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Ex Officio Young Professionals Representative
Brody Stara
Engineer Amgen

2017 ISPE FOUNDATION BOARD OF DIRECTORS

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Andrew Signore
IPSDB
EMBRACE. EVOLVE. EXCEL.

We believe the theme of this Annual Report really captures the spirit of what ISPE has accomplished as a Society in the past year.

We EMBRACED change as we launched several new initiatives, including the ISPE Foundation, a new website, and a conference in the Asia Pacific region.

We EVOLVED as we watched budding programs like Women in Pharma® and our Young Professionals communities grow and mature.

And we EXCELLED in our efforts to deliver world-class education to our members and the industry through our conferences, training, and publications, including hosting our largest-ever Annual Meeting & Expo in San Diego.

In nearly all areas of the organization, ISPE experienced real growth in 2017.

- Global membership surpassed 18,000 members.
- We enjoyed our largest-ever annual conferences in both the U.S. and Europe.
- We published the largest number of Guidance Documents since 2012, strengthening our library of technical documents—already considered the gold standard in our industry.

But we couldn’t have done it without the efforts of our tireless volunteers, our dedicated members, and our great staff in North America and abroad.

We’re looking forward to what 2018 holds for ISPE as we move our publications to digital environments, 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 sponsored by the ISPE Foundation.

The staff and leadership of ISPE are working hard to create the best professional association we can for our industry. But we need your help to do it. We encourage all members to get more involved with YOUR Society in 2018. Volunteer for a committee, contribute to creating a Guidance Document, or simply invest in the future by donating to the ISPE Foundation.

Together, we’ll continue to EMBRACE, EVOLVE, and EXCEL in 2018 and for many years to come.

Timothy P. Howard, CPIP, PE  
Chair  
ISPE Board of Directors

John Bournas  
CEO and President  
ISPE
The success of tomorrow depends on the preparation of today's pharmaceutical professionals, so—in recognition of the importance of lifelong education, training, and research—ISPE announced the launch of the ISPE Foundation in 2017. Funded by the generosity of donors, the Foundation champions ISPE's mission—to serve diverse global communities by advancing, disseminating, and applying knowledge benefiting the industry and the patients our members serve—through three primary initiatives that will influence our future:

- **Building the Workforce of the Future:** Through the ISPE Travel Grant Program, which attracts, supports, educates, and trains talented young people entering the industry, students and young professionals will receive financial support to further their professional development and contribute to building our industry's future workforce.

- **Empowering Women and Increasing Diversity:** The Foundation will support ISPE's recently launched Women in Pharma® (WIP) program, which provides professional training and education, as well as supports mentoring and networking opportunities, for women and ethnically diverse people. By putting ISPE's full support behind the Women in Pharma program, we aim to drive forward the successful career progression of under-represented groups within the pharmaceutical industry.

- **Global Knowledge Exchange:** Translation of ISPE’s highly regarded industry Guidance Documents will make this valuable content available to a growing global workforce through the Emerging Markets Knowledge Exchange. ISPE’s Global Training and Harmonization Fund will also be used to sponsor the training of global regulators in industry best practices.

The Women in Pharma® (WIP) community continued to strengthen and grow in 2017, with a focus on providing women in the pharmaceutical industry a common forum on which to connect and collaborate. The community’s 2017 activities featured mentoring, educational sessions, and social and networking opportunities, all of which helped women in the industry achieve career success and work-life balance.

We also honored the first recipient of ISPE’s Women in Pharma (WIP) Award in 2017, recognizing Wided Najahi-Missaoui, MS, PharmD, University of Georgia (UGA). After earning a pharmacy degree in 1999 from the College of Pharmacy in Monsatir, Tunisia, Wided worked as a retail pharmacist for eight months before moving to Georgia in 2000 with her husband, Ali Missaoui, PhD, plant genetics and genomics. In spite of her arrival in the United States with scant knowledge of English (Arabic is her native tongue and French her second language), her determination and passion led her to earn two master’s degrees: one in pharmaceutics from the University of Iowa and one in biochemistry and molecular biology from UGA.

In addition to raising two boys, now 10 and 13, Wided is currently a fifth-year doctoral student, investigating nanoparticulate drug delivery systems such as liposomes to target therapies for prostate and breast cancer. Her overall goal is to integrate the pathophysiology of cancer with the pharmacology of these drug delivery systems to develop more efficient targeted cancer therapies.

Congratulations Wided!
TAking ISPE's global Growth to the web

In 2017, we launched an entirely redesigned website to better reflect all that ISPE has to offer—incorporating streamlined navigation; clear design; enhanced searchability; improved accessibility to Chapter, Affiliate, and Communities of Practice sites; and a responsive layout.

“Our team worked diligently to craft a website that would be truly beneficial to all of our visitors worldwide, creating an advanced, informative, and easy-to-navigate channel to access our full spectrum of resources and benefits,” said John Bournas, ISPE CEO and president.

ISPE’s focus on delivering fresh, relevant content and additional features at ispe.org did not go unnoticed:

WEB STATS

<table>
<thead>
<tr>
<th>Year</th>
<th>Sessions</th>
<th>Users</th>
<th>Pages</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>1,039,280</td>
<td>664,331</td>
<td>3,240,041</td>
</tr>
<tr>
<td>2017</td>
<td>1,087,969</td>
<td>653,424</td>
<td>3,221,242</td>
</tr>
</tbody>
</table>

Expected for 2018:

- Sessions increase of 22%
- Users increase of 13%
- Page views increase of 14%

**Young Professionals Efforts Grow**

With many of ISPE’s Young Professionals (YP) groups first established in 2016, 2017 marked a year of growth for members who are either just starting out their careers in pharma or are making a career change.

Two major YP initiatives in 2017 included the inaugural “YP Hackathon,” held in Barcelona during the ISPE Europe Annual Conference. This unique and collaborative working session, adapted from the IT industry’s hackathons, inspired young professionals from all disciplines in the pharmaceutical industry throughout Europe to try to solve one of the biggest challenges facing the industry —Digitalisation and Industry 4.0. Guided by Gert Malgaard (Malgaard Consulting) and Damian Greene (PharmaBioSource), the epic brainstorming sessions enabled young professionals to get first-hand insight and feedback from experienced industry leaders, in addition to benefiting from introductory speeches, keynote presentations, and a networking dinner with industry leaders and pharmaceutical industry professionals.

Looking forward, the YP community will continue to organize events that provide opportunities for members to gain access to support and advice while encouraging one another in their professional advancement; participate in discussions that promote, foster, and direct programs for those new to the industry; and explore issues common to younger professionals and seek means of accentuating the positives while finding resolutions for the negatives.

“I joined ISPE as a Young Professional and used my membership to learn about new processes and be at the cutting edge of innovative technologies to better help my clients in addressing their needs. ISPE also helped me obtain key connections, foster relationships through networking and industry involvement, and meet key industry decision-makers from around the world.”

FRANCIS HUMES CAPPELLO, BME, PE, Key Account Manager, Gerflor USA Industry Member with ISPE San Diego Chapter
THE POWER OF FACE-TO-FACE MEETINGS

The astonishing growth of technology has made our world feel smaller than ever, with the ability to live-video conference with people scattered across the globe with a touch of a button. But there’s still no replacement for capturing the energy and synergies found when we gather face-to-face, talking and teaching about the passions that drive us in our careers. To capture that energy and help it power our future, ISPE hosted 13 programs worldwide in 2017, working with 100+ volunteer leaders on program development; showcasing 530 speakers; providing a platform for 70+ regulators from global agencies; and providing conference educational opportunities for 4,300+ 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, including flagship annual events in Rome and San Diego, and 11 topic-focused conferences, workshops, and forums in North America, Europe, and Asia Pacific regions.

2017 HIGHLIGHTS

ISPE ANNUAL MEETING & EXPO
San Diego, CA
Our largest annual meeting ever! Featuring keynote speakers from AstraZeneca, GlaxoSmithKline, McKinsey, and Biogen, attendance topped 1,850 delegates, committee members, and speakers from around the world, featuring 70+ 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 facility tours of Genentech, Gilead, and Illumina sites provided further opportunities for delegates to network and gain insight into the production approaches of other companies.

NORTH AMERICAN CONFERENCES

Other North American highlights included the Aseptic Conference, held in Reston, VA, now in its 26th year, and the Process Validation/Process Validation Statistics Conferences, held in Bethesda, MD, for its fourth year, which focused on the ongoing challenges of implementing and maintaining the lifecycle approach to process validation.

The Quality Manufacturing Conference returned to Arlington, VA, in 2017, providing a unique opportunity to work in teams.
to identify issues and solutions for topics selected from the Federal Drug Administration’s (FDA) 2017 list of priorities for the pharmaceutical industry. It was preceded by a Data Integrity Workshop, giving delegates the opportunity to engage in peer-to-peer problem solving through practical exercises and real-world case studies.

ISPE’s 2nd Biopharmaceutical Manufacturing Conference, in San Francisco, CA, focused on operational agility and launch readiness. Two unique features of the program included a half-day on advanced therapeutics and a special discussion on maintaining business continuity in the aftermath of natural disasters. A unique Biopharmaceutical Leadership Forum, designed for the supply chain executive, preceded the conference.

In 2017, ISPE also sponsored meetings to address new hot topics in the industry, including the Quality Culture and Quality Metrics Conference in Bethesda, MD, which provided tools for improving organization quality culture, and the Serialization Workshop in Philadelphia, PA, to provide guidance on the rollout of regulatory requirements for serialization.

“We honestly enjoy every single event that ISPE has because, year after year over the last eight years, it’s given us double-digit growth and more presence in the pharmaceutical market.”

ANNUAL MEETING ATTENDEE

Attendees at ISPE’s Annual Meeting & Expo discover new technologies, learn from an expert panel, and network with peers.
The ISPE Europe Annual Conference drew more than 500 people to Barcelona, for a gathering described by an attendee as “the best and biggest conference ever.” With 77 education sessions and 50 exhibitors, ISPE CEO and President John Bournas noted that the 2017 event doubled previous ISPE Europe attendance records. Featured tracks included Facilities of the Future, Advanced Aseptic Processing, Data Integrity, and Clinical and ATMP Supply Chain.

Other European meeting highlights included the Second Annual ISPE Europe Biotechnology Conference, where 340 attendees traveled to Dublin, Ireland, to learn about and discuss current challenges and megatrends in biopharmaceutical production. Featured tracks included Technology, Innovation, and Factory of the Future, as well as a track dedicated to process science, knowledge management, and regulatory affairs that asked, “What does quality look like in the future?”

“ISPE Annual Meetings pave the way for connecting with old colleagues from around the globe and meeting new colleagues. I see ISPE as a platform to share knowledge and to build on each other’s expertise when it comes to all things pharma and biotech.”

ANNUAL MEETING ATTENDEE
Trends that were noted included operational excellence, continuous manufacturing, new process analytic tools, single-use technology, and better scalability.

More than 230 participants from 19 countries later gathered in Verona—located in Italy’s high-tech corridor—for a conference focused on the challenges and opportunities of Pharma 4.0. Co-organized by ISPE Europe, ISPE Italy, and the Pharma 4.0 Special Interest Group (SIG), the event featured high-profile speakers from ISPE working groups as well as innovation leaders from pharmaceutical companies, contract manufacturing organizations, equipment vendors, consulting firms, and academia. Topics included end-to-end integration, data integrity and analytics, automation, and the workforce of the future.

ASIA EVENTS

Rounding out the year, ISPE partnered with the Singapore Affiliate on the ISPE 2017 Asia Pacific GAMP® Data Integrity Conference to highlight this important topic and bring expert speakers to the region. 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.
“At the end of the day, ISPE is about breaking down barriers and working together for what is best for the future of medicine. I started as an undergrad student. The connections I made through ISPE were the people who recommended me for interviews for all of my previous and current roles.”

BRODY STARA,
Former Student Member,
Student Chapter President (U Mass Amherst), Young Professional; now Senior Consultant with Ernst & Young
An association is nothing without its members, and ISPE closed out the year in 2017 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—we’ve seen an 11 percent increase in our member retention rate since 2013—an enormous accomplishment in a world with ever-increasing distractions and options.
ANNUAL REPORT

PHARMACEUTICAL ENGINEERING MAGAZINE, KEEPING MEMBERS IN TOUCH

Sharing successes, watching trends, reporting on new discoveries and industry challenges, and connecting our membership through Pharmaceutical Engineering (PE) magazine has been a priority since ISPE’s official magazine was first published 37 years ago. In 2017, our six bi-monthly issues of PE continued that tradition, featuring more than 120 articles on topics as diverse as biologics to CAR-T-cell therapy and includes important news about ISPE and its Chapters and Affiliates. Highlights from the year included:

**January–February**

Robin Kumoluyi, who had just joined Johnson & Johnson Quality Systems and Services as vice president at the time of publication, was profiled as “The New Face of Leadership.” J&J is just one of eight pharmaceutical companies and a non-pharma company that Robin has served in the course of her remarkable 30-year career and, although her achievements would be impressive by any measure, they are even more impressive for the example she set for achievements by women in the pharmaceutical industry.

**March–April**

Joseph Famulare, vice president of Global Compliance and External Collaboration at Genentech at the time of publication and a past chair of ISPE’s Board of Directors, and other leaders discussed “Compliance Challenges for a Global Industry” in the cover story. Famulare noted that compliance is an evolving process with key areas for attention, including GMP (good manufacturing practice) and GDP (good documentation practice) for data integrity and regulatory compliance with the manufacturing license; modernizing processes and facilities; and managing post-approval changes.

**May–June**

Anthony Maddaluna of Pfizer, Inc. was profiled in “A Matter of Well-Being.” The profile traced the four-decade career of Maddaluna through Pfizer to his final role as executive vice president. He ascended the organization through managerial roles overseeing manufacturing plants and processes, and along the way accomplished significant work in the areas of RFID (radio frequency identification) labeling and dealing with drug shortages.

**July–August**

The cover story addressed the birth and potential of an exciting technology in “Just Getting Started: 3D Printing and Bioprinting in Pharmaceutical Manufacturing.” 3D printing shows great promise for producing drug products and may make a significant contribution to personalized medicine solutions for individual patient care.

**September–October**

“A Breakthrough for Industry and Patients” highlighted the development of CAR T-cell therapy. This new therapy uses a patient’s own T-cells to fight cancer, and the first FDA-approved gene-transfer therapy of this kind was Novartis’ Kymriah. Development is underway for additional CAR T-cell products by other companies.

**November–December**

The growing biopharmaceuticals market was captured in “Crossing Over to Large Molecules: Bridges to Biomanufacturing.” Biological products, produced as injections or infusions, contain whole cells or complex proteins. Because of this, they present different manufacturing challenges from the traditional pharmaceuticals called active pharmaceutical ingredients (APIs).
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 2017, ISPE published six Guides—the most we have published since 2013—expanding our efforts to meet the growing demands of the industry and ensuring a solid base for training programs that inevitably spring from these expertly written Guides.

GUIDANCE DOCUMENTS PUBLISHED IN 2017

  7 February 2017

• ISPE GAMP® Guide: Records and Data Integrity
  31 March 2017

• ISPE Good Practice Guide: Decommissioning of Pharmaceutical Equipment and Facilities
  15 June 2017

  17 July 2017

• ISPE GAMP® Good Practice Guide: IT Infrastructure Control and Compliance (Second Edition)
  29 August 2017

• ISPE GAMP® Good Practice Guide: Validation and Compliance of Computerized GCP Systems and Data: Good eClinical Practice
  6 December 2017

ISPE also participated in the translation of two additional Guides—first published in prior years—to make this important information available to a wider global industry. Those titles are:

  6 September 2017

• ISPE D/A/CH Affiliate: Containment Manual (English Translation)
  31 March 2017
A PASSION FOR TRAINING, 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 access the Society’s portfolio of training courses. So, in 2017, ISPE initiated review of a Global Education Strategy and Implementation Plan, with a training audit and audience-based research serving as key components of the assessment. The results of the audit confirmed that the training function should remain core to ISPE’s organizational mission and be defined more broadly to include education, learning, and performance support activities that are available to all members. Additionally, given the proven success and ongoing demand for custom training, ISPE’s decision to align training with organizational goals would provide further opportunities to differentiate ISPE training.

Throughout the year, ISPE continued to lead and facilitate the development of next-generation process technologies and innovative technical solutions. On matters of regulation, our focus remained on those requirements that impact—or will impact—the licensing of facilities, manufacturing processes and operations, and the sustainability of the supply chain over the product lifecycle. We developed and retained relationships with and will continue to provide key access to major regulatory agencies at the most senior levels.

ISPE ONSITE TRAINING COURSES IN 2017 SUPPORTED THE BUSINESS INITIATIVES OF THE FOLLOWING COMPANIES:

- Abbott Laboratories
- AbbVie
- Alkermes
- Allergan, Inc.
- Amgen, Inc.
- AstraZeneca
- Bausch & Lomb, Inc.
- Baxter BioScience Manufacturing
- Bayer CropScience AG
- Elan Corporation
- Eli Lilly and Company
- Emergent BioSolutions, Inc.
- F. Hoffmann-La Roche, Ltd.
- Genentech, Inc.
- Genzyme Corp.
- Gilead Sciences, Inc.
- GlaxoSmithKline
- H Lundbeck A/S
- Health Canada
- Johnson & Johnson
- Merck & Co., Inc.
- Mylan, Inc.
- National Centers for Animal Health USDA
- National Institutes of Health
- Novartis International AG
- 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

TAMPA, FL, TRAINING
San Diego, CA, and Boston, MA

NORTH AMERICA TRAINING

EUROPE TRAINING
Copenhagen, DK, Manchester, UK, Amsterdam, NL

322 TRAINED
170 TRAINED
228 TRAINED

35 COURSES TAUGHT
Networking and sharing best practices helps set the stage for a successful future, and ISPE’s Regulatory Affairs team puts this practice into action every day with its mission of encouraging and facilitating engagement with global regulators to regularly exchange information for the greater good and serving as a technical resource for aligning ISPE’s activities and products with evolving regulatory expectations.

Whether bringing together regulatory staff, volunteer groups, and advisor/consultants to develop ISPE’s strategies for interacting with regulatory agencies and authorities worldwide, or coordinating the integration of regulatory opportunities and relationships throughout Society activities, our Regulatory Affairs team made 2017 a year to celebrate:

- Convened more than 70 regulators from 13 countries for ISPE events in Asia-Pacific, Europe, and the U.S. as attendees or speakers.
- Published the Pew-ISPE Report on Drug Shortages and The ISPE Quality Excellence Report.
- Provided input to health authorities on six draft documents on Serialization, Continuous Manufacturing, Data Integrity, Quality Metrics, Risk-based Prevention of Cross Contamination, Electronic Records and Signatures.
- Implemented a Regulatory Steering Committee to provide strategic direction to the more than 250 volunteers operating in ISPE’s regulatory committees and working groups. In 2017, these volunteers:
  - Implemented first-of-kind industry workshops for knowledge exchange on quality metrics, advancing the industry/regulator dialogue beyond written feedback on proposed regulatory guidance to the real-time conversations necessary for advancing pharmaceutical quality.
  - Led the development of the Regulatory/Quality track and the Regulatory Town Hall, and produced five sessions at the 2017 ISPE Annual Meeting.
  - Developed the Process Validation (PV) Conference and the PV Statistics Conference and published two technical papers.
  - Developed and produced the ISPE Cultural Excellence Conference and published The ISPE Quality Excellence Report.
  - Developed a Quality Metrics training course.
13TH ANNUAL ISPE FACILITY OF THE YEAR AWARDS

ISPE’s Annual Facility of the Year Award (FOYA) program recognizes the accomplishments, commitment, and dedication of companies worldwide that demonstrate innovation and the advancement of pharmaceutical science and manufacturing technology.

Created to recognize the best new or renovated pharmaceutical manufacturing facilities, the program enables the pharmaceutical manufacturing industry to showcase its new products and accomplishments in facility design, construction, and operation in building a superior working environment, while sharing the development of new applications of technology and cutting-edge approaches that are being adopted by the industry.

2017 WINNERS

Equipment Innovation
Cook Pharmica
Location: Bloomington, IN, USA
Project: Flexible Filling Line (FFL)

Facility Integration
Bristol-Myers Squibb
Location: Devens, MA, USA
Project: Biologics Development Building/Clinical Manufacturing Building

Facility of the Future and Process Innovation
Eli Lilly and Company
Location: Indianapolis, IN, USA, and Carolina, PR
Project: Continuous Direct Compression Manufacturing Kits 2 & 3

Operational Excellence
Abbott
Location: Longford, Ireland
Project: Operational Excellence – A New Quality Approach

Project Execution
Jazz Pharmaceuticals Ireland Limited
Location: Athlone, Ireland
Project: Project Rock

Nephron Pharmaceuticals Corporation
Location: West Columbia, SC, USA
Project: Nephron SC

Novartis-Penn Center for Advanced Cellular Therapies
Location: Philadelphia, PA, USA
Project: Novartis-Penn Center for Advanced Cellular Therapies (CACT)

PT. Kalbio Global Medika
Location: Jakarta, Indonesia
Project: Biotech Facility

2017 Overall Facility of the Year
Eli Lilly and Company
Project: Continuous Direct Compression Manufacturing Kit 2 & 3, Indianapolis, IN, USA, and Carolina, PR

The primary goal of Eli Lilly’s continuous direct compression (CDC) process implementation was to rapidly build a network of innovative, state-of-the-art Good Manufacturing Practice Oral Solid Dose (GMP OSD) facilities to deliver new, advanced therapies to patients. While many firms are building OSD continuous processing facilities, Eli Lilly is the only company with multiple, replicated, and operational CDC sites. Eli Lilly and Company was also honored in the Facility of the Future and the Process Innovation Categories.
CONGRATULATIONS

Honoring our own and celebrating the best in our industry is, we believe, about far more than plaques and glittering awards. Rather, ISPE’s International Honor Awards program allows us the opportunity to thank and honor the individuals who have served as mentors and inspirations. It gives us—by highlighting the notable achievements of extraordinary people and companies—something to strive for. And, it provides a platform for advancing the incredible work and advancements that our members and member companies have made in their respective fields and industry.

Please join us in congratulating the 2017 Honorees of ISPE’s 2017 International Honor Awards!

2017 INTERNATIONAL HONOR AWARD WINNERS

Joseph X. Phillips Professional Achievement
Robert W. Tribe

Richard B. Purdy Distinguished Achievement
Robert E. Chew, PE

Max Seales Yonker Member of the Year
François Sallans, PharmD

Named in honor of Max Seales Yonker, an active member, Society leader, and a relentless contributor to ISPE and to the industry, the 2017 Member of the Year Award went to François Sallans, vice president and chief quality officer at Johnson & Johnson, who remarked upon receiving 2017 honors, “We have done a lot since 2012, but we have done nothing at the same time. In Barcelona, we discussed the way forward in drug shortages, and we were pretty satisfied with what we had done. And then, in September, Mother Nature taught us a lesson to a degree we never anticipated. Until then, resilience was a vague and theoretical concept. Now we realized what it meant. In Puerto Rico, what I saw was a lesson in resilience. We found people helping each other. Collaborating. I talked to one technician who lost her house. And this person was in the plant after five days because she cared about the patients she had the privilege to serve. She’s an example of hundreds of people standing up and doing their job. I know you’ve seen it in your people, too. This is the health care industry at its best.”
THE BOTTOM LINE

Following an audit by Dearolf & Merenss, LLP, of ISPE’s 2017 fiscal year, which finished on 31 December 2017, the firm gave ISPE an unqualified opinion 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 2017 at $10.4 million, which equates to an increase of approximately 18 percent over 2016. ISPE showed a positive change in net assets of $1.3 million for the fiscal year. Profitable operations and the favorable effect of market investments were the primary cause of this gain.

Strategic initiatives were focused on ISPE’s continued improvements in products, services, and technical information offered to members and society. ISPE continued to implement new technology and improved business processes during the year to meet these goals. To ensure funding for future strategic initiatives in support of ISPE’s mission, and to protect against business disruptions, ISPE held financial reserves of $4.2 million at year’s end.

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. Financial investments returned over $415,000 in 2017.

Revenues from membership, conferences and meetings, Guidance Documents, publications, and education and training were used to support the ISPE mission of delivering technical and operational solutions in support of the global pharmaceutical and biopharmaceutical industry in the manufacture of quality medicines for patients across the world. ISPE funded projects and programs focusing on Aseptic Processing, Quality Manufacturing, Serialization, Data Integrity, Process Validation, Biotechnology, Women in Pharma, Workforce of the Future, Young Professionals, and many others. Additionally, ISPE staff continued to actively engage in the development of new member, industry, and societal opportunities that will support the mission, vision, and future needs of the organization. ISPE leadership and management remain mindful of the changing U.S. and world economies and their impact on the pharmaceutical and biopharmaceutical industry. ISPE remains ready and prepared to modify the fiscal strategies of the organization to meet the ever-changing needs of the membership and the industry.
### STATEMENT OF FINANCIAL POSITION
FOR THE YEAR ENDED DECEMBER 31, 2017
(With comparative financial information for 2016)

#### ASSETS

<table>
<thead>
<tr>
<th>Category</th>
<th>2017</th>
<th>2016</th>
</tr>
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<tbody>
<tr>
<td><strong>CURRENT ASSETS</strong></td>
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<tr>
<td>Cash and Cash Equivalents</td>
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<td>Short-term investments</td>
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<tr>
<td>Accounts receivable</td>
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<td>Inventory of technical materials</td>
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<td>Prepaid Expenses</td>
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<td><strong>TOTAL CURRENT ASSETS</strong></td>
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<tr>
<td><strong>OTHER ASSETS</strong></td>
<td></td>
<td></td>
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<tr>
<td>Property and equipment = net</td>
<td>633,875</td>
<td>606,277</td>
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<td>Investments</td>
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<td>Deposits</td>
<td>74,973</td>
<td>74,973</td>
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<td><strong>TOTAL OTHER ASSETS</strong></td>
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<td>$3,930,072</td>
</tr>
<tr>
<td><strong>TOTAL ASSETS</strong></td>
<td>$10,473,339</td>
<td>$8,876,094</td>
</tr>
</tbody>
</table>

#### LIABILITIES AND NET ASSETS

<table>
<thead>
<tr>
<th>Category</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CURRENT LIABILITIES</strong></td>
<td></td>
</tr>
<tr>
<td>Accounts payable</td>
<td>$1,028,719</td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>445,680</td>
</tr>
<tr>
<td>Accrued rent</td>
<td>41,812</td>
</tr>
<tr>
<td>Deferred revenues</td>
<td>2,754,223</td>
</tr>
<tr>
<td><strong>TOTAL CURRENT LIABILITIES</strong></td>
<td>$4,270,434</td>
</tr>
<tr>
<td><strong>LONG-TERM LIABILITIES</strong></td>
<td></td>
</tr>
<tr>
<td>Accrued rent</td>
<td>41,812</td>
</tr>
<tr>
<td><strong>TOTAL LIABILITIES</strong></td>
<td>4,270,434</td>
</tr>
<tr>
<td><strong>NET ASSETS</strong></td>
<td></td>
</tr>
<tr>
<td>Unrestricted</td>
<td>6,202,905</td>
</tr>
<tr>
<td><strong>TOTAL LIABILITIES AND NET ASSETS</strong></td>
<td>$10,473,339</td>
</tr>
</tbody>
</table>

### STATEMENT OF ACTIVITIES
FOR THE YEAR ENDED DECEMBER 31, 2017
(With comparative financial information for 2016)

#### REVENUES

<table>
<thead>
<tr>
<th>Category</th>
<th>2017</th>
<th>2016</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PROGRAM REVENUES</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Professional development</td>
<td>$7,627,372</td>
<td>$7,221,486</td>
</tr>
<tr>
<td>Membership services</td>
<td>3,556,185</td>
<td>3,545,794</td>
</tr>
<tr>
<td>Guidance documents</td>
<td>1,324,352</td>
<td>1,035,866</td>
</tr>
<tr>
<td>Advertising fees</td>
<td>612,675</td>
<td>712,675</td>
</tr>
<tr>
<td><strong>TOTAL PROGRAM REVENUES</strong></td>
<td>$13,120,584</td>
<td>$12,515,821</td>
</tr>
<tr>
<td><strong>OTHER</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Investment income</td>
<td>473,752</td>
<td>142,465</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>3,735</td>
<td>14,111</td>
</tr>
<tr>
<td><strong>TOTAL OTHER REVENUES</strong></td>
<td>$477,487</td>
<td>$156,576</td>
</tr>
<tr>
<td><strong>TOTAL REVENUES</strong></td>
<td>$13,598,071</td>
<td>$12,672,397</td>
</tr>
</tbody>
</table>

#### EXPENSES

<table>
<thead>
<tr>
<th>Category</th>
<th>2017</th>
<th>2016</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PROGRAM SERVICES</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Professional development</td>
<td>6,021,019</td>
<td>5,510,944</td>
</tr>
<tr>
<td>Membership services</td>
<td>2,157,645</td>
<td>2,543,745</td>
</tr>
<tr>
<td>Guidance documents</td>
<td>845,041</td>
<td>652,643</td>
</tr>
<tr>
<td>Publications</td>
<td>664,311</td>
<td>917,864</td>
</tr>
<tr>
<td><strong>TOTAL PROGRAM SERVICES</strong></td>
<td>$9,688,016</td>
<td>$9,625,196</td>
</tr>
<tr>
<td>Management and general</td>
<td>2,584,845</td>
<td>2,185,493</td>
</tr>
<tr>
<td><strong>TOTAL FUNCTIONAL EXPENSES</strong></td>
<td>$12,272,861</td>
<td>$11,810,689</td>
</tr>
<tr>
<td>Unallocated payment to nonprofit organization</td>
<td>30,000</td>
<td>-</td>
</tr>
<tr>
<td><strong>TOTAL EXPENSES</strong></td>
<td>12,302,861</td>
<td>11,810,689</td>
</tr>
<tr>
<td><strong>CHANGE IN NET ASSETS FROM OPERATIONS</strong></td>
<td>1,295,210</td>
<td>861,708</td>
</tr>
<tr>
<td><strong>NET CHANGE OF FOREIGN CURRENCY REMEASUREMENT</strong></td>
<td>59,771 (49,537)</td>
<td></td>
</tr>
<tr>
<td>Change in net assets</td>
<td>1,354,981</td>
<td>812,171</td>
</tr>
<tr>
<td><strong>NET ASSETS - BEGINNING OF YEAR</strong></td>
<td>4,847,924</td>
<td>4,035,753</td>
</tr>
<tr>
<td><strong>NET ASSETS - END OF YEAR</strong></td>
<td>6,202,905</td>
<td>4,847,924</td>
</tr>
</tbody>
</table>
OUR PURPOSE
ISPE delivers technical and operational solutions to support our members across the global pharmaceutical and biopharmaceutical industry in the manufacture of quality medicines for patients.

ISPE’s core Members are pharmaceutical professionals who use expert knowledge to create high-quality, cost-effective GMP solutions.

We lead and facilitate the development of next generation process technologies and innovative technical solutions. On matters of regulation, our focus is on those requirements that impact—or will impact—the licensing of facilities, manufacturing processes and operations, and the sustainability of the supply chain over the product lifecycle. ISPE provides a neutral environment where our individual Members and experts belonging to regulatory authorities can engage in open dialogue on issues that will ultimately benefit patients around the world.

ISPE aims to offer increasing and unparalleled value for Members, companies, and stakeholders globally and across all constituent parts of the industry. The result will be the continued improvement and transformation of the pharmaceutical manufacturing industry to better ensure the availability of quality medicines.