

## ISPE Communities of Practice (COPs)

ISPE implemented Communities of Practice (COPs) recognizing the challenge of the pharmaceutical industry to achieve continuous improvement. COPs are groups of people that share a concern or a passion about a topic, and who deepen their knowledge and expertise by interacting on an ongoing basis. ISPE's COPs enable colleagues in specific disciplines to rapidly exchange information and solutions to everyday problems by virtue of online community discussions on the COP websites. Through professional networking and peer collaboration, ISPE COPs produce discipline-specific content that expands members' knowledge and expertise, increases quality, and strives for continuous advancement in the industry.

## SPP COP Membership Has Its Professional Benefits:

You can access and contribute to the development of best practices in Sterile Products Processing by joining the **Sterile Products Processing Community of Practice (SPP COP)**. The SPP COP is an active community concerned with the guidance of the handling of final sealing and aseptic processing technologies that continue to develop every year with changes to regulations.

Other valuable SPP COP membership benefits include:

- Excellent networking opportunities with fellow SPP professionals
- Opportunities to engage in detailed technical discussions with leading technical experts
- Participate in developing practical guidelines that benefit individual companies and the industry in general
- Keep current with the latest trends and innovative thinking in both the industry and regulatory arenas
- Obtain current news and learn about upcoming SPP community activities

## SPP Guidance

The SPP COP is currently focused on the development of the revised ISPE *Sterile Products Processing Baseline® Guide*, Vol. 3. Additionally, areas of interest and respective subjects include:

- GMPs and their guidance
- Collation/collection of interpretation of GMPs
- Cleanroom standards and technology
- Air filtration
- Media fills (process simulation)
- Environmental Monitoring (particles and micro)
- Isolators
- RABs

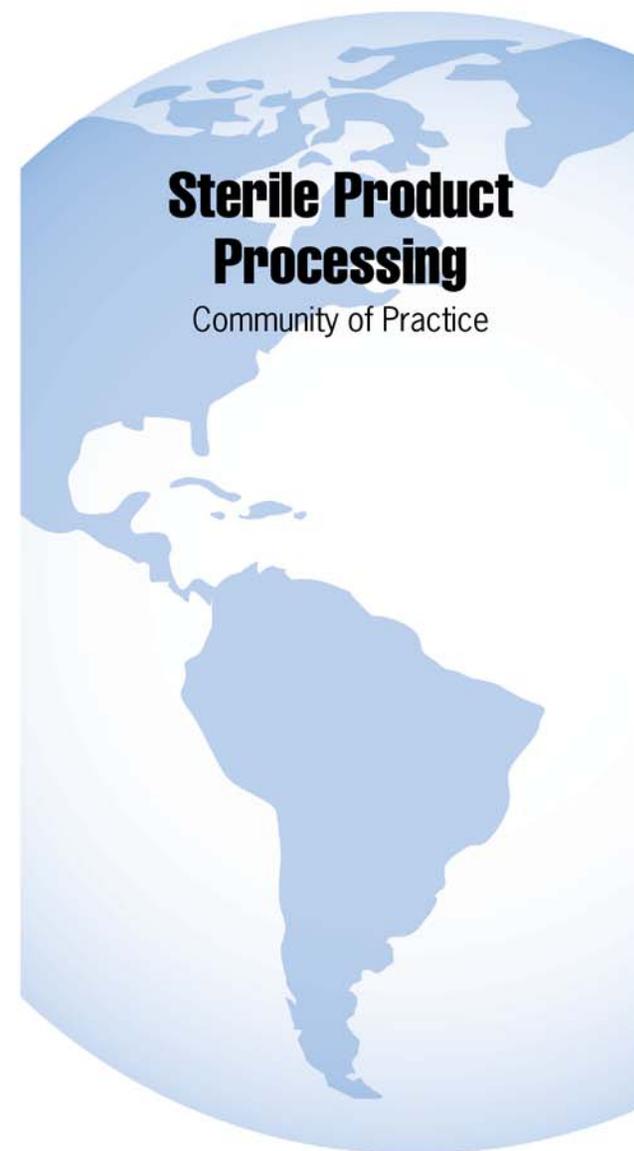
The SPP COP produces Knowledge Briefs, webinars, and educational programs to benefit its members and to share relevant information related to SPP COP issues.

## To Become a Member of this Exciting COP and to Begin Participating Immediately

1. Go to [www.ISPE.org/SPPCOP](http://www.ISPE.org/SPPCOP).
2. Click on the Discussions tab, or any other content tabs of interest. Note you must be a SPP COP member and log in to participate in the discussions.
3. To join the SPP COP go to [www.ISPE.org/cops](http://www.ISPE.org/cops) and click "Join a COP."
4. Then, scroll down to the SPP COP and place a check mark in the box.
5. Click the "Join" button at the very end of the page to confirm your membership in the SPP COP.

Membership in ISPE's SPP COP is complimentary for ISPE Members. Join today to access discussions, tools, and all resources offered by ISPE COPs.

[www.ISPE.org/SPPCOP](http://www.ISPE.org/SPPCOP)



## Development of the SPP COP

ISPE's Sterile Products Processing Community of Practice (SPP COP) was formed in 2005 to provide ISPE members with a proactive forum to support all facets of SPP. The SPP COP allows members to access relevant information through education, training, and discussion forums. The SPP COP enables members to engage in regulatory cooperation and establish links to internal and external groups with common interests.

## Mission of the SPP COP

The SPP COP aims to establish and manage a forum that supports all facets of sterile products processing; enables common interest discussions; provides access to relevant information; and supports member networking opportunities. The SPP COP core competencies are related to design, operation, maintenance, and qualification of sterile manufacturing facilities and sterile manufacturing processes. The SPP COP is a primary influence and contributor to the ISPE *Sterile Manufacturing Baseline® Guide*.

### SPP COP Organizational Structure



## Ways to Get Involved with the SPP Community of Practice

The SPP COP has more than 2,500 members representing the areas of Asia-Pacific, Europe, and North America. The SPP COP is active in the field of sterile products manufacturing and has developed a Baseline® Guide related to sterile products facilities to help amplify the requirements expressed in the GMPs.

There are many ways for COP members to contribute to and learn from the SPP community and Body of Knowledge. By visiting the SPP COP website members can:

- Access *Community Discussions* monitored by SPP COP Steering Committee members to ask questions, share expertise, and find solutions to company and industry-related problems.
- Read technical articles in the most recent editions of the SPP COP E-Letters.
- Download presentations, articles, and other relevant documents.
- Search for SPP COP members by name, company, Affiliate or Chapter, country, etc.
- Easily and conveniently access SPP guidance documents, articles, and other valuable resources.

With so many ways to connect with SPP COP members and access valuable technical knowledge, there is no reason not to get involved. Visit [www.ISPE.org/SPPCOP](http://www.ISPE.org/SPPCOP) today and begin participating in your Community of Practice!

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## Information Provided By How the SPP COP Benefits Members and the Industry

The SPP COP was fundamental during the 2006 review of proposed changes to Annex 1 EU, GMP, with the objective of achieving reasonable international harmony to create consistent pharmaceutical operations worldwide.

The SPP COP also advocates improving the language and clarity of the SPP documents to ensure effective global understanding. One main goal of the SPP COP is to harmonize existing SPP practices with ISO and FDA guidelines.

The SPP COP encourages SPP best practices contained in the *Sterile Manufacturing Facilities Baseline® Guide*, which is designed for use by industry for the design, construction, commissioning, and qualification of new or renovated aseptic/sterile manufacturing facilities. This guide also incorporates facilities for both aseptic processing and terminal sterilization of formulated products, which are generally for parenteral use. It is applicable to formulations that use active ingredients devised from either conventional chemistry or biopharmaceutical processing. The guide is intended primarily for regulatory compliance in the US market, and it also may be helpful to manufacturers for meeting European requirements.

Since its inception, the SPP COP has been successful in disseminating SPP educational programs globally with presentations being given in Barcelona, Berlin, Brussels, China, Edinburgh, Japan, India, London, Paris, Prague, Strasbourg, Singapore, and Zurich. Presentations have also been made in the US during ISPE's Tampa and Washington Conferences, as well as at the Annual Meeting.