



2021

ISPE
Annual
Report

2021 ISPE ANNUAL REPORT

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THOMAS HARTMAN

President & CEO of ISPE

The last 18 to 24 months have presented many challenges, but with that, they also brought exciting opportunities to overcome obstacles through innovation and shape the future of the pharmaceutical industry.

Through quick adaptation, we've seen revolutionary ideas come to life and patients' lives being changed for the better. Due to the personal commitment of ISPE members and their companies, we have seen unprecedented timelines from medicine development to commercialization. Brilliant minds across the pharmaceutical industry including scientists, engineers, quality professionals, manufacturing personnel, international regulators, and many other subject matter experts paved new ground in the delivery of innovative supply chains.

In 2021, ISPE delivered innovative resources to the pharmaceutical industry, as well as opportunities to connect, collaborate, and share pharmaceutical industry knowledge. We recognized that it was more critical than ever to bring the global pharmaceutical community together to exchange thoughts, to support regulatory harmonization, share best practices, and provide solutions to the most complex industry challenges.

We couldn't do what we do without our dedicated members who volunteer their talent and expertise on various committees and share their knowledge produce guidance documents, conference events, professional development and training, and other technical resources that benefit the global pharmaceutical community.

THANK YOU TO OUR MEMBERS for supporting ISPE's mission as the global industry leader in shaping the future of the pharmaceutical industry through manufacturing and supply chain innovation, operational excellence, and regulatory insights to advance industry efforts to develop, manufacture, and reliably deliver quality medicines to patients.

2021

ISPE AT A GLANCE

An association is nothing without its members, and ISPE was fortunate to close out 2021 with more than 19,000 members, a significant increase over the previous year. We consider this a positive measure of the organization's health and relevance during one of the most challenging times in the history of our industry.

Expanding ISPE's footprint, we launched our operations in China and recorded significant milestones including the establishment of offices in Hong Kong and Shanghai. We have established governance with an appointed ISPE Shanghai Board of Directors, and our product platforms are being launched to support the expansion of the pharmaceutical industry in China including planned conferences for 2022.

Representing ISPE's truly global footprint, the 2020-2021 ISPE International Board of Directors included industry experts from the US, Japan, China, Sweden, Germany, and Ireland.

- » **19,878 members worldwide representing 129 countries**
- » **39 Affiliates/Chapters**

ISPE Officers

CHAIR

Joanne Barrick, RPh
Advisor, Global Validation
Eli Lilly and Company

VICE CHAIR

Jörg Zimmermann
Vice President, Vetter Development
Service, External Affairs
Vetter Pharma Fertigung GmbH&Co KG

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Michael Rutherford
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Syneos Health

SECRETARY

Scott Billman
Global Head of Engineering
Biogen

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Frances Zipp
President and CEO
Lachman Consultant Services, Inc.

ISPE Directors

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and Compliance
Moderna

Chris Chen, PhD

CEO
WuXi Biologics (Shanghai) Co., Ltd.

Nina Cauchon, PhD

Director Regulatory Affairs
CMC Amgen Inc.

David Doleski

Compliance Head for Biologics Quality
Operations
Sanofi (Appointed Director)

Teresa Minero

Founder and CEO
LifeBee

Hirofumi Suzuki, PhD

Senior Regulatory CMC Adviser
Bayer Yakuhin Ltd.

Ylva Ek

Chief Quality Officer (CQO)
KeyPlants AB

Lou Kennedy

CEO and Owner
Nephron Pharmaceuticals

Stephen Mahoney, JD

Senior Director, Global Quality &
Compliance
Genentech, A Member of the Roche Group

Alice Redmond, PhD

Chief Strategy Officer
CAI

Emerging Leaders Representative

John Clarke

International Emerging Leaders
Representative (Ex Officio)
Operations Lead
Pfizer

GLOBAL KNOWLEDGE-SHARING

ISPE has long been regarded as the go-to organization for professional development and knowledge-sharing. With the depth and breadth of our members' subject matter expertise, ISPE has continued to deliver best-in-class events, even through the challenges of the pandemic. Through these venues, we seek to enable members and industry to adapt to disruption and thrive far into the future.

2021 KNOWLEDGE-SHARING EVENTS INCLUDED:

- Hosting over 100 discrete conferences, digital engagements and training courses in 2021, educating nearly 10,000 industry professionals representing 100+ countries
- Introducing ISPE Expert Xchange, an interactive, collaborative online experience that unites forward-thinking pharmaceutical professionals with engaged subject matter experts for immersive, topic-focused events
- Returning to in-person events with the 2021 ISPE Annual Meeting & Expo in Boston, Massachusetts, 31 October–3 November 2021
- Facilitating 23 custom training courses for industry-leading organizations, including Agilent, Emergent Biosolutions, GSK, Merck, NovoNordisk, and ThermoFisher

PUBLICATION OF UNPARALLELED TECHNICAL RESOURCES INCLUDED:

- 8 Guidance Documents published—the gold standard for technical documents
- 6 Issues of *Pharmaceutical Engineering*[®] featuring 50+ feature and technical articles in the print magazine and Online Exclusives
- 75+ iSpeak blog posts

REGULATORY AFFAIRS

ISPE's Regulatory Steering Council, comprised of senior industry leaders from multiple pharmaceutical companies, including several former regulators, led ISPE's input to Health Authorities including the EMA, Health Canada, PIC/S, WHO, and US FDA, on documents released for consultation related to Drug-Device Combination Products, Quality Data for PRIME Applications, Point of Care Manufacturing, ICH Q9 revision, and others.

ISPE's Drug Shortages team facilitated discussions among regulators from ANVISA, France's ANSM, the USFDA, and the WHO on business continuity planning for preventing drug shortages and the potential for a global list of essential or critical drugs.

ISPE'S REGULATORY ENGAGEMENT WAS STRONGER THAN EVER IN 2021



Membership

2,000+ members
from regulatory
authorities
representing
71 countries



Events, Training, and Digital Engagements

Regulators
included 68
speakers and
384 attendees
representing
29 countries



Guidance Document Reviewers

Ten regulatory
experts
representing
6 countries

COMMUNITY & CONNECTIVITY

Community and connectivity are key values underpinning ISPE's mission as a global association for pharmaceutical professionals. We connect professionals to the resources, education, and career pathways they need, which can transform the trajectories of their work, their careers, and the lives of patients worldwide. We connect global health authorities and industry to foster communications and interactions to advance quality and harmonization.

ISPE Communities of Practice (CoPs) are the technical engines that generate meaningful content in our gold-standard documents, training programs, and conference programs. ISPE CoPs currently cover 18 unique technical areas in the pharmaceutical industry, including GAMP® which celebrated its 30th anniversary in 2021. Professional communities include Affiliates/Chapters, Women in Pharma®, and Emerging Leaders.

- Introduced the ISPE Networking Lounge, a face-to-face virtual forum that facilitates conversations in small groups for pre-and-during event networking.
- Relunched the ISPE Mobile App and our online community forum—ISPE Engage—for enhanced engagement
- Social media footprint grew to 45k+ Followers on LinkedIn, Facebook, and Twitter

PHARMA 4.0™

ISPE's Pharma 4.0™ initiative provides guidance, aligned with the regulatory requirements specific to the pharmaceutical industry, to accelerate Pharma 4.0™ transformations. Also known as the Smart Factory, the objective of Pharma 4.0™ is to enable organizations involved in the product lifecycle to leverage the full potential of digitalization to provide faster innovations for the benefit of patients.

ISPE's Pharma 4.0™ Special Interest Group (SIG) has developed an operating model to apply the principles of Industry 4.0 to Pharma 4.0™.

In 2021, the Pharma 4.0™ SIG continued to share knowledge around this innovative initiative through 39 Pharma 4.0-related presentations at ISPE Conferences, two ISPE Expert Xchanges, discussions on ISPE Engage, articles in *Pharmaceutical Engineering*®, and blog posts on iSpeak.

TRANSLATIONAL SCIENCE

Advanced Therapy Medicinal Products (ATMPs)

Recognizing industry's need for sharing experiences and good practices in the development, regulatory path, facility design, qualification, and manufacture of ATMPs, in 2021 ISPE launched the Advanced Therapy Medicinal Products/Cell & Gene Therapy (ATMP/C>) Community of Practice (CoP).

Through the ATMP/C> CoP and the existing Biotechnology CoP, ISPE is developing specialized documents and training content. The *ISPE Good Practice Guide: Advanced Therapy Medicinal Products (ATMP)—Autologous Cell Therapy* was published in November 2021 as the flagship document in this topic area. Additionally, the November/December 2021 issue of *Pharmaceutical Engineering*[®] magazine was focused on ATMP/C> topics. Four new biotechnology training programs are also in development, with two launched in 2021 and two to launch in 2022.

At the 2021 ISPE Biotechnology Conference and Workshop, the Director of the CBER/FDA Office of Tissues and Advanced Therapies, Wilson Bryan, MD, presented a talk entitled, "Development of Cell and Gene Therapies During COVID-19 Pandemic." This presentation punctuated the promise of ATMPs/C>s, highlighted the challenges, and emphasized the need for connecting knowledge focused on these burgeoning therapies.

FACILITY OF THE YEAR AWARDS

As the pharmaceutical industry forges new paths, ISPE's Facility of the Year Awards (FOYA) winners exemplify the application of novel tools and approaches to successfully delivering projects that improved efficiencies, overcame unusual challenges, promoted effectiveness, and organized stakeholders and project team participants.

ISPE's FOYA program honorees represent the pharmaceutical industry's future. All around the globe, these forward thinkers recognize the importance of risk-taking, resilience, and solving tomorrow's problems. Their innovations have transformed the way we think and will shape the way we manufacture medicines.



**2021
OVERALL
WINNER**

**Janssen Sciences
Ireland**

2021 FOYA CATEGORY WINNERS

SPECIAL RECOGNITION AWARD FOR OPERATIONAL AGILITY: COVID-19 IMPACT

Gilead Sciences, Inc.

Project: Gilead Sciences, Inc.,
Center for Innovative Drug
Research (CIDR)

Grand River Aseptic Manufacturing

Project: Grand River Aseptic
Manufacturing Large-Scale Fill-
Finish Facility

FACILITY INTEGRATION

Takeda Pharmaceuticals International AG

Project: NINLARO The Grange
Castle Factory P2 Facility

OPERATIONAL EXCELLENCE

ElevateBio

Project: ElevateBio BaseCamp

PROJECT EXECUTION

Janssen Sciences Ireland

Project: BioCork2 – Large Scale
Fed Batch Facility

PROCESS INTELLIGENCE AND INNOVATION

Takeda Pharmaceuticals International AG

Project: Packaging Building and
Automatic Line Clearance

SOCIAL IMPACT

Government Pharmaceutical Organization

Project: Thailand Self Sufficient
for Pandemic Vaccines; Influenza
and COVID-19

HONORABLE MENTION

Biocon Biologics Limited

Project: Biocon Biologics
Manufacturing (B3) Project

Locus Biosciences

Project: Commercial Phage
Production Facility Upfit

Raymond G. Perelman Center for Cellular and Molecular Therapeutics

Project: Raymond G. Perelman
Center for Cellular and Molecular
Therapeutics

ISPE CORPORATE PARTNERSHIPS

In 2021, ISPE launched our Corporate Partnership Program, designed for companies seeking a deeper partnership with ISPE, providing closer alignment with and contribution to our mission within the pharmaceutical industry.

The ISPE Corporate Partnership Program is a customized multi-platform annual agreement designed to meet mutually beneficial and strategic goals. Organizations that participate are rewarded with exclusive benefits, including brand elevation through use of the all-new ISPE Corporate Partnership logo, recognition through ISPE's communication channels, ISPE memberships, and content marketing opportunities reserved exclusively for corporate partners.

We would like to thank our 2021 corporate partners for their continued engagement and support of ISPE's mission.

PLATINUM
SPONSOR

Cognizant

SILVER
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Haskell

GOLD
SPONSOR

**Nephron
Pharmaceuticals**

SILVER
SPONSOR

**Honeywell/
Sparta Systems**

FINANCIALS

ISPE FINANCIAL SUMMARY

ISPE completed another fiscally successful year on 31 December 2021. As operations continued to adjust to impact of COVID-19, positive operational and investment performance combined to provide sufficient funding for ISPE's continued success. ISPE's auditors, Dearolf & Mereness LLP, conducted the 2021 audit and gave ISPE an unqualified opinion, indicating that ISPE's financial statements fairly present, in all material respects, the financial position of ISPE and the China office as of 31 December 2021 and were in accordance with generally accepted accounting principles. Assets and liabilities were in balance on 31 December 2021, at \$11.8 million, which equates to an increase of approximately 10.2% over 2020.

Notwithstanding the challenges of COVID-19, ISPE continued to implement new technology and improved business processes during the year. Overall operating income and expense activities resulted in a gain of \$368,000. Additionally, in 2021 the ISPE Board approved strategic initiatives that resulted in an additional \$587,000 of expenses. These costs were partially offset by \$462,000 in revenue from investments and currency exchange activities. The combined operating, special initiatives, and investing activities resulted in a change in net assets for the year ending 31 December 2021 of a positive \$243,000. To fund strategic initiatives in support of the Society's mission, and to protect against business disruptions such as COVID-19, ISPE holds funds in investment reserves. While positive investment returns are never guaranteed, ISPE's investment portfolio is continually monitored to ensure that appropriate levels of safeguards and risks are in place to take full advantage of the market and to meet the long-term needs of the organization. ISPE held financial reserves of over \$6.8 million at year's end.

Revenues from Membership, publications, meetings, and training were used to support the ISPE Mission of connecting pharmaceutical knowledge to deliver manufacturing and supply chain innovation, operational excellence, and regulatory insights to enhance industry efforts to develop, manufacture, and reliably deliver quality medicines to patients. Additionally, ISPE staff is actively engaged in the development of new products, programs, and Member benefits, as well as the pursuit of new business opportunities that will support the mission, vision, and future needs of the organization. ISPE leadership and management remain mindful of the changing US and World economies, political and social environments, and their impacts on the Society. Accordingly, the Society is prepared to modify the fiscal strategies of the organization in order to meet these challenges and the ever-changing needs of the Membership.

FINANCIALS

STATEMENT OF FINANCIAL POSITION For the Year Ended December 31, 2021*

ASSETS

CURRENT ASSETS	2021	2020
Cash and cash equivalents	\$3,473,823	\$2,339,322
Accounts receivable	767,941	632,501
Inventory of technical materials	31,457	32,746
Prepaid expenses	248,148	297,977
TOTAL CURRENT ASSETS	4,521,369	3,302,546
OTHER ASSETS		
Property and equipment - net	384,654	567,411
Investments	6,780,151	6,758,611
Deposits	95,263	65,272
TOTAL OTHER ASSETS	7,260,068	7,391,294
TOTAL ASSETS	11,781,437	10,693,840

LIABILITIES AND NET ASSETS

CURRENT LIABILITIES	2021	2020
Accounts payable	\$595,713	\$534,416
Accrued expenses	495,771	264,916
Current liabilities	2,856,731	2,350,622
TOTAL CURRENT LIABILITIES	3,948,215	3,149,954
LONG-TERM LIABILITIES		
Contract Liabilities	393,048	347,934
Accrued rent	441,462	440,550
TOTAL LONG-TERM LIABILITIES	834,510	788,484
TOTAL LIABILITIES	4,782,725	3,938,438
NET ASSETS		
Undesignated	6,972,868	6,755,402
Board designated for new initiative	25,844	-
TOTAL NET ASSETS	6,998,712	6,755,402
TOTAL LIABILITIES & NET ASSETS	11,781,437	10,693,840

STATEMENT OF ACTIVITIES

For the Year Ended December 31, 2021*

REVENUES

PROGRAM REVENUES	2021	2020
Professional development	\$4,980,000	\$4,273,837
Membership services	2,824,555	2,740,978
Guidance documents	2,305,773	2,048,895
Advertising fees	896,108	695,407
Magazine revenue	631,763	620,557
TOTAL PROGRAM REVENUES	\$11,638,199	\$10,379,674
OTHER REVENUES		
Investment Income	363,705	215,538
Miscellaneous	47,673	813
TOTAL OTHER REVENUES	411,378	216,351
TOTAL REVENUES	12,049,577	10,596,025

EXPENSES

PROGRAM SERVICES	2021	2020
Professional development	5,017,306	4,120,872
Membership services	1,801,788	1,592,842
Guidance documents	1,105,720	865,282
Publications	653,171	527,277
TOTAL PROGRAM SERVICES	8,577,985	7,106,272
FUNCTIONAL SERVICES		
Management and general	3,167,152	3,652,714
TOTAL FUNCTIONAL EXPENSES	11,745,137	10,758,986
Unallocated payment to nonprofit organization	117,500	-
TOTAL EXPENSES	11,862,637	10,758,986

CHANGE IN NET ASSETS FROM OPERATIONS	186,940	(162,961)
NET CHANGE ON FOREIGN CURRENCY REMEASUREMENT	56,370	(15,170)
Change In Net Assets	243,310	(178,131)
NET ASSETS—START OF YEAR	6,755,402	6,933,533
NET ASSETS—END OF YEAR	6,998,712	6,755,402

*includes comparative information from 2020



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