



## Affiliate and Chapter Training Collaboration Model Pilot

### **Frequently Asked Questions**

This question and answer document has been developed to conveniently address many of the questions you may have concerning the Model's components.

#### ***How would the Affiliate or Chapter benefit from this program?***

We feel that this model will provide Affiliates and Chapters with an opportunity to provide more frequent education events and reduce the workload for volunteers who develop education products.

By utilizing the Affiliate and Chapter's knowledge about their members and their local marketplace, this model will provide the Affiliate/Chapter with another opportunity to generate additional revenue. Through customizing the delivery to the manner considered most beneficial for professionals in the local area, members will be able to increase their knowledge without needing to travel long distances.

Utilizing local instructors and ISPE's content will allow Affiliates and Chapters to reach a broader segment of their membership and potentially attract additional members. Through the selection of specific courses or course modules the Affiliate/Chapter will be able to quickly respond and deliver training that can influence product development and delivery, or provide workforce training or re-training, or to potentially meet the training needs for a newly built regional facility.

For example, course content can be delivered monthly, or in a series of weekly events, perhaps in multiple evenings, at a pharmaceutical company to meet the specific needs of their professionals, or in combination with another one of your events, or in combination with another Affiliate or Chapter.

#### ***Can we provide additional events with the training?***

Yes. We have collaborated with the Affiliates and Chapters to provide international training events and have found that supplementing training with Affiliate/Chapter sponsored evening seminars, table top exhibits, student poster competitions, special events or receptions has facilitated and developed mentoring relationships with current, new and potential members.

#### ***How are training courses developed?***

Subject matter experts who bring valuable and practical industry experience to each topic have developed ISPE's training courses. To date the training courses have been developed using North American and European experts. Many courses are designed to include case studies, workshop exercises and provide a blended learning experience - a combination of web-based and classroom learning.

#### ***What training topics does ISPE offer?***

The majority of the courses are two days in length with 12 hours of content. Some of our courses have also been reviewed by the corresponding Community of Practice to provide additional insight concerning the topic. Additional courses will be added to this list once they have been developed.

ISPE's body of knowledge includes the following training courses:

#### Auditing

- Auditing for GMP

#### 21 CFR

- Complying with Part 11 - Risk Management: Applying the GAMP Good Practice Guide Electronic Records and Signatures Principles

## Biotechnology

- Biopharmaceutical Manufacturing Facilities: Applying the Biopharmaceutical Manufacturing Facilities Baseline® Guide Principles
- Biopharmaceutical Manufacturing Processes: A Comprehensive Overview
- Biotechnology Basics
- Downstream Bioprocessing Calculations and Strategies
- Microbiology for Technical Professionals
- Process Validation for Biotechnology Manufacturing
- Upstream Bioprocessing Calculations and Strategies

## Commissioning and Qualification

- Basic Principles of Commissioning and Qualification: Applying the Commissioning and Qualification Baseline Guide Principles
- Application of Commissioning and Qualification: Applying the Commissioning and Qualification Baseline Guide Principles

## Facilities

- Facility Project Management in the Regulated Pharmaceutical Industry
- HVAC for Pharmaceutical Facilities (3-day course)
- Drug Manufacturing Facility Design and Development

## GAMP5

- Basic Principles of Computerized Systems Compliance: Applying the GAMP5® Guide: A Risk-based Approach to Compliant GxP Computerized Systems

## GMP

- GMPs - Beyond the Fundamentals
- GMP Fundamentals for the Pharmaceutical Industry
- Understanding International GMPs

## Manufacturing

- Clean in Place Fundamentals
- Cleaning Validation Principles
- Clinical Trial Materials: Applying Production, QA and Packaging Processes
- Containment Fundamentals
- Implementing Process Analytical Technology
- Practical Approach to Calibration: Applying the GAMP Good Practice Guide: Calibration Management Principles
- Q7A Essentials: Implementing Good Manufacturing Practices for Active Pharmaceutical Ingredients
- Sterile Drug Manufacturing Facilities: Applying the ISPE Baseline Guide and FDA Guidance Principles
- Technology Transfer for Active Pharmaceutical Ingredients
- Technology Transfer for Finished Dosage Forms, Oral Solids, and Sterile Liquids
- Oral Solid Dosage Forms: Process Monitoring Techniques and Challenges in Scale-up and Technology Transfer

## Validation

- Validation Documentation
- Validation of Automated Equipment: Applying the GAMP VPCS Guide Principles

## Water

- Pharmaceutical Water Generation
- Pharmaceutical Water Operation: Storage, Distribution, System Operation and Validation
- Pharmaceutical Water Systems: Regulations, Purification, Distribution and Validation (3-day European version)

***Does the Affiliate/Chapter need to deliver the course in the current 2-day format?***

No. Courses include 90-minute modules that provide 12 hours of teaching time. For example, each course contains a 90-minute module that can be delivered monthly, or a series of weekly events, perhaps in multiple evenings, at a pharmaceutical company to meet the specific needs of their professionals, or in combination with another one of your events. Affiliates/Chapters can license the entire course or individual modules to meet the needs of their membership and the local industry.

***Does ISPE offer Continuing Education Credits for the Collaboration courses delivered?***

No, we will offer a Certificate of Completion to each delegate. The Affiliate/Chapter will need to provide ISPE with a roster of the course delegates. We will then send a Certificate in a PDF format to each delegate via email.

***Can the Affiliate/Chapter translate the training materials?***

Yes. To ensure consistent delivery, selection of the translator will be made by the Affiliate and approved by ISPE. Review of the translated course materials including instructor notes and the course content will be completed by ISPE, the Affiliate and the instructor. The Affiliate/Chapter will pay for the translation. The Affiliate will provide ISPE with a final set of course materials and ISPE will retain ownership of the course materials

***Can the Affiliate/Chapter customize the ISPE course materials?***

ISPE realized that a new delivery method for our training materials needed to be developed and that minor customization of content is needed due to differences in regulatory or local industry approaches. If additional customization is needed then a scope of work must be developed with the original course developer, the Affiliate/Chapter and International will pay for the customization. All customization of the course content requires prior approval from International. ISPE will retain ownership of the customized course materials.

The Affiliate/Chapter agrees that any translation, modification of the course materials is owned by ISPE and that ISPE holds the exclusive rights to publish and sell the translation and/or modified materials. For the purposes of this Collaboration Model, the Affiliate/Chapter can reproduce the education materials and agrees that each page of the education materials will include "*Copyright © 2008 International Society For Pharmaceutical Engineering, Inc.*" Distributing the course materials via CD or posting it on an intranet or other electronic distribution is not permitted. Re-licensing of the course material is also not permitted.

***Do we need to use ISPE's instructors?***

Ultimately, yes. To ensure consistent global delivery of the content Affiliates and Chapters need to use ISPE instructors that are approved by ISPE. Although we have many instructors in our existing "faculty," we realize that training needs exist in areas where we do not have an instructor. When ISPE instructors are not available, we can utilize a local instructor identified by the Affiliate or Chapter who will complete ISPE's Instructor Qualification Process.

***How does the Instructor Qualification Process work?***

To successfully teach an ISPE course, instructors must be able to provide practical, current and pertinent information, apply real-world experiences and references to their classroom teaching. Individuals interested in teaching ISPE's training courses should have a minimum of six to ten years of relevant industry experience within their area of instruction. Once an instructor submits their credentials for consideration based on the guidelines below, the current ISPE instructors that teach the topic review the credentials and an interview is scheduled with the potential instructor.

Guidelines:

- A minimum of six to ten years of relevant industry experience within the area of instruction indicated on a CV or resume, or, a minimum of two to three years teaching experience within academia as a professor or instructor at the university level is acceptable.
- A list of relevant case study material, articles written and/or examples of hands on experience with the topic.
- A letter from the instructor's employer allowing them to travel to national and international training events to teach.
- Three letters of recommendation or three references including their relationship to the instructor, their titles and contact information.

***Who will acquire a signed agreement from the instructor?***

ISPE will acquire a signed agreement from the instructor to ensure that instructors adhere to ISPE's legal requirements. Affiliates and Chapters can then negotiate with individual instructors to determine a fee for the training.

***Can Affiliates and Chapters use the course materials for a train-the-trainer session?***

No. The course materials have been developed and maintained by ISPE and are ISPE's intellectual property that is protected by copyright. To ensure that we consistently deliver high quality education products, we will qualify and train any potential trainers.

***Can we use the materials to provide on-site training for local companies?***

Yes. ISPE currently has an On-site Training Program that provides customized content to global companies based on our existing courses utilizing our current faculty. We would like to explore this option further and lead the development of current industry specific content for local delivery.

***Can we license ISPE's webinars?***

Yes, the following webinars are available for licensing. Each webinar is approximately 60 minutes.

These recorded Webinars provide intermediate knowledge on a specific topic for mid-career professionals. They have been developed to help individuals who want to supplement their knowledge in preparation for the [Certified Pharmaceutical Industry Professional](#)<sup>SM</sup> (CPIP<sup>SM</sup>) examination, or gain diverse pharmaceutical industry knowledge.

The [Certified Pharmaceutical Industry Professional](#)<sup>SM</sup> (CPIP<sup>SM</sup>) credential recognizes "change agents" as the necessary ingredient to foster industry innovation and enhance drug product quality. The credential establishes a global competency standard for industry professionals, and candidates are assessed through demonstrated education, experience, and a rigorous examination. Completion of any of these seminars does not guarantee successful completion of the [CPIP certification exam](#), and these seminars do not include every subject to the depth of what will be covered on the CPIP exam.

Product Development:

- Formulation, Clinical Phases, and Manufacture
- Technology Transfer
- Production Scale-up and Optimization

Facilities and Equipment:

- Design and Construction/Installation
- Commissioning and Qualification as a Risk Management Strategy
- Operation Maintenance
- Controls and Automation

Information Systems:

- Information Systems

Supply Chain Management:

- Materials Management
- Operational Economics (in development)
- Warehouse and Distribution Management

Production Systems:

- Production Unit Operations - drug (small molecule) and biologics
- Production Management
- Production Control

Regulatory Compliance (Includes drugs, environmental, health, and safety):

- Government Regulations (in development)
- Standards, Practices, and Guides

Quality Systems:

- Risk Management and Quality Management Systems
- Systems Validation

***How can the Affiliate/Chapter benefit from licensing these webinars?***

The webinars are an additional opportunity to provide more education programs for the Affiliate/Chapter members and generate additional revenue.

These pre-recorded one-hour webinars provide downloadable presentations, hot links and contain extensive exercises to reinforce the key learning objectives for each topic. They were designed for individuals that need specific information about the pharmaceutical industry in preparation for the CPIP® credential or for individuals that want to supplement their existing industry knowledge.

Affiliates/Chapters can utilize the webinars in a book-club format where participants can view the webinar(s) prior to the event or at the event and discuss the topic in depth.

***What is the cost to License one of the webinars?***

Please see the *Per Delegate Option* within the Financial Options for the details.

***What are the technical requirements for viewing a webinar?***

A computer with an Internet connection (56K or faster) and

- Microsoft Windows 98 SE, XP, 2000, Windows Vista Home Basic, Home Premium, Ultimate, Business, or Enterprise (32-bit or 64-bit editions)
- Intel Pentium 166 MHz or faster processor
- Minimum of 32 MB RAM (64 MB recommended)
- Microsoft Internet Explorer 5.0 or later, Netscape Navigator 7.1, AOL 9, or Mozilla Firefox 1.5
- JavaScript enabled on the Web browser
- 56K or faster Internet connection

Prior to viewing the Recorded Webinar, the Adobe Flash Player must be installed on your computer. If the Flash Player is not installed you will be prompted to install the play from the Adobe website.

***Does ISPE offer Continuing Education Credits for webinars?***

No, we will offer a Certificate of Completion to each delegate. The Affiliate/Chapter will need to provide ISPE with a roster of the registered participants. We will then send a Certificate in a PDF format to each delegate via email.

## **Financial Models**

ISPE has developed four options to facilitate the delivery of training by Affiliates and Chapters.

1. The **Module Option** provides Affiliates/Chapters with the ability to select the individual modules they feel will best meet the needs of their local members. The fee will be used to maintain the inventory, develop new training modules and defray the project management costs for the successful delivery of the training. Any excess revenue from the delivery of each training event belongs to the Affiliate/Chapter. The fee for one module is \$500. The module can be delivered as many times as desired through 31 December 2009.
2. The second model, **Course Option**, provides Affiliates/Chapters with additional content (a two or three day training course with eight to twelve 90-minute modules) that can be delivered monthly, weekly or in any classroom training manner that meets the needs of the local marketplace. The fee will be used to maintain the inventory, develop new training courses and defray the project management costs for the successful delivery of the training. Any excess revenue from the delivery of each training event belongs to the Affiliate/Chapter. The fee for one course is \$4,000. The course can be delivered as many times as desired through 31 December 2009.
3. The third model does not require an immediate financial commitment. With the **Per Delegate Option** Affiliates/Chapters can utilize any number of courses in whole or in part (modules) and deliver them within their regions and provide ISPE with a share of each event's revenue based on the number of participants. Any excess revenue from each training event belongs to the Affiliate/Chapter. The fee will be used to maintain the inventory, develop new training modules and defray the project management costs for the successful delivery of the training. Any excess revenue from the delivery of each training event belongs to the Affiliate/Chapter. The per delegate fee for each event is 25% of the registration fee, the registration fee will be set by the Affiliate/Chapter. The module, course or webinar can be delivered as many times as desired through 31 December 2009.
4. With the **Royalty Sharing Option** (only for available for Affiliates in South America and Asia Pacific) Affiliates can deliver a two or three day training course with one instructor to their members and non-members. Since the Affiliate and International split expenses and revenue there is no fee for this option. To utilize this option the Affiliate must submit a detailed budget for the event for prior approval and adhere to the mutually agreed upon final budget before delivering the training.

### **What does the fee include?**

The fee includes the following items that can be provided electronically:

1. The detailed course description and marketing materials including sample marketing brochure, postcard and one page flyer templates.
2. The complete course materials including agendas, welcome letter, instructor biography, case studies and exercises including answer keys, instructor speaking notes, and an evaluation form
3. Instructor Survey for AV Requirements.
4. The course materials checklist for duplicating the materials.
5. An on site event checklist.
6. A post event Instructor Debrief Form.
7. A course roster form.

### ***Some of the courses use a technical publication, a Baseline Guide®, a USFDA Mini-regulation or a Good Practice Guide; will they be included in the fee?***

No. The publications will be provided at a significant discount to the Affiliates/Chapters. The cost of the publications should also be included within the registration fees set by the Affiliates/Chapters for each training event.

### ***Who pays the instructor's fees and expenses?***

The Affiliates/Chapters can negotiate instructor compensation directly with instructors and compensate them for services rendered.

***What is the Affiliate/Chapter responsible for?***

Selecting the topic, promoting the event, securing the venue and venue costs, registration management, instructor fees and expenses, duplicating the course materials, managing event logistics and all expenses.

***Can ISPE help the Affiliate/Chapter market the course?***

Yes. We can support your efforts by including your upcoming events within our training and conference brochures, on the global Society calendar, electronic outreach through *Ispeak* (the Society's bi-monthly Members only newsletter), and *Informer* (the Society's monthly electronic bulletin board for Members and non-members) and an inclusion in the Society's Members only journal, *Pharmaceutical Engineering*. To ensure inclusion we must have all the event details at least four months prior to the event.

***Can International help the Affiliate/Chapter by providing additional support?***

Yes, for specific tasks we can provide additional support and will negotiate those costs before the event. For example, if the Affiliate/Chapter feels International would be better suited to handle the promotional aspect of the event, like a dedicated email blast, or registration, the services can be arranged for a fixed fee, or a different Collaboration Model can be chosen.

***If individuals attending the training event want to become Members, do we send the memberships to International?***

Yes. If new memberships are acquired as a result of the training event, the application and fees must be sent to International for processing within five (5) days of the completion of the education event. Please make sure that the Member fully completes the application and selects your Affiliate or Chapter as their preference.

## **Getting Started**

### ***How does the Affiliate or Chapter start the Collaboration process?***

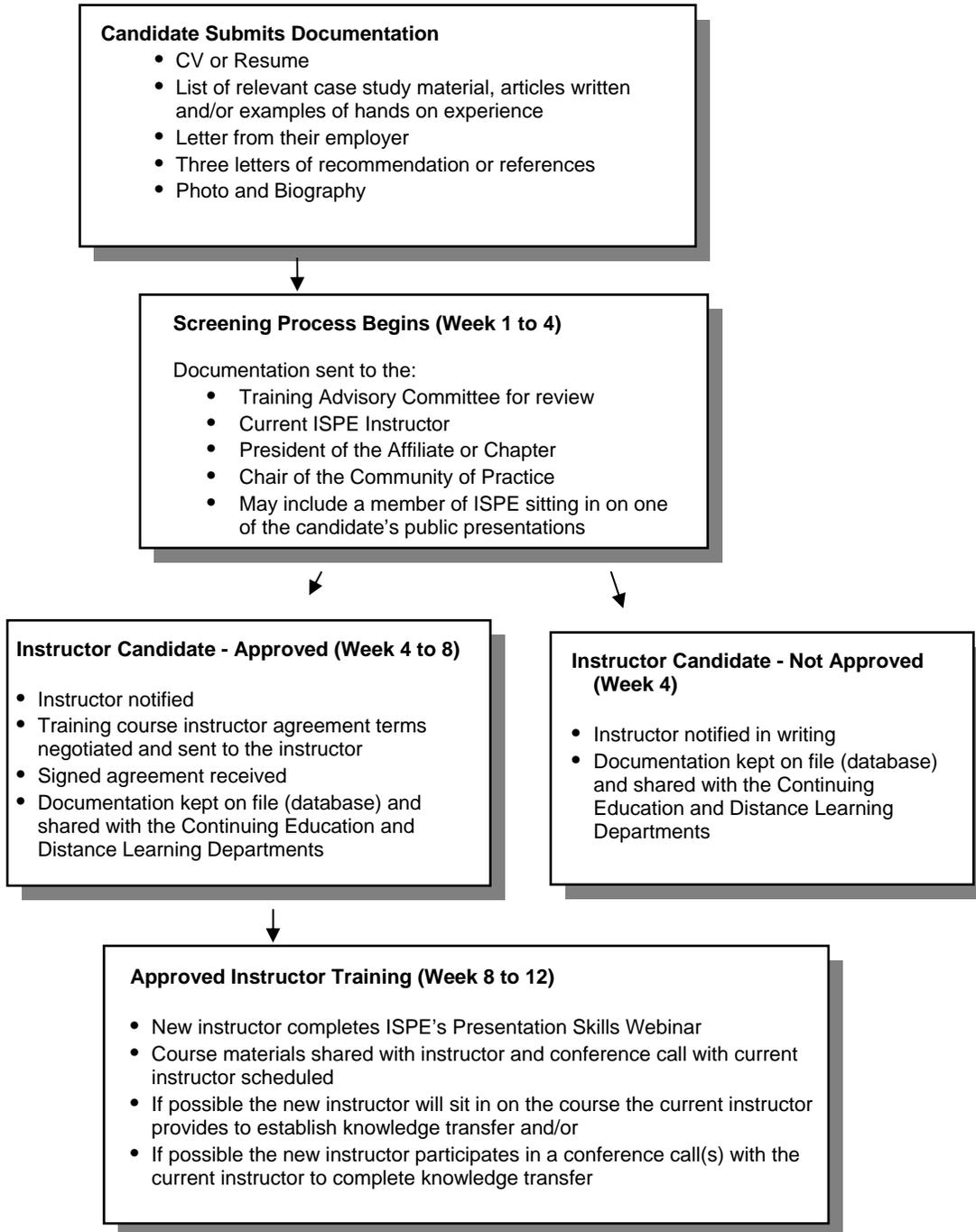
We encourage you to share this Collaboration Model with your education committee to select a topic that is best suited for your region. Some Affiliates and Chapters have found it helpful to survey their members to better determine which topics they prefer. We can provide you with detailed course descriptions and module names to facilitate your efforts.

Once a topic is identified then:

- Affiliate/Chapter contacts International to reserve a date on the International Education Schedule.
- Affiliate/Chapter will research competitors to ensure there are no conflicting competitor activities.
- International contacts the instructor or acquires the names of potential instructors from the Affiliate/Chapter.
- If a local instructor is not available then International begins the Instructor Qualification Process.
- If course customization is required, a Scope of Work and deadlines will be negotiated with Affiliate/Chapter, the developer, instructor and International.
- If course material translation is needed, a Scope of Work and deadlines will be negotiated with the Affiliate/Chapter, the developer, instructor and International.
- International provides instructor fees and estimated travel costs for Affiliate/Chapter budget if an instructor from the international faculty will be used and for which ISPE has already negotiated a fee.
- Affiliate/Chapter will select a venue for the training and is responsible for food and beverages, audio visual and any other venue expenses.
- Affiliate/Chapter sets delegate fee for the event and provides International with a budget.
- International will update ISPE and the Affiliate/Chapter web pages with the event information.
- Course materials and all deliverables are sent to the Affiliate/Chapter electronically.
- Affiliate/Chapter will send the class roster to International who will provide Certificates of Completion electronically to course delegates (if necessary, International can provide a certificate template that the Affiliate can translate and issue to attendees).
- Affiliate/Chapter will send course evaluations and the Instructor Debrief Form to International for processing.
- Affiliate/Chapter will send completed new member applications and revenue to International for processing.
- Affiliate/Chapter will provide Collaboration fee to International

## General Information

### Instructor Qualification Process Flow Chart



## Collaboration Model Components At-A-Glance

<b>Instructor</b>	
Instructor Selected and Trained (from a pool of national and international instructors) by:	ISPE
Instructor Fee Paid by:	Affiliate
Travel Expenses Paid by:	Affiliate
<b>Training Date(s)</b>	
Selected by:	ISPE and the Affiliate
Fee for the Training Events set by:	Affiliate
<b>Venue</b>	
Selection and Contracting of Venue Completed by:	Affiliate
Breakfast, Lunch, Breaks and Reception costs covered by:	Affiliate
Event Logistics Checklist With Instructor Needs Sent from ISPE to:	Affiliate
<b>Topic</b>	
Selected by:	ISPE and the Affiliate
<b>Course</b>	
Content Owned by:	ISPE
Course Materials sent by ISPE to:	Affiliate
Customization Costs Incurred by:	Affiliate
Amount and Type of Customization Required:	ISPE, Affiliate, instructor and original developer of the course will discuss the amount and type of customization and agree upon a detailed scope of work.
Customized Course Materials Reviewed by:	ISPE, Affiliate, instructor and the original developer.
Customized Course Materials Owned by:	ISPE
Course Material Duplication Costs Incurred by:	Affiliate
Discounted ISPE Publications Purchased by the:	Affiliate
Simultaneous Interpretation made by:	Affiliate
Selection of Course Material Translator made by:	ISPE and the Affiliate
Translation of Course Materials paid by:	Affiliate
Ownership of Translated Materials:	ISPE
Review of Translated Materials:	ISPE, Affiliate, Instructor, Developer
Certificates of Completion Provided by:	ISPE
Course Evaluations Returned to:	ISPE
<b>Complimentary Attendance</b>	
Cost of 1 or 2 committee members to audit the event paid by:	Affiliate
Cost of Education Committee or Affiliate Board members attending the event paid by:	Affiliate
<b>Marketing Material</b>	
Overall Marketing Planning:	Affiliate
Marketing of the Event Conducted by:	Affiliate
Content Provided by:	ISPE and the Affiliate
Brochure and Flyer Designed by and Approved by:	ISPE and the Affiliate
Brochure Printed by:	Affiliate
Web Page Updated with Brochure by:	ISPE
Email Blasts to Promote the Event:	Affiliate
<b>Membership</b>	
Membership Applications and Membership Revenue Sent to:	ISPE
<b>Project Management Costs</b>	
Project Management Costs Paid by:	Affiliate

We would be delighted to have an opportunity to work with the Affiliate or Chapter to further expand the reach of ISPE's training body of knowledge and meet the needs of a global pharmaceutical industry. Please indicate which model will work best for the Affiliate or Chapter below.

As always, we look forward to working with you on this exciting new project. Please do not hesitate to contact me at 813-960-2105 if you have any additional questions or concerns.

Cordially,

Alicia Montes  
Director of Training

We would like to use the following model:

	Module Option - \$500
	Course Option - \$4,000
	Per Delegate Fee - 25%
	Royalty Sharing (Only available for South America and Asia Pacific)

Name of the course or webinar: \_\_\_\_\_

Potential training dates: \_\_\_\_\_

Proposed instructor: \_\_\_\_\_

Your signature indicates that we can proceed to implement this pilot of the ISPE *Affiliate and Chapter Training Collaboration Model*.

\_\_\_\_\_  
Affiliate/Chapter Name

\_\_\_\_\_  
Affiliate/Chapter

\_\_\_\_\_  
Date