



2023

ANNUAL REPORT



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MESSAGE FROM THE PRESIDENT AND CEO

Our incredible ISPE community made 2023 an extraordinary year. We are grateful to our community of 22,000+ strong, representing 120 countries, who came together to redefine what is possible. They have embarked on a journey with us, not just as participants but as innovators, creators, mentors, and mentees.

We would like to extend a special thank you to our Affiliates and Chapters. They have paved the way for innovation, locally and globally, through events that have fueled connections and sparked creativity. We are deeply appreciative of our Board of Directors, who expanded our reach, creating new partnerships and forging new connections.

We are very thankful to our Communities of Practice (CoPs), which continue to grow, with 20 active technical communities comprised of over 500 member volunteers. We have collaborated to produce vital guidance documents influencing industries far and wide.

Our community has embraced change with open arms. We have also flourished in the radiant field of training opportunities, all tailored to meet the needs of the pharmaceutical industry. Our collective efforts have led to initiatives, events, training, and digital engagements that have reached across the globe.

As we reflect on 2023, remember that our community creates the heartbeat of ISPE. Our collective dedication and passion defines ISPE's unwavering commitment to finding solutions to the industry's most complex challenges today and tomorrow, while making a big difference in the lives of global patient populations.

Thank you to our members, our Board of Directors, and our staff for an incredible year of achievement. We are lighting up the path to a brighter future and meeting extraordinary demands as masters of an ever-evolving set of industry circumstances and opportunities. This is our challenge as an international group of like-minded professionals, and our collective value proposition to the industry in 2024 and beyond. Together, let's continue to elevate the gold standard, inspire innovation, and shape the future of the pharmaceutical industry.



Thomas B. Hartman
President and CEO
ISPE and ISPE Foundation



2022-2023 ISPE

INTERNATIONAL BOARD OF DIRECTORS

EXECUTIVE COMMITTEE

Michael L. Rutherford

INTERNATIONAL BOARD CHAIR

Principal, Computer Systems Quality and Data Integrity

Rutherford Consulting, LLC

Scott W. Billman

INTERNATIONAL BOARD VICE CHAIR

Senior Vice President of Global Engineering, Technology, and Facilities

Solventum

Jeffrey A. Biskup, PE

INTERNATIONAL BOARD TREASURER

Executive Chairman of the Board

CRB

Vivianne J. Arencibia

INTERNATIONAL BOARD SECRETARY

Vice President, Global Quality Systems and Compliance

Moderna

Jörg Zimmermann

INTERNATIONAL BOARD PAST CHAIR

Vice President, Vetter Development Service, External Affairs

Vetter Pharma-Fertigung GmbH & Co.

Thomas B. Hartman

EX OFFICIO NON-VOTING MEMBER

President and CEO

ISPE

DIRECTORS

Nina S. Cauchon, PhD

Director Regulatory Affairs - CMC
Amgen Inc.

David Churchward

Head of Operations Quality, Compliance and External Affairs
AstraZeneca

Norman A. Goldschmidt

President
Genesis AEC

Michael Martin

CEO
CAI

Sarah C. Pope Miksinski, PhD

Executive Director, CMC Regulatory Affairs
Gilead Sciences, Inc.

Teresa Minero

Founder and CEO
LifeBee

Georg Singewald, PhD

Senior Vice President, Global Head Engineering, Technology and Sustainability
Roche

Hirofumi Suzuki, PhD

Regulatory Affairs CH Japan Manager
Bayer Yakuhin Ltd.

Ylva Ek

Founder
Robur Life Science Advisory AB

Timothy J.N. Watson, PhD

Vice President, Head of CMC Regulatory Affairs
Gilead Sciences

EX OFFICIO

Zen-Zen Yen

EMERGING LEADER REPRESENTATIVE (NON-VOTING)

Head of Engineering, Supply Center Grenzach
Bayer AG

2023 ISPE AT-A- GLANCE

Thanks to you, we grew our community to more than 22,000 members, a significant increase over the previous year. This is a strong testament to our continued growth and resilience as a global community, as the industry bounces back from one of the most challenging times in history.

192

Education
Sessions

479

Speakers/
Presentations

6

Plant Tours

24

Webinars



40 Affiliates and Chapters

- With the introduction of the ISPE Southwest Chapter
- Celebrating the 15th anniversary of the ISPE Philippines Affiliate

6 Guidance Documents

- Involving nearly 300 volunteer authors and reviewers
- Expanding into new areas including pharmaceutical compounding and Pharma 4.0™

22,000+

Members Worldwide

135

Countries Represented

6

International
Conferences

6 Issues of *Pharmaceutical Engineering*® magazine

- 144 Authors
- 90+ Technical articles and features
- Secured the APEX Award for Publication Excellence for the fourth year in a row and a 2023 Grant APEX Award for Public Health Concerns

Communities of Practice (CoPs)

- Expanded to include 20 active technical communities and additional communities
- 600+ active volunteers
- 1,000+ discussions in unique technical areas

Training Opportunities

- Introduction of new training courses at the European Aseptic and Sterile Environment (EASE) facility
- 50 Online Live training courses
- 24 Custom training courses
- 8 In person training courses
- 325 Registrants for On Demand training courses



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 experiences and resources in 2023.

INDUSTRY-CRITICAL INITIATIVES

2023 ISPE Drug Shortages Prevention Model

ISPE published the 2023 ISPE Drug Shortages Prevention Model. This milestone report intends to help prevent drug shortages by providing quality, regulatory, and technical recommendations for the pharmaceutical manufacturing industry.

2023 ISPE Readiness Report Bundle

ISPE published the ISPE Readiness Report Bundle with the Report on ISPE Work to Support Establishment of the European Union Health Emergency Preparedness and Response Authority (HERA). This report helped lay the groundwork for establishing HERA, a European Commission Directorate-General created to prevent, detect, and rapidly respond to health emergencies. The team on the HERA project was comprised of ISPE members from multiple regulatory volunteer groups.

ISPE Baseline® Guide: Volume 8 - Pharma 4.0™

ISPE released the *ISPE Baseline® Guide: Volume 8 - Pharma 4.0™* in December 2023, a significant milestone for ISPE. The guide provides a long sought-after framework for the structural capabilities necessary to successfully implement emerging and digital technologies that can lead to more robust and flexible manufacturing processes. These technologies can help the pharmaceutical industry respond to drug shortages, reduce interruptions in the production and delivery of medicines, and ensure consistent clinical performance of products.

Pharmaceutical Compounding

ISPE introduced two significant initiatives aimed at benefitting the field of pharmaceutical compounding—the release of the *ISPE Guide: 503B Compounding - Regulatory Basis and Industry Good Practices for Outsourcing Facilities* and the launch of the ISPE CoP on Pharmaceutical Compounding.

ISPE developed the 503B Compounding Guide in response to industry demands and regulatory complexities. The guide serves as an invaluable resource for 503B outsourcing facilities, aiding them in understanding the regulatory requirements outlined in the Federal Food, Drug, and Cosmetic (FD&C) Act Section 503B.

ISPE launched the new ISPE CoP on Pharmaceutical Compounding in recognition of the pressing need for best practice sharing, training, and guidance for creative problem solving in compounding pharmacies. This technical group is designed to serve as a dynamic and collaborative community for ISPE members to exchange insights, share best practices, and engage in discussions related to pharmaceutical compounding through the ISPE Engage online platform.

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. The program aligns with international initiatives that promote quality excellence and the US Food and Drug Administration's (US FDA) focus on quality management maturity (QMM) and rating the maturity of manufacturing facilities.

In 2023, the APQ team held a workshop with participation from the US FDA and the University of St. Gallen, focused on the industry adoption of the QMM program. They also initiated a training session on the APQ program, "Quality Management Maturity in Action," which was presented at the 2023 ISPE Annual Meeting & Expo.

REGULATORY AFFAIRS

ISPE's regulatory engagement was more vital than ever in 2022. Our Regulatory Steering Council, comprised of senior industry leaders and former regulators, launched the ISPE Enabling Pharmaceutical Innovation Initiative to catalyze consistent and harmonized interpretation and implementation of ICH guidelines. This initiative aims to expedite patients' access to innovative medicines. The first phase of this initiative entailed conducting a survey and sharing results on current barriers to innovation with the industry and health authorities.

Various regulatory volunteer groups also engaged in the following initiatives:

- Conducted training sessions for Medicines and Healthcare Products Regulatory Agency (MHRA) assessors and inspectors on ICH Q12 implementation with participation from the US FDA
- Presented at meetings with global health authorities, including:
 - The European Medicines Agency (EMA)/ Heads of Medicines Agency (HMA) Multi-Stakeholder Workshop on Shortages (1 March 2023)
 - The Listen-and-Learn Focus Group Meeting of the EMA Quality Innovation Group (13 March 2023)
 - The annual meeting of the EMA Inspectors Working Group with interested parties.
- Engagement with Health Canada's Drug Shortages team to share insights on best practices for engagements between the industry and global health authorities related to drug shortages
- Participated in the US FDA workshop, "Advancing the Utilization and Supporting the Implementation of Innovative Manufacturing Approaches (8 June 2023)
- Became a member of the Duke-Margolis Drug Supply Chain Consortium

By the Numbers

- 2,200+ members from regulatory authorities representing 70 countries

Regulatory Engagement in ISPE Events and Professional Development

- 50+ Speakers
- 200+ Attendees
- 25+ Countries
- Review of 6 ISPE Guidance Documents

19 ISPE Regulatory Volunteer Groups

- 290+ ISPE members
- 30+ Conference sessions, articles, blog posts, and more
- Input provided to various health authorities on 14 documents released for consultation
- ISPE work presented at 6 meetings with health authorities

COMMUNITY AND CONNECTIVITY

ISPE CoPs are technical engines uniting professionals worldwide to generate meaningful content in our gold-standard documents, training programs, and conference programs – covering 20 unique technical areas in the pharmaceutical industry, including GAMP®. 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 connect and collaborate virtually.

In 2023, ISPE continued ramping up its recognition of ISPE member volunteers and hosted appreciation events at the 2023 ISPE Europe Annual Conference and the 2023 ISPE Annual Meeting & Expo. Additionally, ISPE published 12 CoP leader profiles in *Pharmaceutical Engineering*® magazine.

ABOUT THE ISPE FOUNDATION



MISSION STATEMENT

FUELING GLOBAL HEALTH EQUITY BY FOSTERING ACCESS TO KNOWLEDGE AND NURTURING DIVERSE TALENT

The ISPE Foundation’s Four Key Pillars

The ISPE Foundation’s philanthropic pillars provide the pathway to attract and train the diverse workforce our industry needs to advance our mission. As the philanthropic arm of ISPE, the ISPE Foundation is a tax-exempt 501(c)(3) organization. We create and fund programs that address the most pressing needs which will positively impact global health equity now and in the future.



ISPE Knowledge without Borders



Scholarships and Grants



Workforce Diversity



Greatest Needs

We believe that fostering access to knowledge and nurturing a diverse workforce is essential for strengthening the pharmaceutical industry. Each of our philanthropic pillars is aimed at improving the availability of a globally diverse and qualified workforce. This will enable our industry to meet the demands for supplying transformational medicines to worldwide patient populations.



ISPE FACILITY OF THE YEAR AWARDS (FOYA) 2023 CATEGORY WINNERS

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 2023 FOYA Category Winners represent the industry's future. These innovators from around the world recognize the importance of risk-taking, resilience, and problem-solving for tomorrow. Their cutting-edge solutions have transformed the way we manufacture medicines and will improve the quality of life for patients, global communities, and society overall.

OVERALL WINNER AND PHARMA 4.0™



Genentech

PROJECT

Genentech South San Francisco Clinical Supply Center

LOCATION

San Francisco, California, USA

INNOVATION



Chugai Pharma Manufacturing Co., Ltd.

PROJECT

FJ2 Project

LOCATION

Shizuoka Prefecture, Japan

OPERATIONS



WuXi Biologics Ireland Limited

PROJECT

WuXi Biologics Contract Research, Development and Manufacturing Organization (CRDMO) Ireland

LOCATION

County Louth, Ireland

SUPPLY CHAIN



Serum Institute of India Pvt. Ltd.

PROJECT

"NISHWAS" The Breath of Relief

LOCATION

Maharashtra, India

SOCIAL IMPACT



Serum Institute of India Pvt. Ltd.

PROJECT

"NISHWAS" The Breath of Relief

LOCATION

Maharashtra, India

SOCIAL IMPACT



Takeda SA

PROJECT

Glassia Manufacturing Building

LOCATION

Lessines, Belgium

HONORABLE MENTION



Nexus Pharmaceuticals, Inc.

PROJECT

Project Tomorrow—Aseptic Manufacturing Facility

LOCATION

Pleasant Prairie, Wisconsin, USA



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 the use of the exclusive ISPE Corporate Partnership logo, recognition through ISPE’s communication channels, discounted ISPE memberships, and content marketing opportunities reserved solely for ISPE Corporate Partners.

We would like to thank our 2023 ISPE Corporate Partners for their continued engagement and support of ISPE’s mission.

PLATINUM PARTNERS



GOLD PARTNERS



SILVER PARTNERS



FINANCIALS

STATEMENT OF FINANCIAL POSITION

FOR THE YEAR ENDED DECEMBER 31, 2023*

ASSETS

ASSETS

CASH AND CASH EQUIVALENTS	\$5,359,432
ACCOUNTS RECEIVABLE	1,426,281
INVESTMENTS	7,994,526
INVENTORY OF TECHNICAL MATERIALS	25,538
PREPAID EXPENSES	678,257
FIXED ASSETS	623,388
ROU ASSETS - OPERATING LEASE	2,151,753
DEPOSITS	82,297
OTHER ASSETS	10,000
TOTAL ASSETS	\$18,351,472

LIABILITIES AND NET ASSETS

LIABILITIES

ACCOUNTS PAYABLE	\$1,295,383
ACCRUED EXPENSES	920,196
DEFERRED REVENUE	158,759
LEASE LIABILITIES - OPERATING LEASES	2,335,181
EARLY TERMINATION LEASE PAYABLE	359,579
CONTRACT LIABILITIES	3,520,428
TOTAL LIABILITIES	\$8,589,526

NET ASSETS

TOTAL NET ASSETS	\$9,761,946
TOTAL LIABILITIES AND NET ASSETS	\$18,351,472

STATEMENT OF ACTIVITIES

FOR THE YEAR ENDED DECEMBER 31, 2023*

REVENUES

PROGRAM REVENUES

PROFESSIONAL DEVELOPMENT	\$9,931,474
MEMBERSHIP DUES	4,118,733
GUIDANCE DOCUMENTS	2,802,746
MAGAZINE REVENUE	887,273
CONTRIBUTIONS	240,366
TOTAL PROGRAM REVENUES	\$17,980,592

OTHER REVENUES

INVESTMENT INCOME	\$862,907
MISCELLANEOUS	330,099
TOTAL OTHER REVENUES	\$1,193,006
TOTAL REVENUES	\$19,357,577

EXPENSES

PROGRAM SERVICES

PROFESSIONAL DEVELOPMENT	\$9,198,736
MEMBERSHIP SERVICES	2,700,330
GUIDANCE DOCUMENTS	1,658,368
PUBLICATIONS	729,101
TOTAL PROGRAM SERVICES	\$14,286,535

SUPPORTING SERVICES

MANAGEMENT AND GENERAL	\$2,689,034
FUNDRAISING	472,946
TOTAL SUPPORTING SERVICES	\$3,161,980
TOTAL EXPENSES	\$17,448,515

CHANGE IN NET ASSETS

CHANGE IN NET ASSETS

CHANGE IN NET ASSETS WITHOUT DONOR RESTRICTIONS	\$1,909,062
CHANGE IN NET ASSETS WITH DONOR RESTRICTIONS	(114,708)
CHANGE IN NET ASSETS	\$1,794,354
NET ASSETS—START OF YEAR	\$7,967,592
NET ASSETS—END OF YEAR	\$9,761,946



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