

**Tim Postlethwaite, PhD**  
Director of Technical Communities, International Society for Pharmaceutical Engineering

# ISPE Global Technical Communities

ISPE Boston Product Show – 20 September 2023

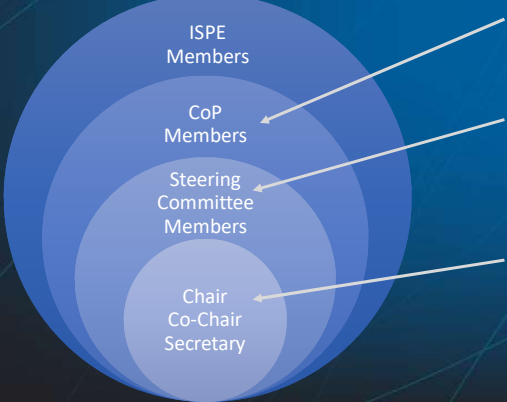
*Shaping the future of the global pharmaceutical industry by providing solutions to complex challenges through manufacturing and supply chain innovation, member and workforce development, technical, regulatory, and quality leadership.*




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## ISPE Communities of Practice (CoPs)

- Collaborating groups of ISPE members addressing **key technical topic areas** in the pharmaceutical industry
- The **technical engines** that drive meaningful content in our gold standard documents, training programs, webinars, and conference content



- Self-identify on ISPE.org profile**
  - Interest or job responsibility in particular area
  - Access to CoP site on ISPE Engage
- Operating group of the CoP**
  - Experts in particular technical area
  - Hold regular meetings
  - Originate ISPE content
- CoP leaders**
  - Manage meetings & other activities
  - Representation on Knowledge Network Council



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## 2023 ISPE Global CoPs

- Active Pharmaceutical Ingredients (APIs)
- Advanced Therapeutics Medicinal Products (ATMPs)
- Artificial Intelligence (AI) **WORK IN PROGRESS**
- Biotechnology
- Combination Products
- Commissioning and Qualification
- Containment
- Critical Utilities
- Disposables/Single Use Technologies
- GAMP®
- Investigational Products
- Oral Solid Dosage
- Pharma 4.0™
- Pharmaceutical Compounding **NEW**
- Process Analytical Technology and Lifecycle Control Strategy
- Process/Product Development
- Project Management
- QC/Analytical **NEW**
- Sterile Products Processing
- Supply Chain, Operations and Packaging (SCOPE)
- Sustainability **WORK IN PROGRESS**
- Sustainable Facilities, HVAC, and Controlled Environments



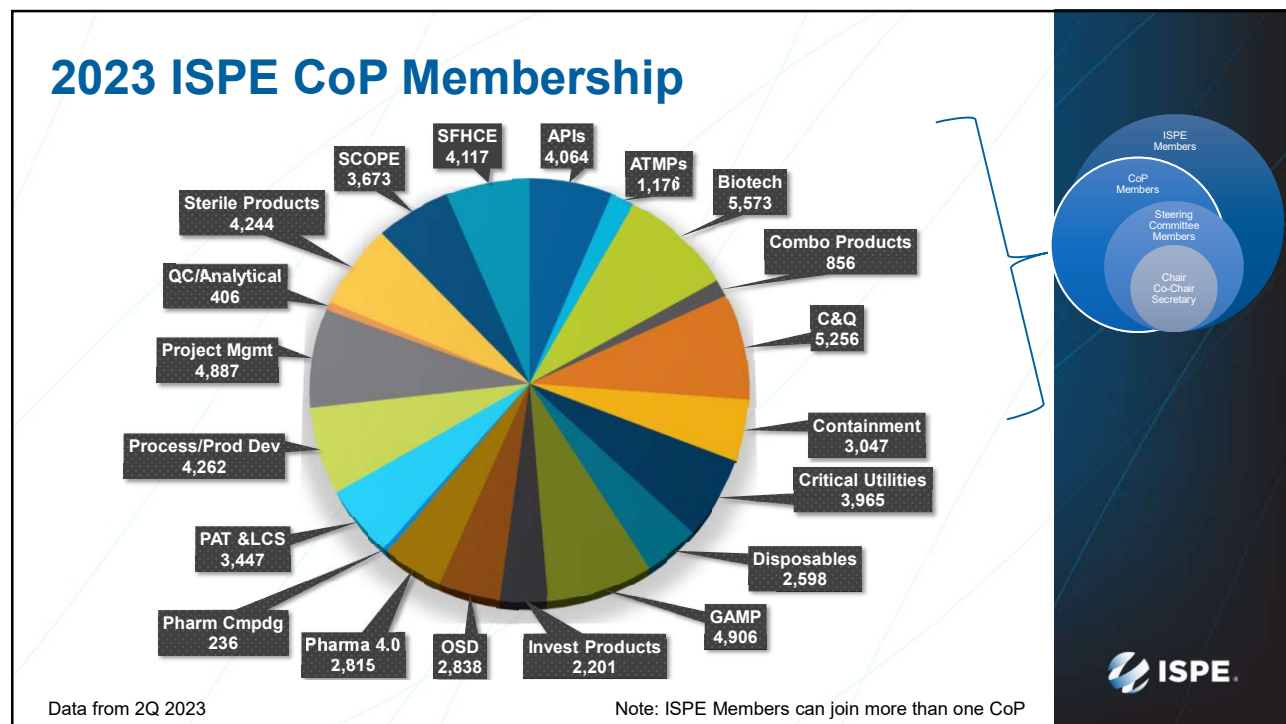
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## 2023 ISPE GAMP® Special Interest Groups (SIGs)

- GAMP® Agile
- GAMP® Blockchain
- GAMP® Cloud
- GAMP® Computer Software Assurance (CSA) **NEW**
- GAMP® Manufacturing Execution Systems (MES)
- GAMP® Risk Management
- GAMP® Software Automation and Artificial Intelligence



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## CoP Sites on ISPE Engage

- Topic-specific sites linked from ISPE.org for each CoP
- Members of CoPs can ask & answer questions, share files, and connect with other subject matter experts

<https://cop.ispe.org/forums/allcommunities>

ISPE

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## ISPE CoP Steering Committees

### Leadership

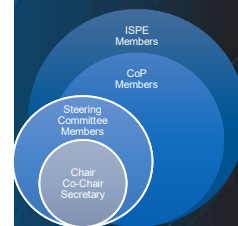
- Chair, Co-Chair, and Secretary
- 2-year terms for each
- Succession: Secretary ⇒ Co-Chair ⇒ Chair
- Participation on Knowledge Network Council (KNC)

### Membership

- Approximately 10-20 subject matter experts
- Current ISPE Members
- Participation in at least 75% of Steering Committee meetings
- ISPE seeks a balanced Steering Committee membership between members from **owner companies/manufacturers** and **vendors/service companies** as well as **global participation**; the inclusion of **underrepresented groups**, **ISPE Emerging Leaders**, and **ISPE Women in Pharma** representatives is strongly encouraged

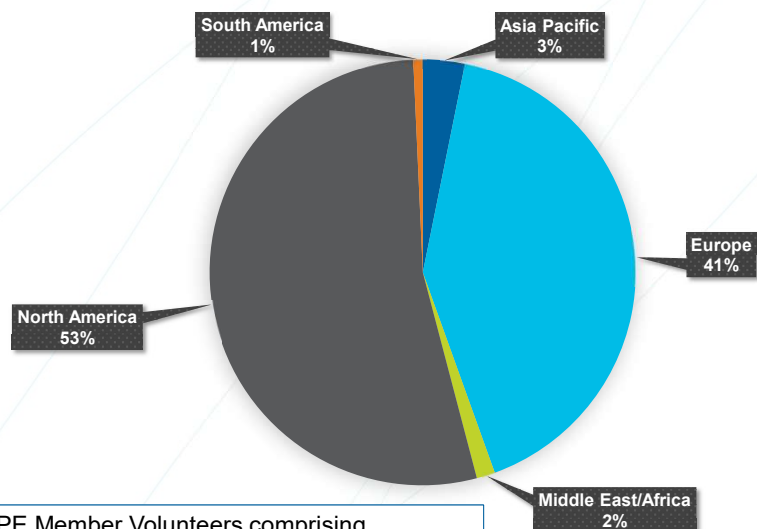
### Deliverables

- CoP Charter (updated every 3 years)
- CoP annual Business Plan
- Regular meetings (monthly, bimonthly, quarterly, etc.)
- Relevant & timely content for the pharmaceutical industry



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## ISPE CoP Steering Committee Membership



560 ISPE Member Volunteers comprising  
37 CoP Steering Committees/Subcommittees/SIGs

Data from 2Q 2023



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# ISPE Content Created by CoP Steering Committees

Guides (e.g., Good Practice, Baseline®, GAMP®, ISPE, PQLI®, APQ)

Handbooks

Guidance Document Papers (e.g., Concept or Discussion Papers)

Pharmaceutical Engineering® Magazine articles

iSpeak Blog Posts

Conference Educational Session Presentations

Training Course Materials

Webinars

Expert Xchanges

Special Initiative Documents (e.g., Drug Shortages Publications)

Compiled Comments on Proposed Regulations

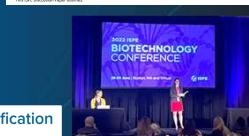
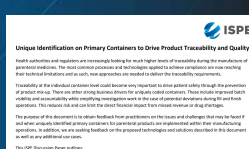


## Commissioning and Qualification Training Course

Science and Risk-based Commissioning and Qualification - Applying the ISPE Baseline Guide, Volume-5, Second Edition: Commissioning and Qualification (T40)



ISPE Blog  
Best Practices for "True Copy Verification" with Paperless Validation Systems



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# 2023 ISPE Knowledge Network Council (KNC)

## KNC Leadership and Other Representation

**Chair** - Robert Perks

**Co-Chair** - Brian Pochini

**Secretary** - Nathan Temple

**Past Chair** - Matthew Gorton

### ISPE Staff

Technical Communities - Tim Postlethwaite  
Conferences & Digital Engagement - Jessica Bleess  
Membership & Chapters/Affiliates - Jessie Hardy  
Publications - Rochelle May  
Professional Development - Brandon Pastore  
Regulatory Operations - Carol Winfield

**ISPE Board Liaison/Chair** - Mike Rutherford

**ISPE President & CEO** - Tom Hartman

## CoP Steering Committee Leaders

### Advanced Therapy Medicinal Products

Erich Bozenhardt (Chair)

### Biotechnology

Michelangelo Canzoneri (Chair)

### Combination Products

Susan Neadle (Chair)

### Commissioning & Qualification (C&Q)

Nathan Temple (Chair)

### Containment

Glenn Lawrence (Chair)

### Critical Utilities (CU)

Roderick Freeman (Chair)

### Disposables/Single Use Technologies

Javier Lozano (Chair)

### GAMP®

Frank Henrichmann (GAMP Global)

### Investigational Products (IP)

Rachel Owen (Chair - Europe)

Cat Hall (Chair - North America)

### Oral Solid Dosage (OSD)

Terry Jacobs (Chair)

### Pharma 4.0™

Christian Wölbeling (Chair)

### Process Analytical Technology & Lifecycle Control Strategy (PAT & LCS)

Hubertus Rehbaum (Chair)

### Pharmaceutical Compounding

To be determined

### Project Management (PM)

Tammy Spain (Chair)

### QC/Analytical

Roujian Zhang (Chair)

### Sterile Products Processing (SPP)

Jason Collins (Chair)

### Supply Chain, Operations, and Packaging (SCOPE)

Teresa Minero (Acting Chair)

### Sustainable Facilities, HVAC, and Controlled Environments (SFHCE)

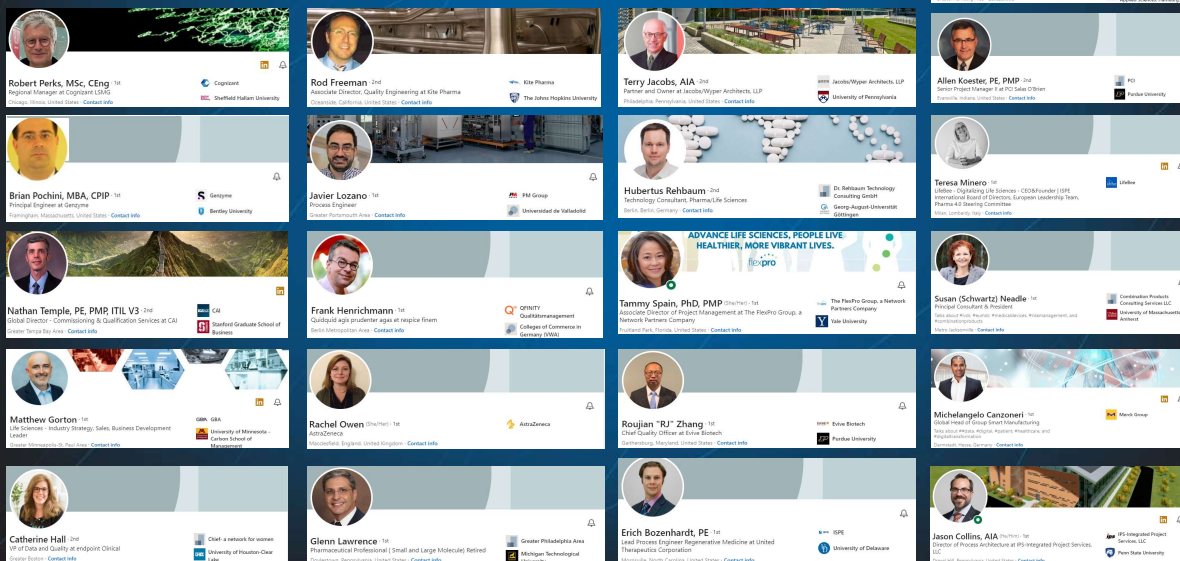
Allen Koester (Chair)



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## 2023 Technical Community Leaders



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## 2022 ISPE Global CoP Steering Committees *By the Numbers*

**20** Active CoP Steering Committees, comprised of **350+** volunteers

- **154** CoP Steering Committee meetings held
- **24** CoP Subcommittee meetings held
- **5** GAMP® SIG meetings held

**4** Guidance Documents published

**8** Guidance Documents initiated

**9** Webinars presented

**12** Pharmaceutical Engineering Magazine articles published

**23** iSpeak Blog posts published

**26** In-person & Virtual Training Courses presented

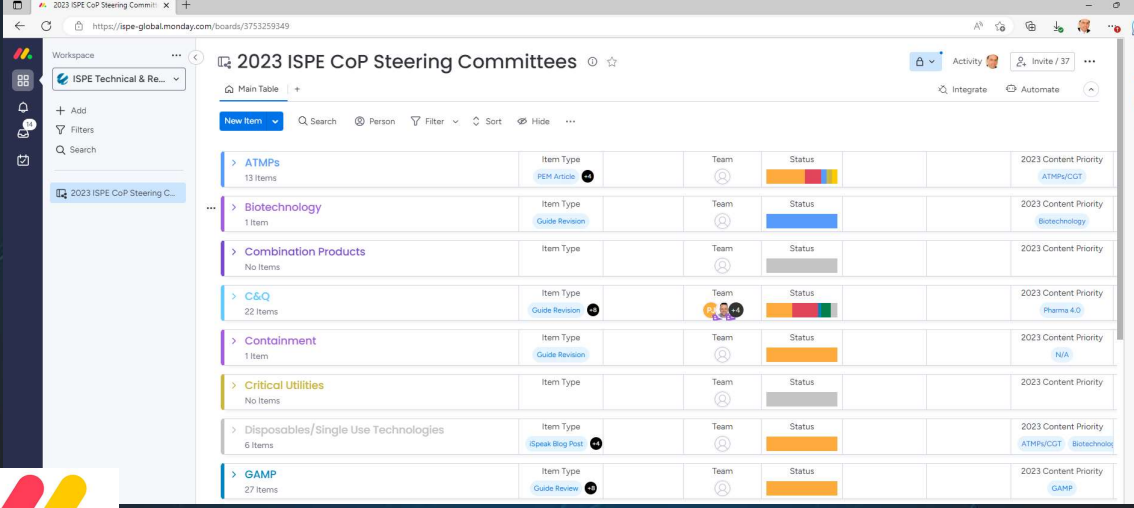
**29** Conference Educational Sessions & Workshops chaired

**61** Conference Educational Presentations & Panels completed



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## Cloud-based Project Tracking & Collaboration

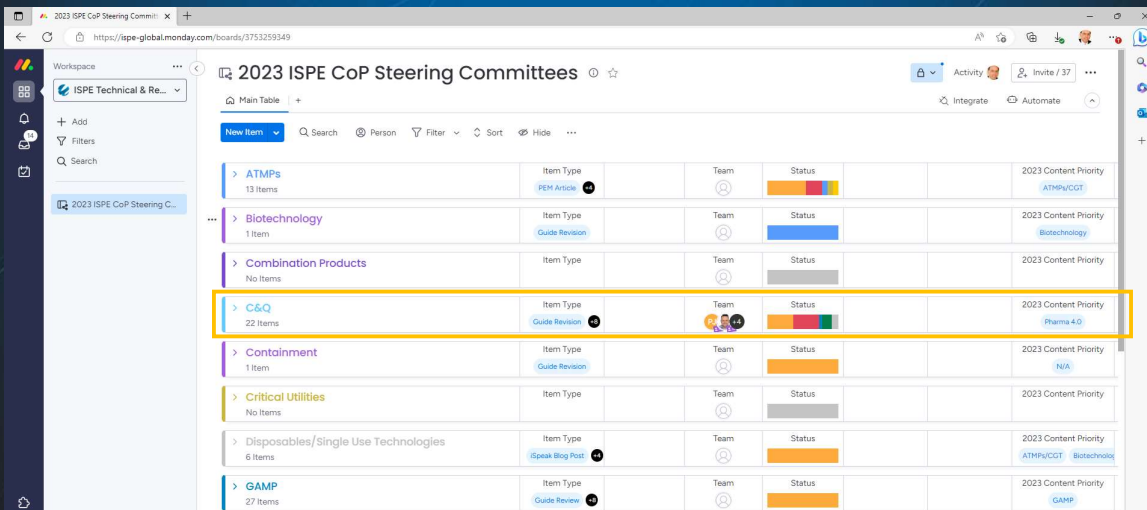


The screenshot displays the Monday.com workspace for '2023 ISPE CoP Steering Committees'. The interface includes a sidebar with navigation options like 'Add', 'Filters', and 'Search'. The main table lists project categories with their respective item counts, item types, team assignments, status bars, and content priorities. The Monday.com logo is visible in the bottom left corner.

Category	Item Count	Item Type	Team	Status	2023 Content Priority
ATMPs	13 Items	Item Article			ATHPa/CGT
Biotechnology	1 Item	Guide Revision			Biotechnology
Combination Products	No Items				2023 Content Priority
C&Q	22 Items	Guide Revision			Pharma 4.0
Containment	1 Item	Guide Revision			N/A
Critical Utilities	No Items				2023 Content Priority
Disposables/Single Use Technologies	6 Items	Speak Blog Post			ATHPa/CGT, Biotechnology
GAMP	27 Items	Guide Review			GAMP

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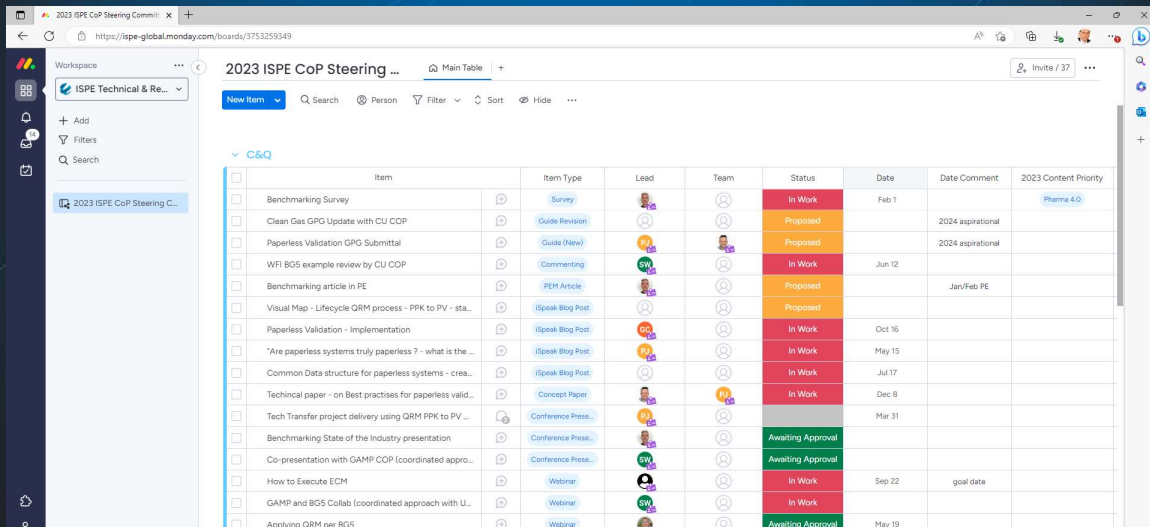
## Cloud-based Project Tracking & Collaboration



This screenshot is identical to the one above, but the row for 'C&Q' (22 Items, Guide Revision, Team, Status, 2023 Content Priority: Pharma 4.0) is highlighted with a yellow border.

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## Cloud-based Project Tracking & Collaboration

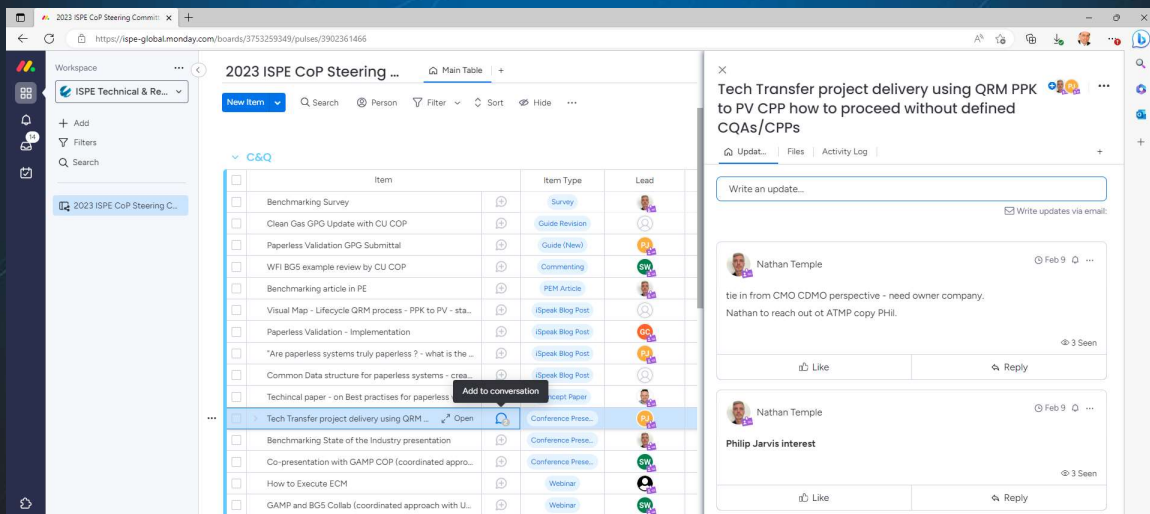


Item	Item Type	Lead	Team	Status	Date	Date Comment	2023 Content Priority
Benchmarking Survey	Survey			In Work	Feb 1		Pharma 4.0
Clean Gas GPO Update with CU COP	Guide Revision			Proposed		2024 aspirational	
Paperless Validation GPO Submittal	Guide (New)			Proposed		2024 aspirational	
WFI BGS example review by CU COP	Commenting			In Work	Jun 12		
Benchmarking article in PE	PEM Article			Proposed		Jan/Feb PE	
Visual Map - Lifecycle QRM process - PPK to PV - sta...	ISpeak Blog Post			Proposed			
Paperless Validation - Implementation	ISpeak Blog Post			In Work	Oct 16		
"Are paperless systems truly paperless? - what is the ...	ISpeak Blog Post			In Work	May 15		
Common Data structure for paperless systems - crea...	ISpeak Blog Post			In Work	Jul 17		
Technical paper - on Best practices for paperless valid...	Concept Paper			In Work	Dec 8		
Tech Transfer project delivery using QRM PPK to PV ...	Conference Pres...			Awaiting Approval	Mar 31		
Benchmarking State of the Industry presentation	Conference Pres...			Awaiting Approval			
Co-presentation with GAMP COP (coordinated appro...	Conference Pres...			In Work	Sep 22	goal date	
How to Execute ECM	Webinar			In Work			
GAMP and BGS Collab (coordinated approach with U...	Webinar			In Work			
Applying QRM per BGS	Webinar			Awaiting Approval	May 19		



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## Cloud-based Project Tracking & Collaboration



**Tech Transfer project delivery using QRM PPK to PV CPP how to proceed without defined CQAs/CPs**

Write an update...

Write updates via email

Nathan Temple Feb 9

tie in from CMO CDMO perspective - need owner company. Nathan to reach out to ATPM copy Phil.

3 Seen

Like Reply

Nathan Temple Feb 9

Philip Jarvis interest

3 Seen

Like Reply



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## Cloud-based Project Tracking & Collaboration

- Roll out platform to ISPE Global CoP Steering Committees in 2023
- Provide access to ISPE Chapter & Affiliate CoP leaders
  - Enable project awareness
  - Identify opportunities to volunteer and participate
  - Provide information on Chapter & Affiliate projects
- Recruit additional ISPE Global CoP Steering Committee Members enabled by increased access to project status and communications



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## Summary

- ISPE Global Communities of Practice are an effective mechanism for subject matter experts to meet, network, discuss challenges, share best practices, and collaborate on ISPE content
- CoP Steering Committees successfully lead the communities and ensure relevant, up-to-date content
- Better connections need to be pursued between the Global CoPs and Chapter/Affiliate CoP teams
- ISPE is open to ideas to engage more participation in the Global CoPs



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# Thank You

To the ISPE Boston Chapter for this opportunity to speak with you in person today



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*Founded in 1980, The International Society for Pharmaceutical Engineering (ISPE) is a not-for-profit association serving 21,000+ Members worldwide, representing 39 Affiliate organizations operating in 90 countries across the globe. ISPE provides solutions to complex pharmaceutical industry challenges through manufacturing innovation, member, and workforce development, technical, regulatory, and compliance collaboration.*

*To achieve this vision, ISPE's membership includes all categories of professional expertise organized by subject matter expertise through approximately 20 technical communities of practice. The subject matter expert communities develop industry guides, conference materials, white papers, and professional development/training programs that form a critical knowledge base to advance pharmaceutical product development, manufacturing, and licensure.*



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