



2024

ANNUAL REPORT

EXECUTIVE SUMMARY

ISPE ascended to new heights in 2024, engaging its membership base of more than 22,000 members—spanning from more than 120 countries from the Americas to Europe to Asia Pacific and beyond—addressing critical industry challenges and pursuing opportunities for continued improvement. ISPE expanded its global reach, with ISPE's thriving network of 40 Affiliates and Chapters welcoming two new petitioning Affiliates, the ISPE Greece and Cyprus Affiliate and the ISPE Middle East Affiliate.

ISPE made significant strides in supporting the pharmaceutical industry's pursuit of digital transformation in 2024, focusing on providing strategic guidance on the exploration and potential implementation of artificial intelligence (AI). ISPE announced ISPE AI® and launched the global ISPE Artificial Intelligence Community of Practice (CoP) in mid-2024. ISPE further enriched its CoP offerings with the launch of the ISPE Sustainability CoP.

In 2024, ISPE produced six ISPE Guidance Documents—covering a wide range of topics, including 503A compounding and unique identification of glass primary containers. ISPE's *Pharmaceutical Engineering*® magazine also delivered impactful articles for ISPE members in 2024—receiving an APEX Award for the fifth consecutive year.

Regulatory engagement remained a cornerstone of ISPE's achievements. ISPE provided more than 11 draft regulations or guidance in response to health authorities' invitations for commentary. Regulatory participation at ISPE events increased significantly in 2024, with over 350 regulatory attendees from 44 diverse countries.

ISPE celebrated the pinnacle of pharmaceutical innovation through the prestigious Facility of the Year Awards (FOYA) program, recognizing companies that have redefined operational excellence, sustainability, and cutting-edge design. The six companies recognized in 2024 set new benchmarks for the industry in innovation, operations, social impact, and more.

ISPE has long been known for its commitment to education—this year was no exception. Through ISPE's collective efforts, ISPE reached over 12,500 professionals through webinars, while more than 2,000 attendees participated in ISPE's in-person and virtual conferences.

Across the globe, ISPE qualified instructors representing over 10 countries delivered professional development courses to more than 1,300 attendees. ISPE also trained regulatory agencies all over the world and hosted four hands-on training courses at the European Aseptic and Sterile Environment (EASE) training center.



In 2024, ISPE supported the industry in workforce development in various ways—fueling the future of the industry by awarding 37 professional development grants to students and recent graduates, connecting its members with over 400 applicants to the Mentor ISPE program, and more.

ISPE is immensely grateful to its community of supporters. We are proud of what we are contributing to the industry and excited about what's to come. Thank you for helping us continue to Shape the Future of Pharma™.





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2023-2024 ISPE

INTERNATIONAL BOARD OF DIRECTORS

OFFICERS

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CRB*

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*Vice President, Global Quality Systems
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Moderna*

Ylva Ek

SECRETARY

*Founder
Robur Life Science Advisory AB*

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IMMEDIATE PAST CHAIR (January-September 2024)

*Interim President and CEO (August - December 2024)
ISPE
Principal/CEO/Owner
Rutherford Consulting, LLC*

Thomas B. Hartman

EX OFFICIO NON-VOTING MEMBER

*President and CEO (January - August 2024)
ISPE*

DIRECTORS

Nina S. Cauchon, PhD

*Director Regulatory Affairs - CMC
Amgen Inc.*

David Churchward

*Head of Operations Quality
Compliance and External Affairs
AstraZeneca*

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*Senior Director, Global Engineering
and Technology
Johnson & Johnson*

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Genesis AEC*

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*CEO
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*Executive Director, CMC
Regulatory Affairs
Gilead Sciences, Inc.*

Teresa Minero

*Founder and CEO
LifeBee*

Georg Singewald, PhD

*Global Head of Quality and Compliance
Roche/Genentech*

Hirofumi Suzuki, PhD

*Regulatory Affairs CH Japan
Bayer Yakuhin Ltd.*

Timothy J.N. Watson, PhD

*Vice President, Head of CMC Regulatory Affairs
Gilead Sciences, Inc.*

EX OFFICIO

Monique Sprueill, PMP

**EMERGING LEADER REPRESENTATIVE
NON-VOTING**

*Director, GCP Quality Lead
Bristol Myers Squibb*

2024 ISPE AT-A-GLANCE

The global ISPE community continued to thrive in 2024, with 22,000 members and more than 1,000 volunteers dedicating countless volunteer hours to meet with regulators, develop Guidance Documents, provide training courses and webinars, contribute to conference programming, and more.

22,000+

Members Worldwide

120

Countries Represented

6

International
Conferences

275+

Presentations

500+

Speakers

6

Facility Tours

38

Webinars



40 Affiliates and Chapters

With the addition of two petitioning chapters, the ISPE Greece and Cyprus Chapter and the ISPE Middle East Chapter



6 Guidance Documents

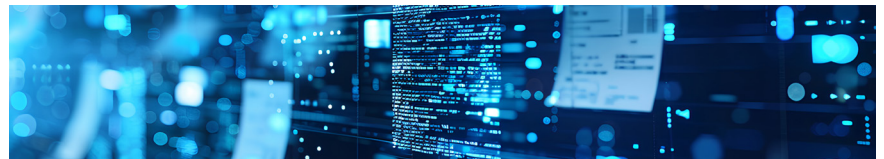
- Involving nearly 250 volunteer authors and reviewers
- Revisions to key ISPE Guides including:
 - [Good Practice Guide: Heating, Ventilation, and Air Conditioning \(Second Edition\)](#)
 - [GAMP® Good Practice Guide: Computerized GCP Systems and Data \(Second Edition\)](#)
 - [Good Practice Guide: Ozone Sanitization of Pharmaceutical Water Storage and Distribution Systems \(Second Edition\)](#)
 - [Good Practice Guide: SMEPAC – Standardized Methodology for the Evaluation of Pharmaceutical Airborne Particle Emissions from Containment Systems \(Third Edition\)](#)





Communities of Practice (CoPs)

- Expanded to include 22 active technical communities and additional communities with the introduction of:
 - Sustainability CoP
 - Artificial Intelligence CoP
- 1,000+ active volunteers
- On the ISPE Engage platform, CoP discussions generated 1,364 posts, with a significant contribution of 345 new discussion threads in 2024



6 Issues of *Pharmaceutical Engineering*[®] featuring:

- 171 authors
- 117 articles, including 47 technical articles
- Leading to an APEX Award for Publication Excellence for the fifth year in a row, on the topic of AI

ISPE Foundation

37 professional development grants awarded to students and recent graduates from 15 countries in 2024



TRAINING CONDUCTED

- 325 registrants for on-demand courses
- 50 online live courses
- 24 custom courses
- 8 in person courses



INDUSTRY-CRITICAL INITIATIVES

Enabling Pharmaceutical Innovation

In 2024, ISPE's Enabling Pharmaceutical Innovation team released the "[Report on the Barriers to Innovation Survey](#)", presenting the results of a 2023 survey on challenges and barriers in developing and implementing innovative technologies, with particular attention to regional regulatory divergence in the interpretation and implementation of ICH guidelines and control strategies. The team also published [case studies](#) illustrating the findings. The report includes conclusions and recommendations and will inform the team's approach to collaborate with regulatory authorities to address how to improve introduction, adoption, and implementation of new technologies.

Advancing Pharmaceutical Quality (APQ)[™]

ISPE's APQ team launched a training course on using [APQ](#), a quality management maturity assessment and benchmarking program that provides a practical set of tools and systematic approaches for organizations to advance the effectiveness of their pharmaceutical quality systems. The program is aligned with international initiatives that promote quality excellence, as well as with the US Food and Drug Administration's (US FDA) focus on quality management maturity and rating the maturity of manufacturing facilities.

ISPE AI and Artificial Intelligence Community of Practice

ISPE announced [ISPE AI](#)[®] in 2024, which seeks to aid the pharmaceutical industry in realizing the potential of AI. The initiative encompasses a multifaceted approach to supporting the industry in AI readiness, beginning with the launch of the ISPE AI CoP. Since its launch, the AI CoP Steering Committee has organized three AI CoP subcommittees around the following topics: (1) applications, models, and data, (2) preparedness and workforce, and (3) regulatory. The AI CoP Steering Committee is also collaborating on ISPE content generation plans and is building upon the endeavors of the ISPE GAMP(R) AI/Machine Learning (ML) Special Interest Group, and ISPE's Pharma 4.0[™] the industry's adoption of digitalization strategies and AI/ML technologies.

Sustainability Community of Practice

ISPE also announced the launch of the ISPE CoP on Sustainability in 2024. Members of ISPE Sustainability CoP aim to bring forward solutions for the industry's unique challenges related to sustainability. This includes gathering insights and engaging in data and knowledge-sharing with the pharmaceutical community. The CoP offers members the opportunity to collaborate with the 21 existing ISPE global technical CoPs to deliver solutions in the area of sustainability, leveraging existing resources such as the [ISPE Baseline Guide: Biomanufacturing Facilities \(Third Edition\)](#) and exploring pertinent topics like the influence on reduction of energy consumption in facility design.

Custom Trainings at the EASE Facility

In 2024, ISPE introduced a new offering for [customized, private training events](#) at the European Aseptic Sterile Environment (EASE) in Strasbourg, France. This initiative combines ISPE's world-class training content with the hands-on experience available at EASE, providing pharmaceutical manufacturers with a unique opportunity to train their employees without compromising their GMP environment.

ICH-Focused Training Opportunities

Additionally, in 2024, ISPE launched several on-demand training programs focused on ICH guidelines one through ten. These programs provide comprehensive, self-paced learning opportunities that cover critical aspects of pharmaceutical development and manufacturing. These on-demand training programs provide a valuable resource for pharmaceutical professionals seeking to enhance their knowledge and skills while maintaining compliance with international standards.

REGULATORY AFFAIRS

ISPE enhanced its regulatory engagement efforts in 2024—delivering a survey report on barriers to innovation which supports regulatory harmonization, increasing regulatory participation at ISPE events, and more.

Members of ISPE's committees, working groups, and initiatives engaged in the following:

- Conducted training sessions for Singapore's Health Sciences Authority (HSA) on ICH Q12 implementation with participation from the US FDA
- Presented at meetings with global health authorities, including:
 - The Annual Meeting of the [EMA's GMP Inspectors Working Group](#) with Interested Parties (March 2024)
 - The EMA Quality Innovation Group (QIG) Listen and Learn Focus Groups (June and November 2024)
 - The EMA Medicine Shortages Single Point of Contact (SPOC) Working Party Meeting (October 2024)
- Participated in the [Duke-Margolis ReVAMP Drug Supply Chain Consortium](#), providing input to select consortium 2024 work products

By the Numbers

- 2,200+ members from regulatory authorities representing 76 countries

Regulatory Engagement in ISPE Events and Professional Development

- 96 regulatory speakers across 23 events
- 350+ regulatory attendees from 44 countries
- Regulatory review of 7 ISPE Guidance Documents

17 ISPE Regulatory Volunteer Groups

- 290+ ISPE members
- 50+ conference sessions, articles, blog posts, and more
- Input provided to various health authorities on 12 documents released for consultation

COMMUNITY AND CONNECTIVITY

Community and connectivity are fundamental values underpinning ISPE's mission as a global association for pharmaceutical professionals. ISPE CoPs are the technical engines uniting professionals worldwide to generate meaningful content in our gold-standard documents, training programs, and conference programs. ISPE CoPs cover 22 unique technical areas in the pharmaceutical industry, including GAMP®. Professional communities include Affiliates and Chapters, Women in Pharma®, and Emerging Leaders. ISPE's networking platform, ISPE Engage, continues to facilitate an open forum for all members and each CoP to connect and collaborate virtually.

In 2024, ISPE recognized the critical contributions of ISPE member volunteers. ISPE hosted appreciation events at the 2024 ISPE Europe Annual Conference and the 2024 ISPE Annual Meeting & Expo. Additionally, ISPE published 12 CoP leader profiles in *Pharmaceutical Engineering*® magazine.

CoP Leaders



Charlie Wakeham



Lorrie Vuolo-Schuessler



Tammy Spain



Nathan Temple



Allen Koester



Rod Freeman

FACILITY OF THE YEAR AWARDS



FOYA | 2024
ISPE Facility of the Year Awards

The ISPE Facility of the Year Awards (FOYA) program recognizes state-of-the-art projects utilizing new, innovative technologies to improve the quality of products, reduce the cost of producing high-quality medicines, and demonstrate advances in project delivery. FOYA provides a platform for the pharmaceutical science and manufacturing industry to showcase its accomplishments in facility design, construction, and operation, while sharing the development of new applications of technology and cutting-edge approaches.

For more information on the program, how to get involved, and an overview of the 2024 FOYA Category Winners visit [ISPE.org/FOYA](https://www.ispe.org/foya).

OVERALL WINNER AND INNOVATION CATEGORY WINNER



Eli Lilly Kinsale Limited
Location: Kinsale, Ireland
Project: IE2b

2024 FOYA CATEGORY WINNERS



OPERATIONS, PROJECT EXECUTION

Pfizer Asia Pacific Manufacturing Ltd
Location: Tuas, Singapore
Project: Pfizer API Facility Extension



SOCIAL IMPACT

Chugai Pharma Manufacturing Co., Ltd.
Location: Tokyo, Japan
Project: UK4 Project



OPERATIONS, FACILITY FIT

Takeda Austria GmbH
Location: Linz, Austria
Project: beePFS – Prefilled Syringe Filling



HONORABLE MENTION

United Therapeutics Corporation
Location: Research Triangle Park, North Carolina, USA
Project: Lightyear



HONORABLE MENTION

Zydus Pharmaceuticals Ltd.
Location: Gujarat, India
Project: Oral Solid Dosage Manufacturing Facility

CORPORATE PARTNERSHIP PROGRAM

The ISPE Corporate Partnership program is a strategic, annual partnership designed for companies wanting to enhance their industry leadership and exposure to a global network of pharmaceutical manufacturers and service providers. Corporate Partners benefit from exclusive opportunities, including expanded brand visibility through the ISPE Corporate Partnership logo, recognition across ISPE’s communication channels, discounted ISPE memberships, and dedicated content marketing opportunities.

We would like to thank our 2024 ISPE Corporate Partners for their continued engagement and support of ISPE’s mission.

PLATINUM PARTNERS



SteelcoBelimed



GOLD PARTNERS



OPTIMA

VALGENESIS®

SILVER PARTNERS



FINANCIALS

STATEMENT OF FINANCIAL POSITION

FOR THE YEARS ENDED DECEMBER 31, 2024 AND 2023

ASSETS

ASSETS	2024	2023
CASH AND CASH EQUIVALENTS	\$2,748,992	\$5,359,432
ACCOUNTS RECEIVABLE	1,203,642	1,426,281
INVESTMENTS	9,939,465	7,994,526
INVENTORY OF TECHNICAL MATERIALS	-	25,538
PREPAID EXPENSES	831,364	678,257
FIXED ASSETS	594,834	623,388
ROU ASSETS - OPERATING LEASE	1,975,476	2,151,753
DEPOSITS	84,772	82,297
OTHER ASSETS	10,000	10,000
TOTAL ASSETS	\$17,388,545	\$18,351,472

LIABILITIES AND NET ASSETS

LIABILITIES	2024	2023
ACCOUNTS PAYABLE	\$636,611	\$1,295,383
ACCRUED EXPENSES	551,024	\$920,196
DEFERRED REVENUE	247,941	158,759
LEASE LIABILITIES - OPERATING LEASES	2,462,698	2,335,181
EARLY TERMINATION LEASE PAYABLE	-	359,579
CONTRACT LIABILITIES	3,570,224	3,520,428
TOTAL LIABILITIES	\$7,468,498	\$8,589,526

NET ASSETS	2024	2023
TOTAL NET ASSETS	\$9,920,047	\$9,761,946
TOTAL LIABILITIES AND NET ASSETS	\$17,388,545	\$18,351,472

STATEMENT OF ACTIVITIES

FOR THE YEARS ENDED DECEMBER 31, 2024 AND 2023

REVENUES

PROGRAM REVENUES	2024	2023
PROFESSIONAL DEVELOPMENT	\$9,372,516	\$9,931,474
MEMBERSHIP DUES	4,429,980	4,118,733
GUIDANCE DOCUMENTS	2,614,528	2,802,746
MAGAZINE REVENUE	248,151	887,273
CONTRIBUTIONS	198,541	240,366
TOTAL PROGRAM REVENUES	\$16,863,716	\$17,946,512

OTHER REVENUES	2024	2023
INVESTMENT INCOME	\$767,440	\$862,907
MISCELLANEOUS	465,186	514,078
TOTAL OTHER REVENUES	\$1,232,626	\$1,376,985
TOTAL REVENUES	\$18,096,342	\$19,323,497

EXPENSES

PROGRAM SERVICES	2024	2023
PROFESSIONAL DEVELOPMENT	\$9,222,233	\$9,965,052
MEMBERSHIP SERVICES	2,951,088	2,618,409
GUIDANCE DOCUMENTS	2,010,302	1,370,055
PUBLICATIONS	879,972	1,421,374
TOTAL PROGRAM SERVICES	\$15,063,595	\$15,374,890

SUPPORTING SERVICES	2024	2023
MANAGEMENT AND GENERAL	\$2,518,831	\$1,600,679
FUNDRAISING	402,538	438,866
TOTAL SUPPORTING SERVICES	\$2,921,369	\$2,039,545
TOTAL EXPENSES	\$17,984,964	\$17,414,435

CHANGE IN NET ASSETS

CHANGE IN NET ASSETS	2024	2023
CHANGE IN NET ASSETS WITHOUT DONOR RESTRICTIONS	\$111,378	\$1,909,062
CHANGE IN NET ASSETS WITH DONOR RESTRICTIONS	46,723	(114,708)
CHANGE IN NET ASSETS	158,101	1,794,354
NET ASSETS—START OF YEAR	9,761,946	7,967,592
NET ASSETS—END OF YEAR	\$9,920,047	\$9,761,946



ISPE.org

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