



2022 ANNUAL REPORT

MESSAGE FROM THE PRESIDENT AND CEO

Responding to unprecedented challenges from the pandemic, our industry has witnessed revolutionary ideas and newly established best practices that emerged and transformed the landscape of drug development and commercialization of critical medicines.

New operating paradigms surfaced that removed white space in development timelines. A more resilient approach was adopted in managing supply chains and working with regulators. More companies introduced innovative approaches to advance their clinical pipelines toward licensure.

Complementing these efforts, ISPE continued to push the envelope to ensure we delivered innovative technical resources as well as opportunities to connect, collaborate, and exchange knowledge that ultimately helps propel the pharmaceutical industry forward.

Our more than 20,000 members are at the heart of ISPE, supporting the pharmaceutical industry. We are a united community working daily to improve the quality of life for patients and global communities.

Thank you to our members, our thousands of volunteers that serve on committees, our Affiliates and Chapters, our Board of Directors, ISPE staff, and international regulators for your ongoing efforts in shaping the future of the global pharmaceutical industry.



THOMAS HARTMAN

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ISPE BOARD OF DIRECTORS

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Service, External Affairs
Vetter Pharma Fertigung GmbH&Co KG

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Quality and Data Integrity
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Pharmaceutical Services
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CRB

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ISPE

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Vice President, Global Quality Systems
and Compliance, Moderna

Nina S. Cauchon, PhD

Director Regulatory Affairs – CMC
Amgen Inc.

Chris Chen, PhD

CEO
WuXi Biologics (Shanghai) Co., Ltd.

David Doleski

Head of Global Quality Audit and
External Engagement
Sanofi

Ylva Ek

Founder
Robur Life Science Advisory AB

Sarah C. Pope Miksinski, PhD

Executive Director in
CMC Regulatory Affairs
AstraZeneca

Teresa Minero

Founder and CEO
LifeBee

Georg Singewald, PhD

Global Head Engineering,
Technology and Sustainability
F Hoffmann-La Roche AG

Hirofumi Suzuki, PhD

Product Supply Japan, Head of Product
Supply Coordination
Bayer Yakuhin Ltd

Timothy J.N. Watson, PhD

Executive Director and Team Leader,
CMC Advisory Office
Gilead

EMERGING LEADERS REPRESENTATIVE

Heather Bennett

CQV Manager
ACCO Engineered Systems

2022 ISPE AT-A- GLANCE

An association is nothing without its members, and ISPE was fortunate to close out 2022 with more than 20,000 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.

20k+

Members
Worldwide

122

Countries
Represented

39

Affiliates
and Chapters

6

International
Conferences

17

Webinars

4

Expert
Xchanges

1

VIP
Roundtable
Discussion

7

Guidance
Documents

6

Issues of
*Pharmaceutical
Engineering®*
featuring

80+

Technical
Articles
and Online
Exclusives

75+

iSpeak
Blog Posts

56

Online Live
Training
Courses

20

Custom
Training
Courses

7

In-Person
Training
Courses

GLOBAL KNOWLEDGE- SHARING

ISPE RESOURCES reach
professionals representing more
than **60** countries with over
18,000 educational experiences

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 experiences and resources in 2022.

INDUSTRY-CRITICAL INITIATIVES

GAMP® 5

GAMP® aims to deliver a cost-effective framework of good practice to ensure that computerized systems are effective and of high quality, fit for intended use, and compliant with applicable regulations.

Maintaining the principles and framework of the first edition, *ISPE GAMP® 5: A Risk-Based Approach to Compliant GxP Computerized Systems (Second Edition)* updates their application in the modern world including the increased importance of service providers, evolving approaches to software development, and expanded use of software tools and automation. The 2022 release highlights the use of critical thinking by knowledgeable and experienced SMEs to define appropriate approaches.

Annex 1

Annex 1, the EU's revised GMP requirements for manufacturing sterile medicinal products, will take effect on 25 August 2023. Annex 1, to be adopted by PIC/S and WHO, will have a global impact.

With the publication of the long-awaited revision of Annex 1, we were pleased to see a number of comments by ISPE and our members included in the final document. The revised requirements, set to take effect on 25 August 2023, govern the manufacturing of sterile drugs made in the EU and imported products. ISPE and our stakeholder members have been and continue to be very involved on this topic.

Advancing Pharmaceutical Quality

ISPE's Advancing Pharmaceutical Quality (APQ) program is an industry-led 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 system (PQS). The program is aligned with international initiatives that promote quality excellence, as well as with the FDA's focus on quality management maturity and rating the maturity of manufacturing facilities.

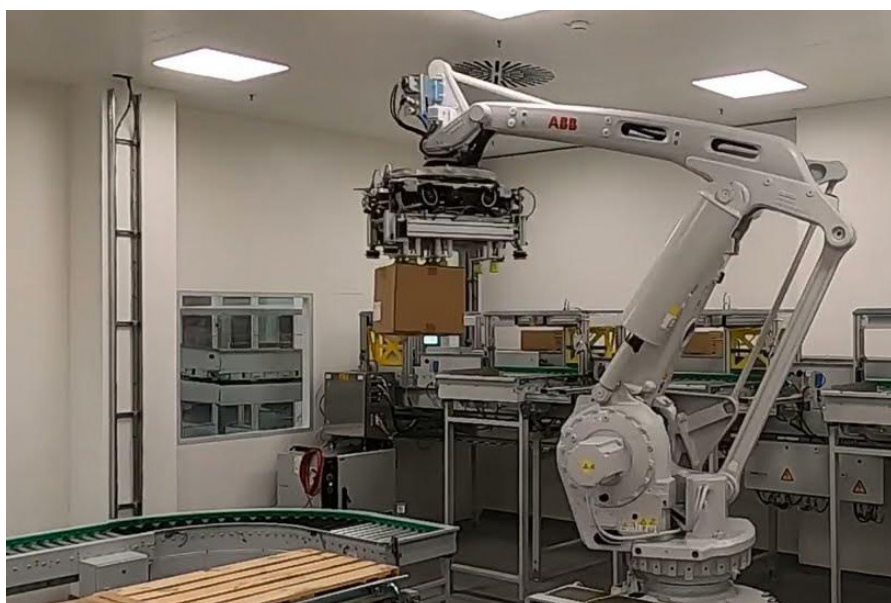
The program consists of five Good Practice Guides: one for each of the four elements of an ICH Q10 Pharmaceutical Quality System plus Cultural Excellence, bookended by an optional benchmarking tool developed by University of St.Gallen.

The APQ Guide series includes:

- **Change Management (CM) System**
- **Corrective Actions and Preventive Actions (CAPA)**
- **Management Responsibilities and Management Review**
- **Process Performance and Product Quality Monitoring System**
- **Cultural Excellence**

FACILITY OF THE YEAR AWARDS

As the pharmaceutical industry forges new paths and breaks new grounds in drug developments, ISPE's Facility of the Year Awards program celebrates the innovative game-changers who are guiding the industry forward and setting the standard for pharmaceutical facilities of the future. Companies like the 2022 FOYA Category Winners represent the 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 manufacture medicines and will improve the quality of life for patients, global communities, and society overall.



2022 OVERALL AND PHARMA 4.0™ CATEGORY

**Takeda
Pharmaceuticals
International AG**

Location: Singen, Germany

Project: TaSiVa

2022 FOYA CATEGORY WINNERS

INNOVATION CATEGORY

CRISPR Therapeutics

Location: Framingham,
Massachusetts, USA

Project: CRISPR Therapeutics

PROJECT EXECUTION CATEGORY

Janssen Biologics, BV

Location: Leiden, The Netherlands

Project: Vaccine Launch Facility
(VLF) Expansion

SUPPLY CHAIN CATEGORY

Takeda Pharmaceuticals International AG

Location: Madrid, Spain; Grange
Castle, Ireland; Osaka Japan;
Thousand Oaks, California, USA

Project: Alofisel Global Program

SOCIAL IMPACT CATEGORY

Catalent

Location: Bloomington Indiana

Project: Project Mercury

Janssen Biologics, BV

Location: Leiden, The Netherlands

Project: Vaccine Launch Facility
(VLF) Expansion

HONORABLE MENTION

Iovance Biotherapeutics, Inc.

Location: Philadelphia,
Pennsylvania, USA

Project: Iovance Cell Therapy
Center (iCTC) 136,000-square-
foot, three-story, greenfield facility
houses manufacturing, central
utilities, warehousing, laboratory,
and administrative spaces.

REGULATORY AFFAIRS

ISPE's regulatory engagement was stronger than ever in 2022.

Our Regulatory Quality Harmonization Committee, comprised of senior industry leaders and former regulators, led ISPE's input to various health authorities on 16 documents released for consultation, including the long-awaited revision of the EU GMP Annex 1, Manufacture of Sterile Medicinal Products, mentioned above.

2,600+

Members from Regulatory Authorities Representing 86 Countries

19

ISPE Regulatory Volunteer Groups Made Up of

260+

ISPE Members

Expert Guidance Document Reviewers from

5

Global Health Authorities

Regulatory Engagement in ISPE Events and Professional Development

50+

Speakers

190+

Attendees

30+

Countries

COMMUNITY & CONNECTIVITY

Community and connectivity are key values underpinning ISPE's mission as a global association for pharmaceutical professionals. ISPE Communities of Practice (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 20 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. ISPE's networking platform ISPE Engage continues to facilitate an open forum for all members and each CoP to virtually connect and collaborate.

CORPORATE PARTNERSHIP PROGRAM

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 unique benefits, including brand elevation through use of the exclusive ISPE Corporate Partnership logo, recognition through ISPE's communication channels, ISPE memberships, and content marketing opportunities reserved solely for ISPE Corporate Partners.

We would like to thank our 2022 corporate partners for their continued engagement and support of ISPE's mission.

PLATINUM PARTNER

Unispace

GOLD PARTNERS

Cognizant

Nephron

ValGenesis

SILVER PARTNERS

AspenTech

Honeywell Sparta

PQE Group

STO Building Group

Haskell

MAASI Enterprises

Schneider Electric

Veqtor

ISPE FINANCIAL SUMMARY

ISPE completed another fiscally successful year on 31 December 2022. Program operations adjusted to a post COVID-19 pace, and positive operational performance allowed ISPE to exceed its goals. ISPE's auditors, Dearolf & Mereness LLP, conducted the 2022 audit and gave ISPE an unqualified opinion, indicating that ISPE's financial statements fairly present, in all material respects, the financial position of ISPE as of 31 December 2022 and were in accordance with generally accepted accounting principles. Assets and liabilities were in balance on 31 December 2022, at \$16.3 million, which equates to an increase of approximately 38.1% over 2021. Actual performance accounted for a 16.3% increase in Assets and liabilities in 2022, compared to a 10.2% increase in 2021. The additional increase of 21.8% in 2022 was the result of a Financial Accounting Standards Board (FASB) reporting requirement change.

Notwithstanding the challenges of a post COVID-19 environment, ISPE continued to implement new technology and improved business processes during the year. Overall, operating income and expense activities resulted in a gain of \$1,608,000. The ISPE Board also approved strategic initiatives that resulted in an additional \$327,000 of expenses. Financial markets proved difficult to navigate in 2022 and ISPE's investment and currency exchange activities resulted in loss of \$922,000. The combined operating, special initiatives, and investing activities resulted in a positive change of \$359,000 in net assets for the year ending 31 December 2022.

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 just under \$6.3 million at year's end.

Revenues from membership, publications, conferences, and professional development 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, 2022*

ASSETS

CURRENT ASSETS	2021	2022
Cash and cash equivalents	\$3,473,823	\$5,226,340
Accounts receivable	767,941	1,565,331
Inventory of technical materials	31,457	27,944
Prepaid expenses	248,148	441,016
TOTAL CURRENT ASSETS	\$4,521,369	\$7,260,631
OTHER ASSETS		
Property and equipment - net	384,654	227,111
Right of use assets		2,507,840
Investments	6,780,151	6,163,438
Deposits	95,263	100,397
TOTAL OTHER ASSETS	\$7,260,068	\$8,998,786
TOTAL ASSETS	\$11,781,437	\$16,259,417

LIABILITIES AND NET ASSETS

CURRENT LIABILITIES	2021	2022
Accounts payable	\$595,713	\$1,185,431
Accrued expenses	495,771	1,050,759
Right of use liabilities		328,915
Contract liabilities	2,856,731	3,080,014
TOTAL CURRENT LIABILITIES	\$3,948,215	\$5,645,119
LONG-TERM LIABILITIES		
Right of use liabilities		2,280,774
Contract liabilities	393,048	347,758
Deferred rent	441,462	429,372
TOTAL LONG-TERM LIABILITIES	\$834,510	\$3,057,904
TOTAL LIABILITIES	\$4,782,725	\$8,703,023
NET ASSETS		
TOTAL NET ASSETS	\$6,998,712	\$7,556,394
TOTAL LIABILITIES & NET ASSETS	\$11,781,437	\$16,259,417

STATEMENT OF ACTIVITIES For the Year Ended December 31, 2022*

REVENUES

PROGRAM REVENUES	2021	2022
Professional development	\$4,980,000	\$8,584,973
Membership services	2,824,555	3,060,582
Guidance documents	2,305,773	3,129,744
Advertising fees	896,108	935,059
Magazine revenue	631,763	688,931
TOTAL PROGRAM REVENUES	\$11,638,199	\$16,399,289
OTHER REVENUES		
Investment Income	363,705	(927,606)
Miscellaneous	47,673	45,946
TOTAL OTHER REVENUES	\$411,378	\$(886,000)
TOTAL REVENUES	\$12,049,577	\$15,517,629

EXPENSES

PROGRAM SERVICES	2021	2022
Professional development	5,017,306	6,607,043
Membership services	1,801,788	2,342,986
Guidance documents	1,105,720	1,592,683
Publications	653,171	824,705
TOTAL PROGRAM SERVICES	\$8,577,985	\$11,367,417
SUPPORTING SERVICES		
Management and general	3,167,152	3,672,319
TOTAL FUNCTIONAL EXPENSES	\$11,745,137	\$15,039,736
Unallocated payments	117,500	85,000
TOTAL EXPENSES	\$ 11,862,637	\$15,124,736

CHANGE IN NET ASSETS FROM OPERATIONS	\$186,940	\$392,893
NET CHANGE ON FOREIGN CURRENCY REMEASUREMENT	\$56,370	\$(33,783)
Change In Net Assets	243,310	359,110
NET ASSETS—START OF YEAR	\$6,755,402	\$6,998,712
PRIOR PERIOD ADJUSTMENT		\$198,572
NET ASSETS—END OF YEAR	\$6,998,712	\$7,556,394



ISPE.org

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