE and ISPE's New Journal – similar to responding to a call for papers, individual COP members may submit articles for publication or the COP Steering Committee may organize a call for articles if it is asked to help with a special issue of PE dedicated to the COP's technical discipline.
- Reviewing articles for PE and ISPE's New Journal – this is a task to be facilitated by the steering committee by forming a sub team of reviewers comprised of community members.
- Moderating E-Discussions and Encouraging Active Participation
- E-Discussions facilitate communication and networking among like-minded professionals via email. For E-Discussions to work properly it is extremely important for steering committee members and sub team members to moderate the lists to ensure the lists are being used appropriately and questions are being posed and answered.

XI. Getting Started: Forming New Communities of Practice

Communities of practice are different than standard ISPE committees, councils, and task teams, in that they are organic and self-organizing. Ideally communities will emerge naturally. Although they can be seeded, the impetus for a new community generally comes from the recognition of a specific need or problem.⁴

For communities to be successful, there must be a group of dedicated “champions” that are truly passionate about the cause of the COP. Issues that must be considered before forming a new community include:

- Conducting research and determining if there is a real need for the COP
- Defining the scope of the COP
- Finding participants
- Identifying common needs and interests
- Clarifying the purpose and terms of reference of the community

The following steps are to be followed in order to develop a new ISPE COP:

1. At least two “champions” propose the formation of a new ISPE Community of Practice to ISPE's Director of Business Initiatives.

4

- Ideally each “champion” will be located in a different geographic location such as North America and Europe.
2. The “champions” read ISPE’s Community of Practice Start-Up and Operations Handbook and discuss questions and comments with ISPE’s Director of Business Initiatives.
 3. The two “champions” agree to serve as equal co-Chairs of the newly proposed COP.
 4. Assisted by ISPE, conduct research regarding the number of professionals practicing or potentially interested in the proposed discipline to be represented by the new community.
 5. Provide ISPE with information related to the following:
 - Identify what the domain, community, and practice will focus on (This will serve as the foundation from which to build the new COP)
 - Identify what the specific industry needs or relevant issues are to be addressed
 - Identify what specifically the COP is trying to address
 - Identify how the proposed COP will benefit its members, industry, and ISPE
 - Identify what the particular values and manner of working will be for the COP
 6. Identify and recruit a minimum of eight other steering committee members willing to serve on the steering committee.
 7. Present proposal to establish new community of practice to the COPC for discussion and approval. The COPC will serve as a sounding board for providing ideas and suggestions for establishing the new COP.
 8. Conduct first meeting of the proposed steering committee in person or via conference call to clearly identify the purpose and terms of reference for establishing the new COP.
 9. Once formal approval has been provided by the COPC to establish the new COP, regular monthly conference calls of the steering committee will be necessary.
 10. Create a strong governance structure that is to be completed by the end of the second conference call. Sub teams necessary for establishing the infrastructure of the community are to be identified. (See appendix for sample governance structure.)
 11. Identify short and long-term goals and deliverables. These should be based on the common needs and interests of community members and the Society.
 12. COP Steering Committee works with ISPE’s Business Initiatives department to get the COP online using the new COP software. Facilitators for the online community must be identified and complete training provided by ISPE’s Business Initiatives department.

13. Invite members to get involved with the new COP by developing a membership recruitment campaign and soliciting input from members for what the COP should focus on.
14. Direct new members to benefits offered by the COP and encourage input and active participation.
15. Facilitate the creation of the “practice” or body of knowledge of the community and determine how it will be disseminated to community members. Methods include:
 - Proposing and developing educational seminars for global ISPE conferences
 - Writing technical documents such as Best Practice Guides, new Baseline® Guides, white papers, and articles for PE and the New Journal.
 - Suggesting topics and speakers for ISPE On-line Seminars
 - Reviewing articles for PE and the Journal of Pharmaceutical Innovation
 - Developing strategic relationships and collaborating with other organizations and professional associations that are established in the same discipline as the COP.

XII. Growing and Sustaining COPs

Once the initial process of establishing new communities is completed, the focus must turn to further developing and sustaining the new communities. Otherwise enthusiasm may wane and the communities can potentially self destruct. The following must be addressed in order for communities to evolve:

- Maintain members’ interest and involvement – The ongoing success of a good community depends on members’ continued interest and involvement. A good coordinator (Chair) will be constantly seeking to maintain that using a variety of methods. One example is ensuring that members of the virtual community meet at least one time per year in person to foster and keep personal relationships strong. Personal events also serve to motivate and reward people for their contribution and introduce new and challenging perspectives in the subject area.
- Grow the community – Members will come and go throughout the life of any community so it will be necessary to be continuously recruiting new members. This serves to replace lost members as well as to keep a fresh perspective of the community. Similarly, roles and responsibilities will often be rotated between members over time. The ongoing success of the community will be affected by how well new members are welcomed and integrated within the community.

- Develop the body of knowledge – By this stage the community should be taking a proactive role and assuming responsibility for developing the relevant body of knowledge.
- Move the agenda forward to add value – Communities thrive when they are supported by the organization and this must be a “two-way street.” It is therefore imperative the community develops in alignment with the overall organizational goals, rather than according to its own individual agenda. This will significantly increase the chances of ongoing support from the Society.

A. Sustain and Evolve Checklist

1. Assess Alignment with Business and COP Goals
 - Have you revisited the charter of each COP to ensure its goals align with organizational goals?
 - Has the COPs focus changed? Does it need to?
2. Promote and Sustain COP Activity
 - How do you refresh content and promote continuous learning amongst COP members?
 - How do you find new members that would benefit from and add to the COP?
 - How do you market/communicate COP tools, practices, and outcomes?
 - How do you train new members on the processes of effective participation?
3. Assess Health and Measure Outcomes
 - Have you met the 10 Traits of Successful COPs?
 - Have you conducted a short member satisfaction survey yearly to help you understand what they like, don't like, need to improve, etc.?
 - Has the community reported on its measures monthly or at appropriate intervals?
 - Is it achieving goals?
4. Realign Processes
 - Does the Design Team have plans to meet at least yearly to realign COP processes to meet member needs?
 - How will you realign business winning processes based on what the COP learns (i.e., how do you create a continuous feedback loop into the business winning process)?
 - Has the COP interfaced with other COPs to learn/improve the way it interacts?

XIII. Characteristics of Successful COPs

ISPE's GAMP Forum represents the epitome of a successful COP. Based on the model of success demonstrated by GAMP, COPs must:

1. Reflect the realities and needs of the COP and its members
2. Widen geographical areas by setting up local groups and developing closer links with ISPE Affiliates and Chapters
3. Spread deeper and wider into diverse technical areas
 - Coordination of diverse groups (SIGs) and documents
 - Link to ISPE Technical Documents and Education Committees
4. Think big – but start small by creating achievable short-term objectives and contemplating big long-term goals
5. Keep a small, focused core by operating efficiently and coordinating tightly
6. Grow by spawning sub-groups with clear objectives within a clear structure

APQC, the American Productivity and Quality Center, has conducted extensive research on communities of practice, including what is required for communities to be successful. According to APQC, effective leadership is critical to the success or failure of communities of practice. Additionally, a strong leader or facilitator, especially in a largely online environment, can mean the difference between success and failure. Other traits that are important to the success of communities include passion for the topic, leadership ability, networking skills, meeting facilitation skills, and knowledge of the organization.⁵

A. Ten characteristics of successful COPs as identified by APQC include:

1. A compelling, clear business value proposition for all involved (organization, COP, individuals.)
2. A dedicated, skilled facilitator or leader
3. A coherent, comprehensive knowledge map for the core content of the COP
4. An outlined, easy-to-follow knowledge sharing process.
5. An appropriate technology medium that facilitate knowledge exchange, retrieval, and collaboration
6. Communication and training plans for members and others outside of the COP
7. An updated, dynamic roster of COP members
8. Several key metrics of success to show business results
9. A recognition plan for participants
10. An agenda of critical topics to cover for the first three to six months of existence

⁵ Vestal, Wesley. *Online Communities and Associations Excerpt*. APQC 2005.

One very important point to remember when developing communities of practice as identified by APQC is that the support provided by ISPE and its role in creating communities is not the most important factor determining success. Once the communities are selected, the most critical success factor is the skill of the community leader. "Management can hamper or kill a community strategy, but it cannot make communities thrive."⁶

XIV. Benefits of COPs

When assessing the value and benefits provided by communities of practice, most noteworthy is the notion that successful COPs positively impact individual COP members and leaders, ISPE, and pharmaceutical manufacturing companies. Specifically, individuals benefit from participating in COPs from:

1. Opportunity to share knowledge and experiences with other like-minded professionals through convenient global networking forums.
2. Access to tools to enhance productivity and keep current on industry trends and developments.
3. A means to stay current with industry trends through efficient networking opportunities
4. Fostering a greater sense of professional commitment and enhancing members' professional reputation

Benefits of COPs to ISPE are:

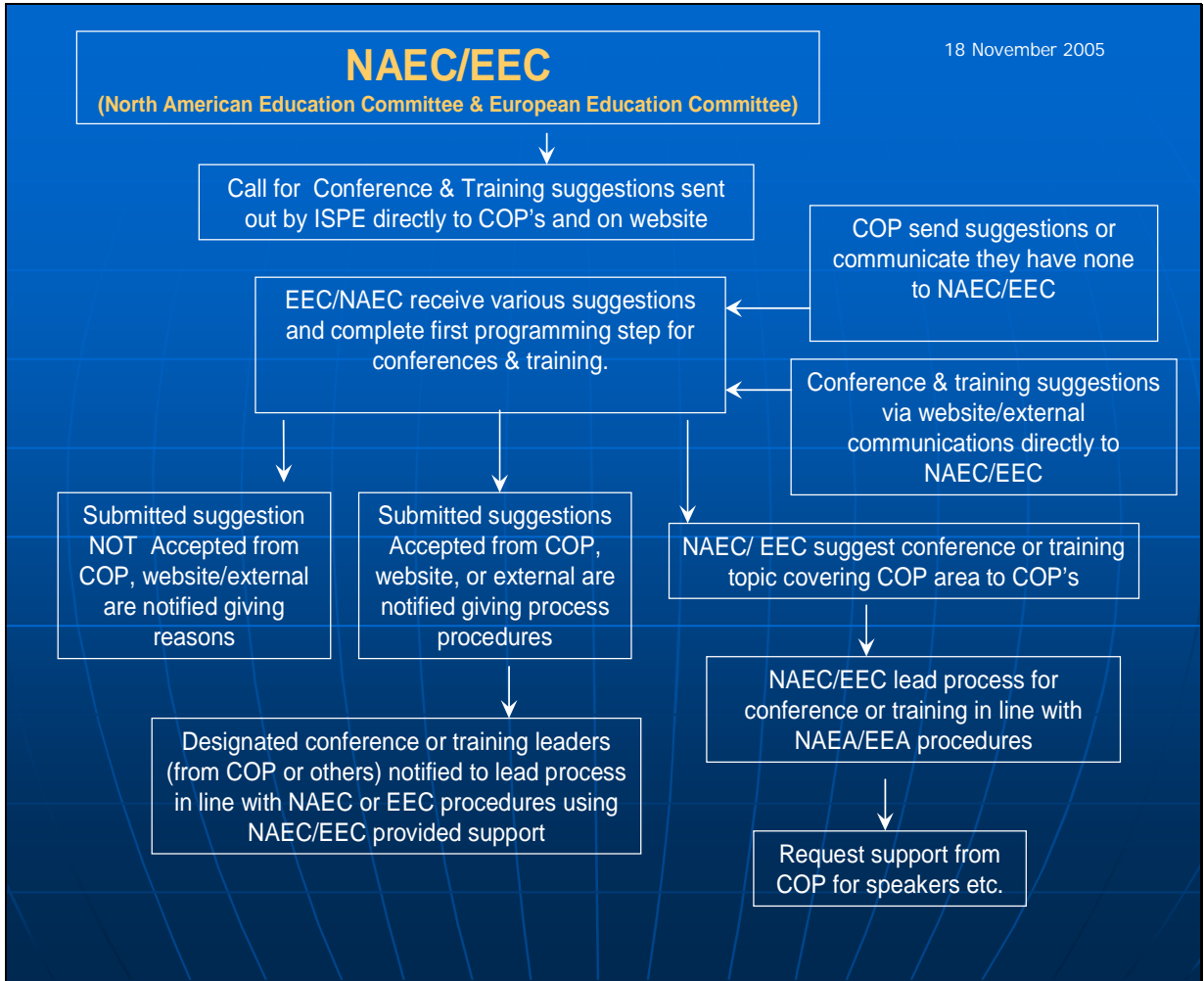
1. They define the market, identify the product, and identify the best people to deliver the product
2. Added member benefit and a means for getting new and existing members actively involved in activities of the Society

Benefits of COPs to companies are:

1. Development of a community-specific Body of Knowledge by subject matter experts
2. Ability to positively influence the pharmaceutical manufacturing profession
3. Generate new knowledge in response to problems and opportunities

⁶ APQC International Benchmarking Clearinghouse. *Building and Sustaining Communities of Practice: Continuing Success in Knowledge Management*. APQC 2001.

APPENDICES





COP ROADMAP FOR SUCCESS

ST = in the next couple of months

MT = 6 to 12

LT = 12 to 18 months

Define the ISPE COP Structure

- Structure within each COP:
 - Vision and defined scope – review and ensure it is current and published on web site **(ST – COP Volunteers)**
 - Revisit charter of COP to ensure goals align with needs of members
 - Succession plan and term length for COP leadership **(ST – COP Volunteers)**
 - Globally and balanced (industry / suppliers) steering committees **(ST – COP Volunteers)**
 - E-Letter contact **(ST – COP Volunteers)**
 - Technical document manager **(ST – COP Volunteers)**
 - Moderators for on-line discussions **(ST – COP Volunteers and ISPE)**
 - Identify and train Web content manager **(ST – COP Volunteers and ISPE)**
 - Identify Subject Matter Experts **(MT – COP Volunteers)**
 - Alignment with education and training **(MT – COP Volunteers and ISPE)**
 - Flesh out the existing Member Benefits document **(ST – ISPE)**
 - Adhere to process for adding new COPs **(ST – COP Volunteers and ISPE)**
 - Align local COPs with regions and affiliates **(LT – COP Volunteers and ISPE)**
 - Fully implement COP start-up guide **(ST – COP Volunteers and ISPE)**
 - Manage overlaps between COPs – define scope **(ST – COP Volunteers)**
 - Ensure that COPs are completely integrated with ISPE's overall vision **(LT – COP Volunteers and ISPE)**
 - Identify products that we need that we don't have'
 - COPs drive everything the Society does
 - COPs create overall vision for their area of expertise
 - COPs own all content within their area of expertise

Support from ISPE

- Update and utilize COP Operations Manual **(ST – ISPE)**
- Clarify relationships with COPs and other committees **(MT – COP volunteers and ISPE)**
- Create list of tools and resources needed to support COPs **(ST – COP Volunteers and ISPE)**
- Provide ISPE staff and resources to support expansion **(LT – ISPE)**
- Align COPs into the ‘taxonomy’ infrastructure of ISPE **(MT – COP Volunteers and ISPE)**

Recruit and Retain COP members

- Develop a communication strategy on benefits and ways to participate: **(MT – COP Volunteers and ISPE)**
 - Targeted to different audiences, e.g., COP members, broad membership, regions/affiliates
 - Section on COP site
 - Standard examples
 - Developing content
 - Public presentation of materials
 - Format for electronic and face to face presentations of materials
- Assemble leaders and high energy with ISPE members in the industry segment **(ST – COP Volunteers and ISPE)**
 - Refine existing welcome method being conducted by Business Initiatives by including volunteers
 - Short term work list
 - People see what we are working on; annual objectives
 - Align expertise and interest based on survey with getting objectives accomplished
- Enlist SME’s to manage the generation of technical content **(ST – COP Volunteers)**
 - Get commitment to foster, maintain, promote, create, and manage the various areas of content (E-Discussions, E-Letters, documents, articles, publications, on-line seminars, etc.)
 - Content needs to be reviewed in wider forum – need infrastructure to support this
 - Categorize content by ISPE member vs. non-member access and disseminate
- Provide list of standard volunteer opportunities **(ST – ISPE)**

Develop Communications Strategy

- Refine new member invitation and process overview. New members to be invited by COP leaders, introduced to the community, shown the tools, and provided an overview of resources and members
- Provide regular informal reports to COP members from each COP – what is going on, what has been accomplished, ways to become actively involved, upcoming activities and events, new content generated by the

COP. Should be “push” via email and posted to Web site (**MT – COP Volunteers**)

- Implement one-way E-Bulletin for each COP (**ST – ISPE**)
- Recognize participation by COP members (**MT – COP Volunteers and ISPE**)
 - Recognition on Web site – ratings by fellow members; COP member of the month
 - Celebrate successes
 - Thank you notes sent to COP member or their boss
 - Complimentary or discounted documents, products, etc.
 - List of new members every month on Web site
 - Photos of COP members on website
 - E-Letters, ISPEAK, and Informer
 - Face to face meetings
 - Get on agenda for one of conferences
 - Breakfast, COP night – networking focused, get on educational agenda
 - Update at Annual Meeting about what COPs are doing – Membership Luncheon
 - Should this include online collaboration for members that cannot attend?

COP Activities and Responsibilities

- Create ways for COP members to participate both personally and virtually (**MT – COP Volunteers**)
 - Develop Web site content and maintain up to date
 - Identify and train Web content manager
 - Develop approval process for what content is posted
 - Develop process for encouraging feedback on what content is posted and what additional content should be posted
 - Hold face to face general COP meetings
 - Hold virtual meetings and networking events via WebEx
 - Contribute to the development of ISPE Educational Conferences including seminars, sessions, and workshops
 - Contribute to the development of training courses
 - Assist ISPE in promoting and marketing education and training related to COPs
 - Give 5-minute COP presentations at Chapter/Affiliate events, training courses, conferences, general COP meetings, etc.
 - Hold face to face networking events at ISPE Conferences and Annual Meeting
 - Breakfast, lunch, roundtables, COP night
 - Present online seminars
 - Source content for ISPE E-Letters
 - Moderate and participate in E-Discussions

- Encourage members to make postings for information requests and have a dedicated leader or committee members coordinate connection and communication
- Write technical documents, Good Practice Guides, and articles for *Pharmaceutical Engineering* and *The Journal of Pharmaceutical Innovation*
- Form subcommittees to review articles related to COP topics
- For Annual Meeting, each COP should pick 1-3 hot topics in the field and have “high touch” content in place and proactively reach out to members
- During meetings, trainings, or conferences:
 - Share COP member success stories
 - Identify member knowledge and information needs
 - Acknowledge knowledge contributions, such as providing a plaque or letter from senior leader
- Develop organizational structure to manage technical content on long-term basis
 - Probably a subcommittee under COP Steering Committee
 - Administrator to make changes to content per the content SC

Identify and Enable Technology to Support COPs

- Create tips for using IT tool and give refresher courses during COP meetings
- Fully Implement and Use E-Discussions (**ST – ISPE and COP Volunteers**)
 - New user-friendly name to replace LISTSERV
 - Clear instructions for users – one page document
 - Simplify enrollment.
 - Choose topics and identify moderators
 - Train moderators in their roles
- COP Web sites (**ST – COP Volunteers and ISPE**)
 - Update Web site for each COP
 - Content must be current
 - Web site must be welcoming and friendly
 - Identify Web Content Manager to allow COPs to manage their own content
 - Organized process for developing content, each COP uses template, also for posting and downloading content
 - Provide training to COP member(s) responsible for COP web site
 - Maximize visibility and use of existing resources – online seminars, articles, content that already exists
- Develop Metrics to Monitor Success (**ST – ISPE**)
 - Use and implement Web trends – need to reconfigure.
 - Metrics of usage – activity, growth of usage.
 - Number of hits, replies, postings, downloads, uploads.

- Reissue survey one year from now
- **Develop URS (User Requirements Specification) for Long-Term IT Solution**
 - Identify and implement appropriate COP software (**MT – ISPE**)
 - Welcoming and community type Web interface
 - Create a roster of COP members
 - Ability for members to identify other COP members, and search by key attributes
 - Determine opt-in and access policies
 - Identify frequent contributors and subject matter experts
 - On-line meetings and chat sessions
 - Photos and bios of COP members
 - Access to data in COP and across ISPE
 - Search Engine that searches COPs and archived articles, publications, links to E-Discussions archives – capability to include natural language/key word search and advanced search features such as topic, by type, by discussion, by date and by location
 - Need structured searches and abstracts for the searches
 - Define the document repository and sharing process
 - Approval process for what content is posted
 - Process for feedback on content (e.g., responses, ratings, questions)
 - Content access policy: What is available for members vs. non-members
 - Document control and review process



ISPE TECHNICAL DOCUMENT PROPOSAL TEMPLATE

This document is intended for use by ISPE groups proposing the development of an ISPE Technical Document. All proposals for ISPE Technical Documents are managed by the ISPE Technical Documents Executive Committee (TDEC), following defined processes.

There are several categories of technical documents in which material can be published, including:

- Baseline Guides
- Good Practice Guides
- Articles
- White papers

The TDEC will determine the most suitable category of publication for a proposed document. Descriptions of existing publications are available on the ISPE Web Site and documents may be viewed at ISPE events.

USING THIS TEMPLATE:

NOTE: The final page of this template provides a blank proposal which must be completed and sent separately to the TDEC.

- The completed proposal should not exceed two pages.

1. Provide the full name of the ISPE group making the proposal and name and contact details of a liaison to the TDEC:

- Where a proposed document is accepted for development, the ISPE group will be responsible for helping to provide resources required to develop the document. This will include task team leads, contributing authors, and reviewers. The ISPE group is also expected to help oversee development of a document and provide time for the task teams to meet face to face during ISPE meetings.
- The liaison does not need to be the suggested task team lead. It should be someone who is sufficiently knowledgeable about the topic to present the proposal to the TDEC. The liaison also should be able to commit time to developing the proposal, where required, and working with the TDEC until links with the task team are established.

**2. Topics considered by proposed technical document:**

This should include a brief description of the topics which are expected to be covered by the document. Bullet points are acceptable. Any relationship to existing ISPE Technical Documents or other proposed documents should be detailed.

3. A working title of the proposed document should be supplied.**4. Reasons for the proposal:**

All new documents should have a 'pull' from industry, not be driven by an individual or groups. This 'pull' should be detailed in the reasons section of the proposal; e.g., a recognized need by industry for guidance in a specific topic area which the proposed technical document will help alleviate.

5. Potential benefits to the industry:

This section should describe how the document is expected to benefit industry, e.g., guidance on the implementation or interpretation of a new regulation/standard. It should also detail the sector, e.g., HVAC professionals, Quality Professionals, or Manufacturing, that is expected to benefit and at what level the document will be pitched, e.g., new employees or experienced personnel requiring specific information regarding the document's topic.

6. Suggested Task Team Lead(s)

If the ISPE group has a suggestion for one or more leads for the Task Team that will develop the document, their name, full contact details, (with geographical location) should be included.

It is preferred that at least one lead is from manufacturing (end user) company.

7. Where to send the proposal

The completed proposal should be sent via email to:

ISPE Publications: c/o Gloria Hall (GHall@ispe.org) with copy to Lynda Goldbach (LGoldbach@ispe.org)

8. What happens next?

The ISPE TDEC will consider the proposal and assign it to the appropriate subcommittee. Where possible, the subcommittee meets with the COP liaison, to discuss any questions or concerns. The subcommittee will determine whether the proposed document should be developed for publication and if so, the appropriate type of document, e.g., Good Practice Guide or Baseline® Guide.

The subcommittee will notify the ISPE group liaison of their decision.

ISPE COP Education Topic Submission Form

ENGINEERING PHARMACEUTICAL INNOVATION



Please complete this form to submit a topic to ISPE for any type of educational offerings (ie. conferences, training, web-learning, etc.). You will be notified upon decision.

1. Who is requesting the education?		
Name of COP or Group:		
Name:		
Title:		
Address:		
Postal Code:	City:	Country:
Phone:	Fax:	
Email Address:		

2. Proposed Topic Name(s):

3. What industry professionals or COP is this topic geared toward? For example, explain the need for this topic and how the topic is valuable to industry professionals.

4. Why is this topic relevant to the audience? Is it a “hot” industry topic? Please provide a list of what participants can expect to learn after completion of the offering. For example, at the end of this education, participants will be able to understand the basic principles of validation.

5. What is innovative about this topic?

ISPE COP Education Topic Submission Form

ENGINEERING PHARMACEUTICAL INNOVATION



6. Suggested Topic Length: 45 minutes 2-3 hours (or ½ day)
- 4-6 hours (or 1 day) 8-10 hours (or 1½ days) 10 -12 hours (or 2 days)

7. Suggested Type of Educational: Web Seminar On-line Training
- Training (venue-based) Conference Seminar Publication

8. In which language will the topic be delivered, specify?

9. Potential Leaders/Speakers on the topic

Lead/Speak?	Name:	Title:	Company:	Phone:	E-mail address:

10. Please add any additional comments that we should know concerning this request.

Submit this completed form by:

EMAIL: training@ispe.org

FAX: +1-813-264-2816

COP NETWORKING EVENT TEMPLATE

Guidelines

- Ideas for proposed networking events must be submitted to ISPE using this template. Required information includes indicating:
 - What type of event
 - Whether the event will be an informal cocktail hour or if a full meal will be served
 - What networking activities are being planned
 - Where the event should take place
 - Whether transportation is needed
 - Whether a formal program is being planned and if so, what type of program it is
 - What are the names and contact information for potential sponsors?
 - Whether restrictions on who can attend are being recommended. An example of this would be to limit attendees to only those attending the COP educational event
 - What the recommended time duration of the event is
 - Whether spouses (and children) should be permitted to attend
 - How many attendees are anticipated and what the figure is based on
- All ISPE COP events and should be proposed such that the opportunity exists for multiple COPs to participate if they choose
- Proposed COP events must not conflict with or potentially be confused with ISPE events.
- Proposed COP events must not take place at a time when the need for sponsors would redistribute regular ISPE sponsors accustomed to sponsoring at global ISPE events
- Proposals should be submitted in writing to Scott Ludlum, ISPE Director of Business Initiatives, at sludlum@ispe.org
- ISPE is to manage all logistical and business aspects of proposed networking events. Although COPs may make recommendations such as which sponsors to contact, which venue to choose, what type of entertainment is desired, what type of food and beverages are desired, etc., ISPE makes the final decision and contacts the appropriate entities to organize the event
- ISPE COP networking events are to be managed by ISPE with the necessary resources being allocated by ISPE
- As ISPE budgets for networking events at all global events, all expenses related to ISPE COP networking events must be covered by revenue generated by sponsors
- Admission is free to ISPE members while non-ISPE members pay a nominal administrative fee of US \$30

