CELEBRATING 40 YEARS 1980 2020

AGILITY. COLLABORATION. INNOVATION.

ISPE®

ANNUAL REPORT 2020

2019–2020 International Board of Directors

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AGILITY. COLLABORATION. INNOVATION

Normal life in many ways came to a halt in 2020 as a result of COVID-19. As a result, the global pharmaceutical industry shifted into full speed. The Pharmaceutical Industry accelerated discovery, development, and manufacturing at risk to meet the challenges presented by the Pandemic. The men and women who develop, manufacture and supply pharmaceuticals were also on the front lines, working to save lives and overcome the crisis.

The pandemic, while horrific on so many fronts, also brought moments of great challenge, opportunity and success on many fronts. The theme of this year's Annual Report captures the spirit of what came out of the determination and dedication of ISPE Staff, Members and the pharmaceutical industry—greater **Agility**, greater **Collaboration**, and greater **Innovation**.

ISPE's commitment to advancing the educational and technical proficiency of our Members and the industry never faltered. We maintained our promise to provide solutions to complex industry challenges through knowledge sharing, delivering guidance, and by facilitating conversations on issues that will ultimately benefit patients around the world.

Strides made in 2020 include:

- Transforming our in-person events into immersive digital experiences that allowed our Members and industry to continue learning, knowledge-sharing, and networking
- Publishing five Guidance Documents, strengthening our library of technical documents—considered the gold standard in our industry
- Launching the Eurasia Affiliate, growing our base of Affiliates and Chapters, the backbone of ISPE
- Participating in the Department of the Air Force Acquisition COVID-19 Task Force (DAF ACT) Initiative to Support Domestic Manufacturing of Active Pharmaceutical Ingredients. The identified findings are applicable to all countries with interest to improve the resiliency of their domestic supply of API's for their respective patient populations.

But we could not have done it without the efforts of our tireless volunteers, our dedicated Members, and our worldwide ISPE staff.

We are looking forward to what 2021 holds for ISPE as we continue to facilitate neutral environments for industry and regulators to engage in open dialog via our conference platforms, explore the next frontier of the industry via Pharma 4.0™ and Facilities of the Future, and launch programs to support the Workforce of the Future, Women in Pharma®, and Global Knowledge Exchange initiatives sponsored by the ISPE Foundation.

The staff and leadership of ISPE are working hard to create the best professional association possible for our industry. But we need your help to do it. We encourage all Members to get more involved with YOUR Society in 2021. Volunteer for a committee, contribute to creating a Guidance Document, or simply invest in the future by donating to the ISPE Foundation.

Together, we will continue to strive for even greater **Agility**, **Collaboration**, and **Innovation** in 2021 and for many years to come.

Thomas Hartman
President & CEO
ISPE

CELEBRATING 40 YEARS

ISPE: CELEBRATING 40 YEARS OF CONNECTING PHARMACEUTICAL KNOWLEDGE

The International Society for Pharmaceutical Engineering (ISPE) was founded in 1980 by a handful of people who believed the pharmaceutical industry needed an organization that would deal with practical applications of science and technology for technical professionals. The much-needed forum provided by ISPE began with a Membership of engineers in North America. In time, ISPE Membership expanded beyond engineering to include a broad representation from pharmaceutical professionals worldwide.

Flash-forward to 2020, and ISPE is a leading not-for-profit association serving its 17,000+ Members representing all scientific and technical areas of the pharmaceutical manufacturing industry. ISPE remains committed to advancing its Members' educational and technical efficiency through forums for the exchange of ideas and practical experience, and technical resources like ISPE Guidance Documents—considered the gold standard in our industry. ISPE supports the international pharmaceutical industry by leading multiple programs and critical areas of interest, including Drug Shortages Initiative, Advancing Pharmaceutical Quality (APQ), Continuous Manufacturing, GAMP®, Product Quality Lifecycle Implementation (PQLI)®, and Regulatory Quality Harmonization.

ISPE takes great pride in the impact we have made by educating and uniting regulators, owner companies, service providers, and consultants to develop industry leading solutions. We look forward to leading, collaborating, sharing, and breaking new ground in the years to come.

ISPE is committed to fostering communications and interactions to advance common interests among the pharmaceutical industry and regulatory agencies.

2020 IN REVIEW: REGULATORY AND QUALITY CONTENT AND INTERACTIONS

The shift to virtual conferences in 2020 allowed a greater number of global regulators to participate in ISPE events as speakers, panelists, and attendees. Participation increased to than more than 150 regulators from 20+ countries.

ISPE was selected as one of a limited number of organizations to provide feedback on the second targeted consultation for the EU GMP Guidelines Annex 1 revision, and on the PIC/S GMP Guide Annexes for ATMPs and Biologics. ISPE member input was provided on those and seven other drafts released for consultation by global Health Authorities.

Numerous regulatory panel discussions were held at ISPE conferences, with regulators answering questions on topics such as Annex 1, digitization, practicalities of harmonization, COVID-19 learnings, possibilities for using distant assessment now and in the future, and the value of industry/regulatory interaction and collaboration for crises management.

ISPE continues to work with a group of 11 other associations identified as interested parties in communication with the EMA on topics such as drug shortage prevention in context with COVID-19, digitization, GMP for importers, EC GMP Guide Chapter 4 on Documentation/CSV Annex 11, GMP for IMPs (Investigational Medicinal Products), audit management in a changing environment, and more.

ISPE delivered three days of customized training for ANVISA assessors.

ISPE launched the Advancing Pharmaceutical Quality (APQ) Program with the publication of the first ISPE APQ Guide: Corrective Action and Preventive Action (CAPA) System. The program seeks to improve the state of pharmaceutical quality and ensure sustainable compliance.

ISPE's regulatory-focused volunteer groups - which comprise more than 250 volunteers connected ISPE members to the latest regulatory developments by delivering practical solutions delivered through ISPE educational events and publications, including seven webinars, six conference sessions, the 2020 Continuous Manufacturing workshop, the 2020 Annual Meeting Regulatory and Quality track and Global Regulatory Town Hall, five articles published in Pharmaceutical Engineering magazine, and seven other papers and blogs published on the ISPE website.

Lastly, ISPE launched the Regulatory Digest, a quarterly newsletter dedicated to informing members, global regulators, and the industry at large about ISPE's activities related to regulatory and quality.

ANNUAL MEETING AND CONFERENCES

GLOBAL REACH THROUGH VIRTUAL MEETINGS

"The range of subjects and the speakers engaged provided broad and experience-based content."

— ISPE Annual Meeting Attendee

The continued growth of technology enabled ISPE to have a global reach in the delivery of educational programs through live and on-demand video conferencing with people scattered across the globe with a touch of a button. ISPE hosted 2 in-person and 7 virtual programs worldwide in 2020, working with 100+ volunteer leaders on program development; showcasing 485 speakers; providing a platform for 90+ regulators from global agencies; and providing conference educational opportunities for 3,200+ members and non-members across the industry.

In addition to the traditional programs offered in North America and in Europe, we expanded on opportunities to partner with our Chapters and Affiliates around the globe that included our flagship annual events held virtually, and 7 topic-focused conferences, workshops, and forums in North America, Europe, and Asia Pacific regions.

2020 HIGHLIGHTS ISPE ANNUAL MEETING & EXPO

The ISPE Annual Meeting featured keynote speakers from Sparks Therapeutics, CSL Behring, GlaxoSmithKline, and FDA along with committee members, and speakers from around the world, featuring 60+ education sessions in six different tracks. More than 250 industry and regulatory experts shared their expertise and vision for the future of the industry, and networking opportunity with educational posters and exhibition hall that provided further opportunities for delegates to network and gain insight into the production approaches of other companies.

2020 FOF conference.

NORTH AMERICAN CONFERENCES

Other North American highlights included the Facilities of the Future Conference held in San Francisco, CA 30 – 31 January and the Aseptic Conference, held in Bethesda, Maryland 2 – 3 March, now in its 29th year.

ISPE's 5th Biopharmaceutical Manufacturing Conference (1 – 2 June) focused on innovation in facilities, production methods and technologies that enable a competitive and sustainable biopharmaceutical product supply for the future. This conference included experts that are developing, implementing, and operating advanced supply chains providing high quality medicines to global markets. Program presentations addressed challenges of new modalities, process, operational and facility innovations, and supply chain strategies bringing reliability, efficiency, and modernization for today's manufacturing and tomorrow's new therapies. The conference featured views and case studies by biopharmaceutical industry professionals, in additional to perspectives from regulatory officials. Regulators provided insights on CMC approaches, and CGMP developments for emerging technologies and individualized treatments.

Immediately following, 3 – 4 June, ISPE held the Continuous Manufacturing Workshop, now a 2 day event. Interest in continuous manufacturing of pharmaceuticals had exploded in the past few years, fueled by the recent regulatory approvals of the first few drug products to be manufactured by this emerging technology. The 2020 ISPE Continuous Manufacturing Workshop included industry practitioners, regulators and academics to discuss the recent successes and remaining challenges for continuous manufacturing of small molecule drug substances and drug products. The workshop provided an in-depth view of the manufacturing technologies and regulatory approaches for successful development, implementation, and lifecycle management of continuous manufacturing both for new molecules and for batch to continuous conversions.

ANNUAL MEETING AND CONFERENCES

ISPE EUROPE ANNUAL CONFERENCE

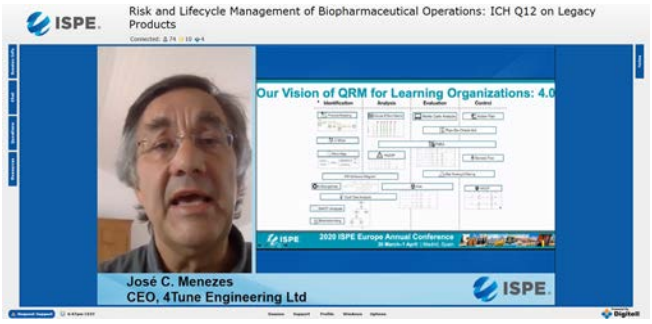
At the 2020 ISPE Europe Annual Conference on 16–17 September, which was a virtual conference, regulatory panel discussions included more than 20 regulators from eight countries and the European Medicines Agency (EMA), Medicines and Healthcare Products Regulatory Agency (MHRA), Pharmaceutical Inspection Co-operation Scheme (PIC/S), European Directorate for the Quality of Medicines (EDQM), and World Health Organization (WHO). Highlights included panel discussions on Distant Assessments During and After COVID-19, COVID-19 Challenges and Drug Shortages and COVID-19.

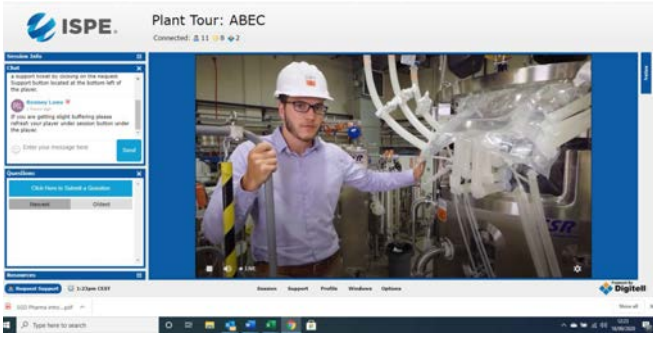
A regulatory panel discussed the topic of Distant Assessments on GMP and Inspection Reliance. Driven by digitalization, these assessments help the industry and regulators manage inspection challenges related to the COVID-19 pandemic. The panelists' comments suggest that virtual inspection can work, but there are definite challenges to the execution, including the need for common and harmonized processes and technology. Additionally, there are concerns about how companies can create rapport and build trust with regulators without face-to-face meetings. Despite the challenges, distant assessments seem to be worth pursuing as a way to support development of new, innovative drugs or and avoid drug shortages for patients.

Further discussions focused on Learnings from COVID-19 and explored how the industry and regulators are managing the challenges presented by COVID-19 and what can be learned for the future. In summary, panelists liked a holistic approach, particularly that overall quality requires full supply chain integration. Where there is good accessibility to information, more flexibility could be imagined.

"Highlights of the conference were the panel discussions and the virtual plant tours. The regulatory panel discussions focused on current and relevant topics in the recent COVID climate. The innovative virtual plant tours complimented a really strong programme."

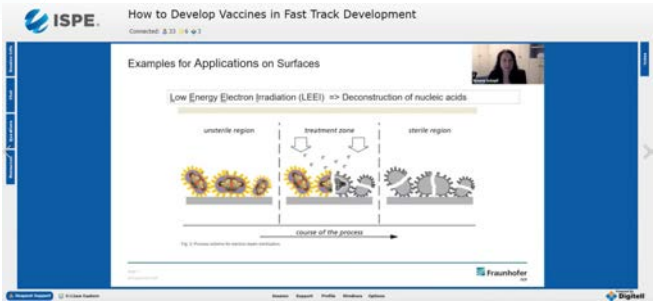
—EUROPE ANNUAL MEETING ATTENDEE





Virtual plant tour of ABEC.

ANNUAL MEETING AND CONFERENCES



2020 ISPE BIOTECHNOLOGY VIRTUAL CONFERENCE

The ISPE Europe Biotechnology Conference focused on how ATMPs, Aseptics and Drug Products Meet Digitalisation. Biologics continue to develop to the most important group of medical drugs in future and in October 2020, ISPE continued the series of successful Biotechnology conferences with a virtual conference. Case studies featuring new concepts to industrialisation, virtual plant tours to new, state-of-the-art facilities and a workshop where current industry practise and new ways of operations were explored, engaged our participants during this two-day event. The tracks focused on Quality and Regulatory changes for ATMPs, Digitalisation and Pharma 4.0, Transfer of Manufacturing Processes and Analytical Procedures between Facilities and ATMPs.

2020 ISPE PHARMA 4.0™ VIRTUAL CONFERENCE

At the 2020 ISPE Pharma 4.0™ Virtual Conference, 17–18 November 2020, 174 attendees gathered online to discuss and learn about the progress of the pharma-specific industry 4.0 approach, In Europe the protected trademark is “ISPE Pharma 4.0”. Interactive case studies and panel discussions ensured that participants stayed engaged and could participate throughout the two days.

Certain conclusions were that the holistic approach to Pharma 4.0™ is crucial to overcome the main implementation challenges. Whereas Pharma 4.0™ projects are often seen as technological projects, thinking outside of silos is always key—it is necessary to widen the plans, include competencies, involve organization, have strong sponsorship.

Panelists from the respective tracks highlighted that changes cannot be managed by one function within an organization; there has to be a multi-functional approach. Although the concept “digital transformation” may be easy to define, it can be difficult to ensure everyone has the same understanding and expectations.

ASIA EVENTS

ISPE partnered with the Asia Pacific Affiliates on the 2020 ISPE Asia Pacific Pharmaceutical Manufacturing Conference “Bracing for Impact: Best Practices for Maintaining Pharmaceutical Supply Chain Continuity in a Complex and Dynamic Environment”. The conference focused on helping attendees gain practical understanding of current data integrity issues, and presentations included: regulatory requirements and compliance; data integrity and enabling technologies; and data integrity execution and a risk-based approach that encourages companies to align their data integrity strategies with regulatory priorities and industry-critical initiatives. It was preceded by Executive Forum, giving delegates the unique opportunity to engage in peer-to-peer problem solving through practical exercises and real-world case studies.

16TH ANNUAL ISPE FACILITY OF THE YEAR AWARDS

2020 WINNERS

EQUIPMENT INNOVATION
F. Hoffmann-La Roche Ltd.
Project: Building 98 (B098)
Location: Basel, Switzerland

FACILITY INTEGRATION
Pfizer Inc.
Project: Andover Clinical Manufacturing Facility
Location: Andover, Massachusetts, USA

FACILITY OF THE FUTURE
Sanofi
Project: Digitally-Enabled, Integrated Continuous Biomanufacturing Facility
Location: Framingham, Massachusetts, USA

PROCESS INNOVATION
Janssen Pharmaceuticals
Project: Mirror 1: A Continuous Manufacturing Platform
Location: Beerse, Belgium

PROJECT EXECUTION
Bristol Myers Squibb
Project: Cruiserath Biologics Campus
Location: Cruiserath Campus, Tyrellstown, Dublin 15, Ireland

SOCIAL IMPACT
GlaxoSmithKline
Project: Attachment Inhibitor Project
Location: Parma, Italy

United Therapeutics
Project: Dinutuximab Dedicated Oncology Medical & Analytical Laboratory (DDOMAL)
Location: Silver Spring, Maryland, USA

OPERATIONAL EXCELLENCE
Eli Lilly and Company
Project: Lilly Innovation Development Center
Location: Indianapolis, Indiana, USA

HONORABLE MENTION
Boehringer Ingelheim Biopharmaceuticals China Ltd.
Project: OASIS
Location: Shanghai, China

J&J, Janssen Pharmaceuticals, Inc.
Project: Raritan CAR-T Clinical Manufacturing Facility
Location: Raritan, New Jersey, USA

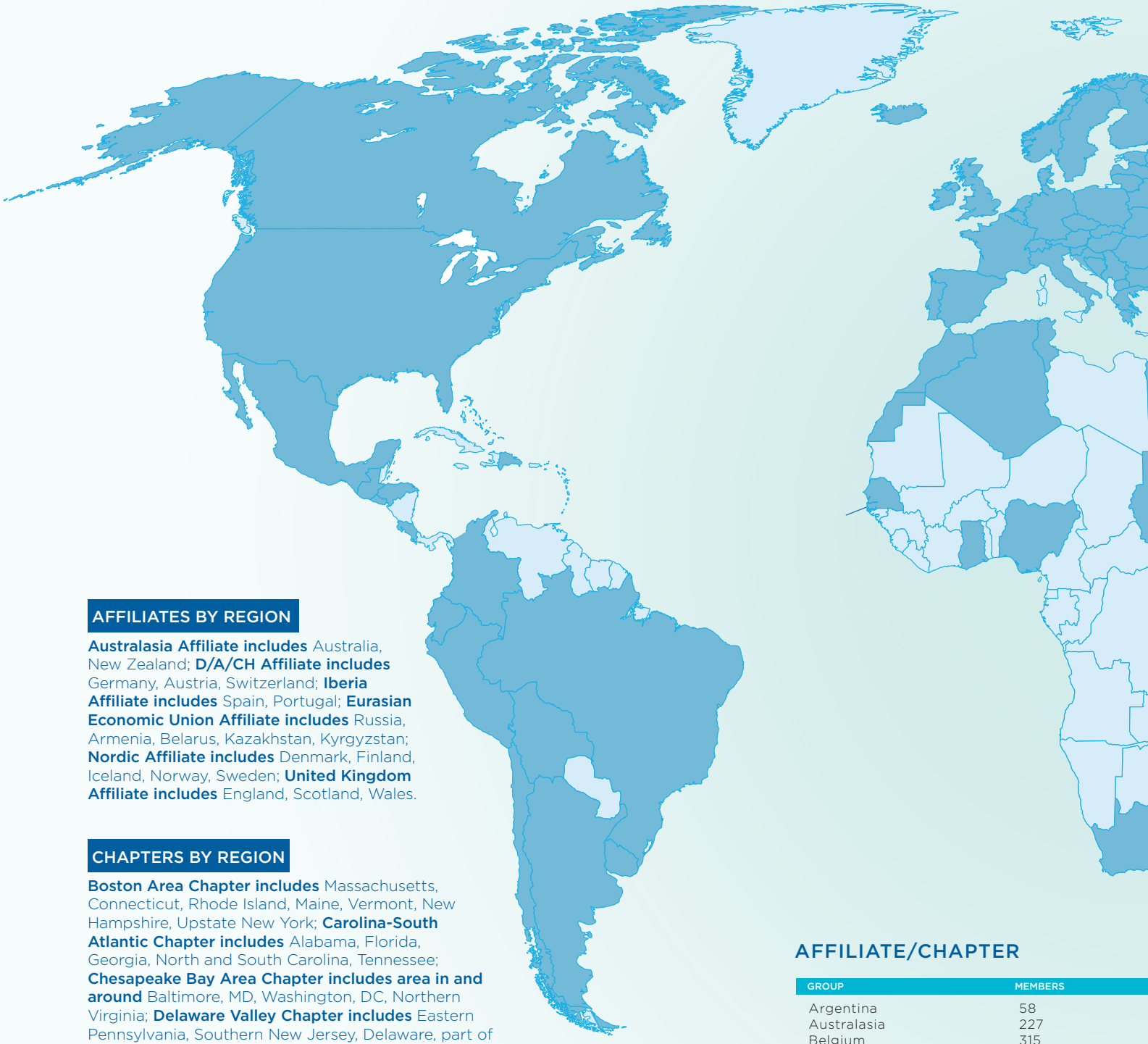
2020 FACILITY OF THE YEAR AWARDS OVERALL WINNER

Sanofi
Project: Digitally-Enabled, Integrated Continuous Biomanufacturing Facility
Location: Framingham, Massachusetts, USA

Sanofi was awarded the 2020 Facility of the Year (FOYA) Overall Winner at the 2020 Virtual FOYA Banquet during ISPE's 2020 Virtual Annual Meeting & Expo for its Digitally Enabled Integrated Continuous Biomanufacturing Facility project in Framingham, Massachusetts, USA.

Sanofi pushed the concepts of digitization to fully integrate process control, data collection, and analytics and built a fully integrated bioprocessing facility that takes the application of disposable process technology and flexible facility design to a new level. They used the best of already proven technology and design and expanded the use to allow design and construction of a facility that enables continuous processing. Through an innovative collaboration with equipment suppliers they were able to expand the use of single-use technology to include, media and buffer preparation, upstream, downstream, and column packing. This combined with a commitment to a 'born lean' design philosophy has created an industry factory 4.0 lighthouse.

ISPE MEMBERS WORLDWIDE



AFFILIATES BY REGION

Australasia Affiliate includes Australia, New Zealand; **D/A/CH Affiliate includes** Germany, Austria, Switzerland; **Iberia Affiliate includes** Spain, Portugal; **Eurasian Economic Union Affiliate includes** Russia, Armenia, Belarus, Kazakhstan, Kyrgyzstan; **Nordic Affiliate includes** Denmark, Finland, Iceland, Norway, Sweden; **United Kingdom Affiliate includes** England, Scotland, Wales.

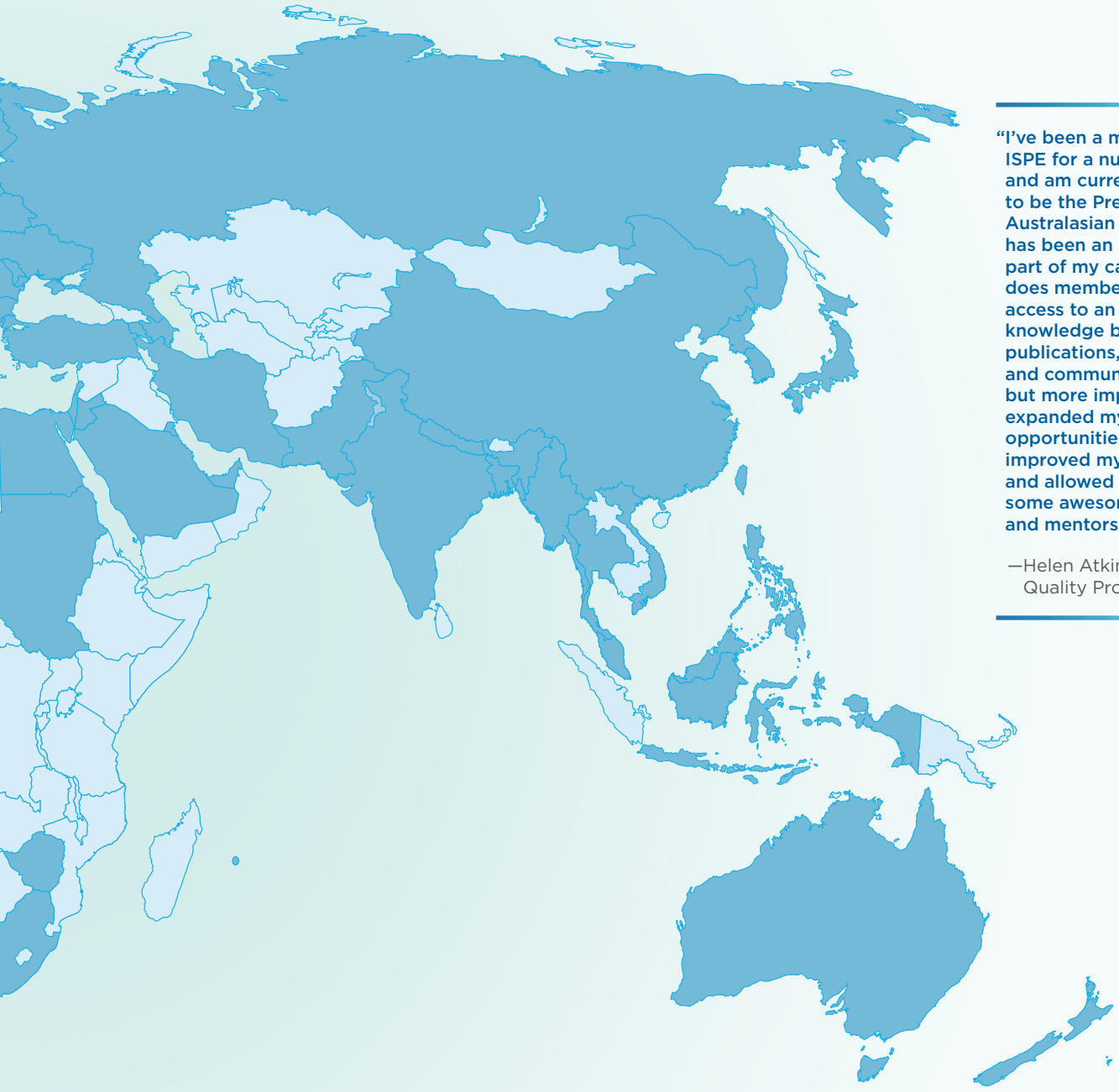
CHAPTERS BY REGION

Boston Area Chapter includes Massachusetts, Connecticut, Rhode Island, Maine, Vermont, New Hampshire, Upstate New York; **Carolina-South Atlantic Chapter includes** Alabama, Florida, Georgia, North and South Carolina, Tennessee; **Chesapeake Bay Area Chapter includes area in and around** Baltimore, MD, Washington, DC, Northern Virginia; **Delaware Valley Chapter includes** Eastern Pennsylvania, Southern New Jersey, Delaware, part of Maryland; **Great Lakes Chapter includes** Ohio, Indiana, Illinois, Michigan, Wisconsin, Kentucky; **Greater Los Angeles Area Chapter includes** Los Angeles, Orange, Ventura, and Riverside Counties; **Midwest Chapter includes** Missouri, Kansas, Iowa, Nebraska, Minnesota; **New Jersey Chapter includes** New Jersey, New York, Northeastern Pennsylvania; **Pacific Northwest Chapter includes** Washington, Oregon; **Rocky Mountain Chapter includes** Colorado, Utah; **San Diego Chapter includes** Southern California and north to Orange County; **San Francisco/ Bay Area Chapter includes** Northern California; **South Central Chapter includes** Texas, Oklahoma, Louisiana.

AFFILIATE/CHAPTER

GROUP	MEMBERS
Argentina	58
Australasia	227
Belgium	315
Boston	1346
Brazil	130
Canada	361
CASA	1003
Chesapeake	311
Czech/Slovakia	55
Delaware	767
Eurasian	80
France	197
D/A/CH	1105

An association is nothing without its members, and ISPE closed out the year in 2020 with nearly 18,000 members, continuing the growth pattern of the last several years. Even more impressive—and indicative of our ability to accurately gauge and meet modern members' needs worldwide—ISPE membership continued to grow during one of the most challenging years in the history of our industry.



"I've been a member of ISPE for a number of years and am currently proud to be the President of the Australasian Affiliate. ISPE has been an important part of my career. Not only does membership provide access to an incredible knowledge base through its publications, training events and communities of practice, but more importantly it has expanded my networking opportunities globally, improved my confidence, and allowed me to meet some awesome role models and mentors."

—Helen Atkinson,
Quality Professional

GROUP	MEMBERS	GROUP	MEMBERS
Great Lakes	605	New Jersey	685
Greater Los Angeles	378	Nordic	425
Iberia	182	Pacific Northwest	143
India	292	Philippines	140
Indonesia	272	Poland	94
Ireland	612	Rocky Mountain	275
Italy	485	San Diego	313
Japan	729	San Francisco	727
Korea	121	Singapore	274
Malaysia	367	South Central	155
Mexico	89	Thailand	275
Midwest	499	Turkey	136
Netherlands	221	UK	793

COUNTRIES WITH MEMBERS

COUNTRIES WITHOUT MEMBERS

PUBLICATIONS

PHARMACEUTICAL ENGINEERING® MAGAZINE: FOCUS ON KEY CONTENT PRIORITIES

For 40 years, Pharmaceutical Engineering® (PE) has provided ISPE members with information about trends and developments in the pharma industry. In 2020, PE continued to expand the PE Online portion of the ISPE.org site with Online Exclusives articles and continued the Open Access program for nonmember access to select content. The six bi-monthly issues of PE featured articles on topics including biopharma/cell and gene therapy, sustainability, aseptic, and the transition to digitalization.

January–February

The pharmaceutical industry's success is fueled by people, so PE initiated a year-long series of profiles of Industry Leaders, a look at the lives and careers of those who are changing the face of the industry.

March–April

An array of sustainability topics were explored, including real-world experiences, energy efficiency, and bioremediation of pharmaceuticals.

May–June

The introduction of ICH Q12, a transformational product life-cycle management guideline, provided a wide scope of applicability across drug substances and products, drug-device combination products, and new molecular entities and authorized products.

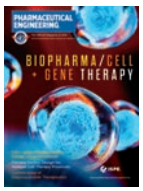
July–August

The ISPE Aseptic Conference provided a report on over two decades of the ISPE Barrier Isolator Survey, which has tracked the application of barrier technology and informed the industry of developments in aseptic.

September–October

Digitalization offers promise to transform the industry through capturing, analyzing, and using data to support everything from R&D to drug manufacture, supply chain management, patient engagement, and quality assurance and control, among other objectives.

November–December



Cell and gene therapy applications including simulations for facility design, facilities for multiple cell therapy processes, oligonucleotide therapeutics development, and more were explored in this annual revisit to fast-developing approaches.

GUIDANCE DOCUMENTS

ISPE Guidance Documents, today acknowledged as the gold standard for the pharmaceutical manufacturing industry's technical content, have been offering practical answers to the complex, dynamic challenges facing pharmaceutical operations and facilities around the world since the first Guide, the ISPE Baseline® Guide: Volume 1 – Bulk Pharmaceutical Chemicals, was published in 1996. In 2020, ISPE published five Guides, expanding our efforts to meet the growing demands of industry for current best practices that meet and exceed regulatory expectations. ISPE Guidance Documents continue to ensure a solid base for training programs that inevitably spring from these expertly written Guides.

GUIDANCE DOCUMENTS PUBLISHED IN 2020

- ***ISPE Good Practice Guide: Critical Utilities GMP Compliance – How to Be Compliant and Ready to Prove It***
  June 2020
- ***ISPE Guide: Cleaning Validation Lifecycle – Applications, Methods, and Controls***
  August 2020
- ***ISPE GAMP® RDI Good Practice Guide: Data Integrity by Design***
  October 2020
- ***ISPE Advancing Pharmaceutical Quality Guide: Corrective Action and Preventive Action (CAPA) System***
  November 2020
- ***ISPE Good Practice Guide: Equipment Reliability***
  December 2020

PROFESSIONAL DEVELOPMENT

A PASSION FOR EDUCATION, A COMMITMENT TO LIFELONG LEARNING

To excel, we must continue to grow, and in order to grow, we must continue to learn, train, educate, and share. ISPE's professional development and training programs provide our members with a path forward, but we knew it was time to ensure and expand access to the Society's portfolio of training courses. So, in 2020, in response to the COVID pandemic, ISPE accelerated it's goal to move it's professional development into the virtual realm. Online Live training was successfully launched in March and continued through the remainder of 2020.

There was also continued success in custom training. ISPE partnered with multiple companies to provide the industry with educational courses that were specifically tailored to individual needs.

Throughout the year, ISPE continued to lead the pharmaceutical community through instruction of GAMP® practices to ensure the integrity of our data. We developed and retained relationships with quality instructors who will continue to provide knowledge and experience throughout our community.

ISPE TRAINING COURSES CONTINUE TO SUPPORT THE BUSINESS INITIATIVES OF COMPANIES SUCH AS:

- Abbott Laboratories
- AbbVie
- Alkermes
- Allergan, Inc.
- Amgen, Inc.
- Astelllas
- AstraZeneca
- Bausch & Lomb, Inc.
- Baxter BioScience Manufacturing
- Bayer CropScience AG
- Elan Corporation
- Eli Lilly and Company
- Emergent BioSolutions, Inc.
- FDA
- F. Hoffmann-La Roche, Ltd.
- Genentech, Inc.
- Genzyme Corp.
- Gilead Sciences, Inc.
- GlaxoSmithKline
- H Lundbeck A/S
- Health Canada
- Hikma
- Johnson & Johnson
- Lonza
- Merck & Co., Inc.
- Mylan, Inc.
- National Centers for Animal Health USDA
- National Institutes of Health
- Novartis International AG
- Novo Nordisk
- Ortho-Clinical Diagnostics
- Pfizer, Inc.
- Regeneron Pharmaceuticals, Inc.
- Sanofi Pasteur
- Synthes, Inc.
- U.S. Department of Veterans Affairs
- Ulma Packaging USFDA
- W.L. Gore Associates

NORTH AMERICA TRAINING

OVER 400 TRAINED

EUROPE TRAINING

OVER 130 TRAINED

COURSES TAUGHT

OVER 25 COURSES

TRAINING WEB STATS

1,615,139 SESSIONS

926,864 USERS

3,704,753 PAGEVIEWS

THE BOTTOM LINE

ISPE completed another fiscally successful year on 31 December 2020. Despite significant impacts on operations from COVID-19, positive operational and investment performance combined to provide sufficient funding for ISPE's continued improvements in products, services, and information offered to Members and the Society. ISPE's auditors, Dearolf & Mereness LLP, conducted the 2020 audit and gave ISPE an unqualified opinion, indicating that ISPE's financial statements fairly represented the organization's financial position and were in accordance with generally accepted accounting principles.

Assets and liabilities were in balance on 31 December 2020, at $10.7 million, which equates to a decrease of approximately 13.4% over 2019 and was a direct result of the impacts of COVID-19. Notwithstanding these challenges, ISPE continued to implement new technology and improved business processes during the year. Overall operating income and expense activities resulted in a gain of $160,000. Additionally, in 2020 the ISPE Board approved strategic initiatives that resulted in an additional $577,000 of expenses. These costs were partially offset by $239,000 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 2020 of a negative $178,000.

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. The organization's 2020 financial reserves gained $215,000 over 2019. 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.

FINANCES

STATEMENT OF FINANCIAL POSITION

FOR THE YEAR ENDED DECEMBER 31, 2020

(With comparative financial information for 2019)

ASSETS		
CURRENT ASSETS	**2020**	**2019**
Cash and Cash Equivalents	$ 2,339,322	$ 4,021,763
Short-term investments	-	-
Accounts receivable	621,243	829,354
Inventory of technical materials	32,746	34,626
Prepaid Expenses	297,977	242,206
TOTAL CURRENT ASSETS	**3,291,288**	**5,127,949**
OTHER ASSETS		
Property and equipment = net	567,411	720,151
Investments	6,758,611	6,526,026
Deposits	65,272	51,890
TOTAL OTHER ASSETS	7,391,294	7,298,067
TOTAL ASSETS	$ **10,682,582**	$ **12,426,016**

LIABILITIES AND NET ASSETS		
CURRENT LIABILITIES		
Accounts payable	$ 523,158	$ 1,337,677
Accrued expenses	264,916	462,324
Contract Liabilities	2,698,556	3,265,495
TOTAL CURRENT LIABILITIES	**3,486,630**	**5,065,496**
LONG-TERM LIABILITIES		
Accrued rent	440,550	426,987
TOTAL LIABILITIES	**3,927,180**	**5,492,483**
NET ASSETS		
Unrestricted	6,755,402	6,933,533
TOTAL LIABILITIES AND NET ASSETS	**$ 10,682,582**	**$ 12,426,016**

STATEMENT OF ACTIVITIES

FOR THE YEAR ENDED DECEMBER 31, 2020

(With comparative financial information for 2019)

REVENUES		
PROGRAM REVENUES	**2020**	**2019**
Professional development	$ 4,273,837	$ 8,795,727
Membership services	3,361,535	3,583,325
Guidance documents	2,048,895	1,760,669
Advertising fees	695,407	717,355
TOTAL PROGRAM REVENUES	**10,379,674**	**14,857,076**
OTHER		
Investment income	215,538	768,529
Miscellaneous	813	14,318
TOTAL OTHER REVENUES	**216,351**	**782,847**
TOTAL REVENUES	**10,596,025**	**15,639,923**

EXPENSES		
PROGRAM SERVICES		
Professional development	4,120,872	7,508,983
Membership services	1,592,842	1,793,783
Guidance documents	865,281	808,205
Publications	527,277	619,106
TOTAL PROGRAM SERVICES	**7,106,272**	**10,730,077**
Management and general	3,652,714	3,586,242
TOTAL FUNCTIONAL EXPENSES	**10,758,986**	**14,316,319**
Unallocated payment to nonprofit organization	–	50,000
TOTAL EXPENSES	**10,758,986**	**14,366,319**
CHANGE IN NET ASSETS FROM OPERATIONS	**(162,961)**	**1,273,604**
NET CHANGE OF FOREIGN CURRENCY REMEASUREMENT	(15,170)	(75,235)
Change in net assets	(178,131)	1,198,369
NET ASSETS— BEGINNING OF YEAR, AS STATED	**6,933,533**	**5,760,209**
Change in Accounting Princiiple - Revenue Recognition	–	(25,045)
NET ASSETS— BEGINNING OF YEAR, AS RESTATED	**6,933,533**	**5,735,164**
NET ASSETS—END OF YEAR	**$ 6,755,402**	**$ 6,933,533**

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