



ISPE Pharma Best Practices Webinar Series

ISPE Membership Connect with Fran Zipp and Tom Hartman

3 September 2020 1100 – 1145 EDT



Fran Zipp

Chair, ISPE International Board of
Directors and President & CEO,
Lachman Consultant Services, Inc.



Tom Hartman

President and CEO
ISPE

©2020 ISPE - ALL RIGHTS RESERVED

Unprecedented Times: What a Year 2020 Has Been!

Speaker: Fran Zipp

©2020 ISPE - ALL RIGHTS RESERVED

Fran Zipp

Chair, ISPE International Board of Directors
President & CEO, Lachman Consultant Services, Inc



Events of 2020 Have Been Unprecedented

- Unprecedented challenges
- Unprecedented collaboration
 - Between regulators
 - Between manufacturers
- Development of diagnostics, vaccine candidates, potential therapeutics



We Regrouped



And learned that reaching out to each other and to our community was of paramount importance

We all learned how to connect remotely

We learned how to be a part of a broader community

We worked on adjusting our manufacturing processes to meet the needs of accelerated availability of key products to market

Events of 2020 Have Been Unprecedented

We all need each other during times of uncertainty

True of all Affiliates and Chapters, domestic and international

Webinars

Baseline Guides

ISPE Communities of Practice

Networking

Knowledge Platform

ISPE's vision defines our mission, recharges our spirit, and energizes our members





Thomas B. Hartman

President and CEO, ISPE

“ISPE filled the pharmaceutical knowledge gaps for me through their “gold standard” documents and networking with industry experts.”

The Future of ISPE

Providing solutions to complex pharmaceutical industry challenges through manufacturing innovation, member and workforce development, technical, regulatory, and compliance collaboration.

Focus

- Member Value
- CoPs and Knowledge Networks
- Content Priorities
- Affiliates and Chapters
- Expand Footprint and Impact
- ISPE Foundation

Global Pandemic

Challenges and Opportunities

- Virtual Conferences and Partner Showcase
- Free and Paid Webinars
- Live and On Demand Learning
- New Mobile App – *Coming Soon*
- Remote Staff
- Communities of Practice

©2020 ISPE

ALL RIGHTS RESERVED



2019 - 2020 ISPE International Board of Directors

Officers



Frances M. Zipp
Chair
President & CEO
Lachman Consultant Services, Inc



Joanne R. Barrick, RPh
Treasurer
Advisor, Global Validation
Eli Lilly and Company



Jörg Zimmermann
Secretary
Vice President, Vetter Development Service, External Affairs
Vetter Pharma-Fertigung GmbH & Co.



James A. Breen, Jr., PE
Past Chair
Vice President, Lead Biologics Expansion
Janssen Pharmaceuticals



Thomas B. Hartman
CEO and President
ISPE

Directors



Vivianne J. Arencibia
Independent Consultant
Arencibia Quality Compliance Associates



Gunter Baumgartner
Senior Vice President,
Head of Global Engineering
Takeda Pharmaceuticals International AG



Scott W. Billman
Global Head of Engineering
Biogen



Chris Chen, PhD
CEO
WuXi Biologics (Shanghai) Co., Ltd.



Ylva Ek
Chief Quality Officer (CQO)
KeyPlants AB



Lou W. Kennedy
CEO and Owner
Nephron Pharmaceuticals



Stephen C. Mahoney, JD
Senior Director, Global Quality & Compliance
Genentech, A Member of the Roche Group



Christine M. V. Moore, PhD
Global Head and Executive Director, GRACS
CMC Policy
Merck & Co, Inc.



Alice Redmond, PhD
Vice President, European Operations
CAI



Caroline Rocks, CEng
Senior Program Manager
AbbVie, Inc.

Cast Your Vote

ISPE International Board of Directors ELECTION

Deadline: Friday, 18 September 2020



©2020

ISPE - ALL RIGHTS RESERVED

Jessie Hardy

Sr. Director, Membership & Chapters
ISPE since 2019



©2020 ISPE - ALL RIGHTS RESERVED



Connecting Pharmaceutical Knowledge

Exclusive Member Benefits

Community Connection

Connect with your colleagues from around the globe

Pharmaceutical Engineering® Magazine

The flagship publication for the pharmaceutical industry

ISPE FREE Pharma Best Practices Webinar Series

Leading SMEs covering critical, relevant topics in pharmaceutical manufacturing

Personal and Professional Development Opportunities

Paid Webinars, Online Learning, Guidance Documents, etc.



ISPE Pharma Best Practices Webinar

Complimentary Series

- Each webinar features leading subject matter experts covering critical, relevant topics in pharmaceutical manufacturing.
- ISPE Members have unlimited access to complimentary webinars 30 days after the live webinar.
- Launched in 2019 – Now with 19 complimentary Webinars available in the webinar library



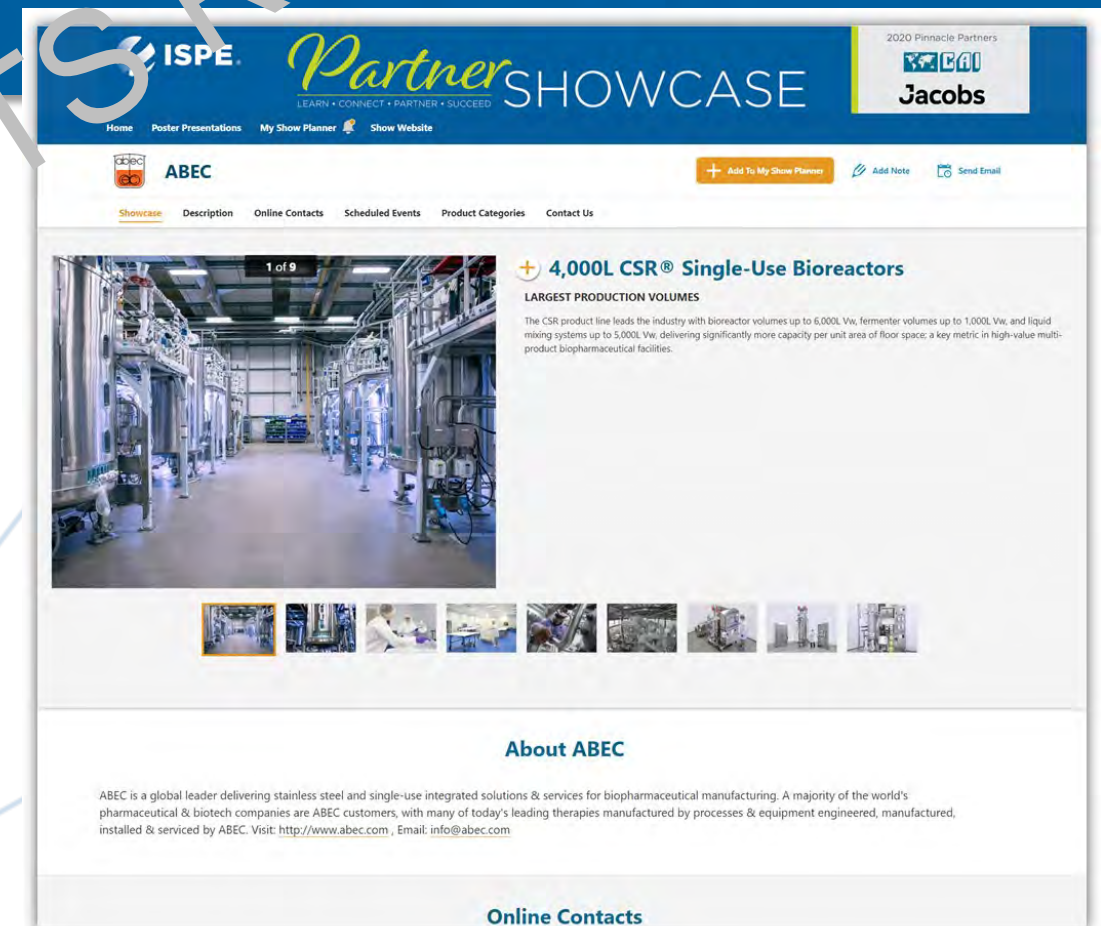
[ISPE.org/webinars](https://www.ispe.org/webinars)

Partner

LEARN • CONNECT • PARTNER • SUCCEED

SHOWCASE

- Network from Anywhere
- Participate in Live Demos
- Engage in 1:1 Chat
- Connecting ISPE Members with the latest technologies and solutions
- Save time with technology and solutions recommendations



FREE ISPE Face Mask Membership Renewal Offer

Renew Today!

- Valid for anyone who renews in September
- No Special Code Needed
- Limited Quantities
- Valid ONLY for September



ISPE.org/renew

Barbara Peck

Manager, Community and Industry
Recognition
ISPE since 2014

Areas of Responsibility

- Communities of Practice (CoPs)
- Communities of Practice Steering Committees Staff Project Manager
- Webinar Content Editor and Host
- Facility of the Year Awards Program Manager



Communities of Practice (CoPs)

Communities of practice are groups of people who share a concern or a passion for something they do and learn how to do it better as they interact regularly.

Members engage in joint activities and discussions, help each other, and share information. They build relationships that enable them to learn from each other.

Members of a community of practice are practitioners. They develop a shared repertoire of resources: experiences, stories, tools, ways of addressing recurring problems.

**More than
8900 ISPE
members
have joined
one or more
CoPs**

Volunteer Committees

Volunteers donate their time on working groups in a variety of areas:

- Communities of Practice (CoPs)
- Special Interest Groups (SIGS)
- Professional Networking Groups
- Regulatory Committees
- Guidance Document Teams
- Conference Program Committees
- Affiliate Leadership Teams
- And many others

Steering Committees are working groups who produce **CONTENT** for ISPE



Pharma Best Practices Webinar Series



ISPE
Extended Learning
ISPE Pharma Best Practices Webinar Series

GAMP®5, FDA CSA, and the Future of Computer Systems Validation

29 July 2020 1000 – 1130 EDT

Sion Wyn
Conformity Ltd

Heather Watson
GSK

Lorrie Schuessler
Syneos Health

Charlie Wakeham
Waters Corporation



ISPE
Extended Learning
ISPE Pharma Best Practices Webinar Series

Foundation of Proof – Exploring the Cryptography Behind Blockchain

25 August 2020 1100 – 1230 EDT

James Canterbury
Canst & Young LLP

In 2019, we begin this series to allow CoPs to share best practices on technical topics.

Over the last year, our team has expanded the webinar offerings to provide even more topics **requested by members** to meet their professional development needs.

We have a full calendar of sessions planned for 2020 and are already planning more in 2021.

If you have any suggestions for topics you'd like to see, let us know at ispeak@ispe.org.

[ISPE.org/webinars](https://www.ispe.org/webinars) for upcoming sessions

Facility of the Year Awards (FOYA)



FOYA

Facility of the Year Awards
An **ISPE** Program

[ISPE.org/FOYA](https://www.ispe.org/foya)

ISPE's **Facility of the Year Awards** is an annual program that recognizes state-of-the-art projects utilizing new, innovative technologies to improve the quality of products, to reduce the cost of producing high-quality medicines, and demonstrate advances in project delivery.

2021 Program

We are accepting applications for the 2021 Program. The deadline to submit is Friday, 20 November 2020.

You're **INVITED** to **FOYA DAY 2020**

Join us on 3 November 2020 during the ISPE Virtual Annual Meeting for **TWO** FOYA Education Sessions and the Virtual Banquet. All members are invited to attend. Mark your calendars and stay tuned for information on how to join us!



Q&A

©2020 ISPE - ALL RIGHTS RESERVED



Does my membership in ISPE automatically renew or do I need to register each year?



How much time does it take to be an effective Board Chair for ISPE?



Is the Annual Meeting still taking place in Philadelphia?

©2020 ISPE - ALL RIGHTS RESERVED



Will conferences still be virtual
in 2021?

©2020 ISPE - ALL RIGHTS RESERVED



How do I become a member of a
Community of Practice (CoP)?

©2020 ISPE - ALL RIGHTS RESERVED

ISPE Communities and Special Interest Groups

- ❖ Active Pharmaceutical Ingredients
- ❖ Biotechnology
- ❖ Commissioning and Qualification (C&Q)
- ❖ Containment
- ❖ Critical Utilities
- ❖ Disposables
- ❖ GAMP®
- ❖ HVAC and Sustainable Facilities
- ❖ Investigational Products
- ❖ Oral Solid Dosages (OSD)
- ❖ Project Management
- ❖ Process/Product Development
- ❖ Process Analytical Technology & Lifecycle Control Strategy (PAT&LCS)
- ❖ Regulatory and Quality Networking
- ❖ Sterile Products Processing
- ❖ Supply Chain, Operations, Packaging Excellence (SCOPE)
- ❖ Women in Pharma
- ❖ Young Professionals

Special Interest Groups

- ❖ GAMP Blockchain SIG
- ❖ GAMP Data Integrity SIG
- ❖ GAMP MES SIG
- ❖ Pharma 4.0 SIG



What recommendations do you have for recent graduates or young professionals to get involved at ISPE?



What ISPE Guidance documents are being updated?

©2020 ISPE - ALL RIGHTS RESERVED