



# **ISPE UPDATE**

**GCSG Annual Conference**

**30<sup>th</sup> Anniversary**

**April 23-26, 2017**



# ISPE Overview

Beth Gardner (Takeda)

Investigational Product Steering Committee  
Chair (North America)

# ISPE Overview: Let's Talk Acronyms

ISPE = International  
Society for  
Pharmaceutical  
Engineering

IP = Investigational  
Products

CoP = Community of  
Practice



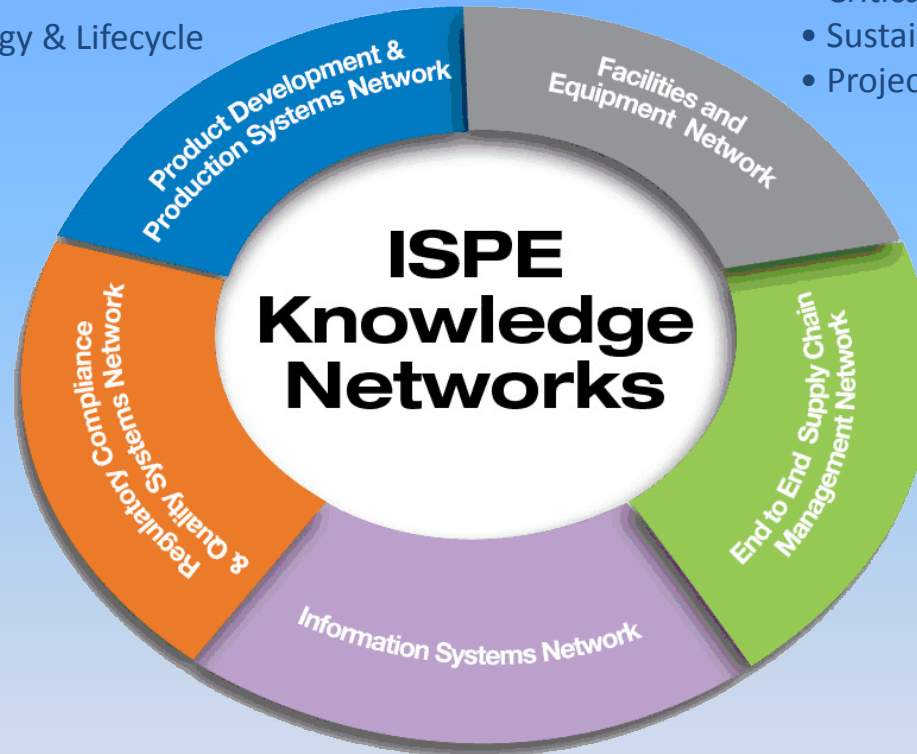
# ISPE Overview

- Active Pharmaceutical Ingredients
- Biotechnology
- Disposables
- Oral Solid Dosage
- Process Analytical Technology & Lifecycle Control Strategy
- Sterile Products Processing

- Process Validation Teams
- PQLI
- Regulatory & Compliance Committee

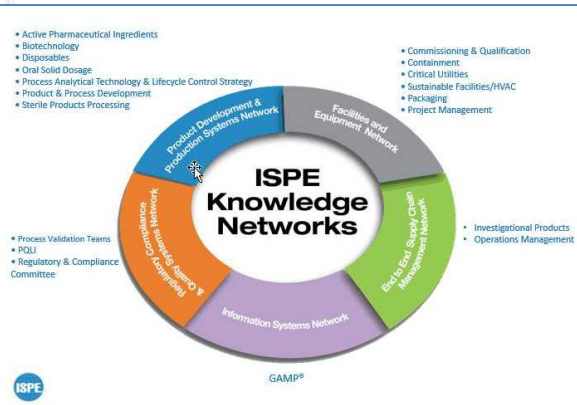
- Commissioning & Qualification
- Containment
- Critical Utilities
- Sustainable Facilities/HVAC
- Project Management

- Investigational Products
- Operations Management
- Packaging

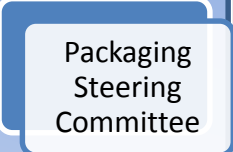
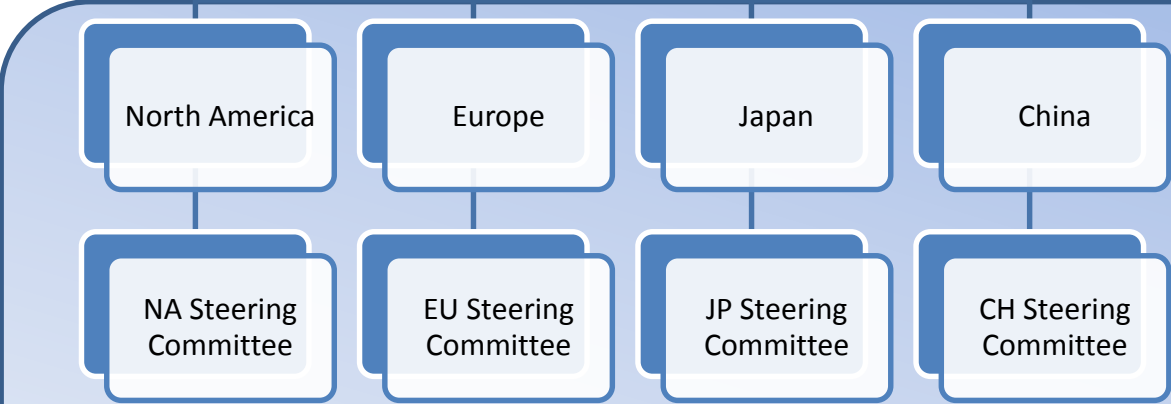
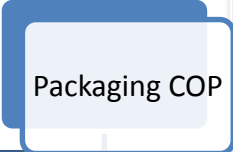
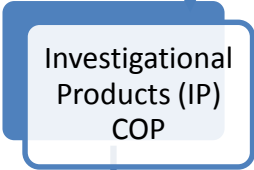


GAMP®

# ISPE Overview (cont.)



## End to End Supply Chain Management Knowledge Network



*Volunteers at Large & Task Teams*

# GCSG and ISPE Project



Memorandum of Understanding (MOU) Signed!



# Ask Me About The ISPE IP COP

***I'M HERE ALL WEEK***





# **METRICS BENCHMARKING**

**Sandy Cook**

# VALUE OF METRICS



# VALUE OF METRICS



# VALUE OF BENCHMARKING





# A BIT OF HISTORY

## ISPE IP COP Metrics Task Team

### Membership:

- ◆ *Leader:* Kent Hassett (Advisor, Eli Lilly and Company)
- ◆ Sandra Cook (Owner & President, Cook Consulting)
- ◆ Stefan Meier (Master Planning, Hoffmann-La Roche)
- ◆ Doug Meyer (Associate Director, Biogen)
- ◆ Steven Yoder (Global Director, Fisher Clinical Services)





# A BIT OF HISTORY

## ISPE IP COP Metrics Task Team

### Objectives:

- ◆ Evaluate existing Clinical Supply Chain metrics
- ◆ Identify those most relevant for driving improvement
- ◆ Standardize means for data capture
- ◆ Stage IP community to conduct useful comparative benchmarking



# SO MANY OPTIONS

## Clinical Supplies Metrics:

- ◆ Over 55 identified

- ◆ Operational
- ◆ Conformance
- ◆ Customer Service Response
- ◆ Availability of Materials
- ◆ Release
- ◆ Distribution
- ◆ Clinic
- ◆ Forecast Accuracy
- ◆ Changes
- ◆ IRT
- ◆ Training
- ◆ Budget
- ◆ Quality



# SURVEY SAYS...

200+ clinical supply professionals



*Which 5 of these would be most valuable for your organization to measure, obtain a baseline, and use to compare performance across the industry*





# SURVEY SAYS...

## Top 5 selected:

- ◆ On Time In Full for Packaging Completion
- ◆ On Time Delivery of Depot Stock Transfers
- ◆ Temperature Excursions During Shipment
- ◆ Enrollment Forecast Accuracy
- ◆ Planning Stability/Number of Changes

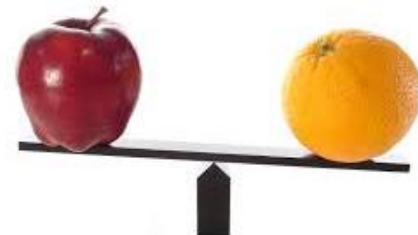




# WORKSHOPS

## Common Definitions:

- ◆ Enables different organizations to conduct measures similarly
- ◆ Ensures collection yields clean and useful data that can be used for industry comparisons

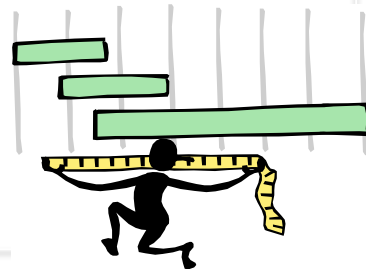




# ROLL OUT

## Kick off webinars with POCs/MRs:

- ◆ Each metric in detail
- ◆ Methods for reporting data
- ◆ Timelines



# CONFIDENTIALITY OF DATA

All data will be kept confidential and blinded

All data will be managed by a third party (ISPE)



**METRICS BENCHMARKING**



**ZIP IT**

# CONFIDENTIALITY OF DATA

Basic descriptive data of each participating organization will be collected and used in analysis and reporting

- ◆ CRO or sponsor company
- ◆ size of organization
- ◆ % of work conducted externally

Individual & company identity will not be reported





# RESULTS

All participating companies will receive outputs each quarter

Future webinars are planned for open forum discussions:

- ◆ Challenges? Solutions?
- ◆ Discussions of results and performance?
- ◆ Future metrics to measure?





# DURATION

It is anticipated the benchmarking will continue for ~ 2-3 years



# CHANGING METRICS

It is anticipated that the specific metrics to be benchmarked will change to 5 new measures after ~ 1-1.5 years





# PARTICIPANTS

Over 35 organizations to date have volunteered to participate



**METRICS BENCHMARKING**



# WHAT ABOUT US?



*I wonder if my company is participating?*

*How can we get involved?*



# ASK US ABOUT METRICS BENCHMARKING

***WE'RE HERE ALL WEEK***





# **REVERSE SUPPLY CHAIN**

**Greg Hottell**



# Reverse Supply Chain: IP Accountability, Returns & Reconciliation

- What is **reverse supply chain** in clinical trials?
  - ❑ Involves traceability, retrieval, and destruction of all remaining investigational product at the conclusion of a clinical trial
- Why we are talking about it?
  - ❑ It is a **requirement** for conducting clinical trials, yet...
  - ❑ It is a frequent **pain point** for companies engaged in clinical trials

According to some simple math:

Requirement + Pain Point = **Key Area for Improvement**

# IP Accountability, Returns & Reconciliation

## The Ground we Have Already Covered...

The 2016 GCSG US Annual Meeting – Managing Returns Workshops

**4**  
**Workshops**

involving

**50+**  
**Participants**

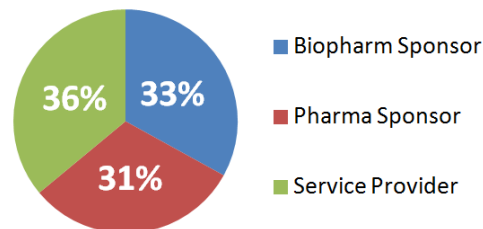
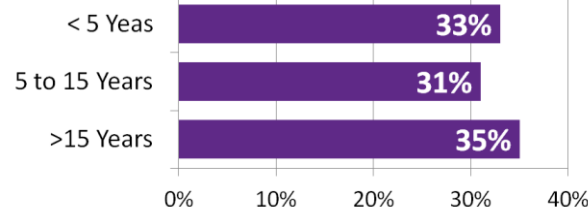
representing

**38**  
**Companies**

### Workshop Methodology:

- Live polling
- Hands-on focus groups

### Experience in Clinical Trials



**71%**  
**Topic of Rising Importance**

**54%**  
**Dissatisfied with R&R processes**

*Infographic by Greg Hottell*

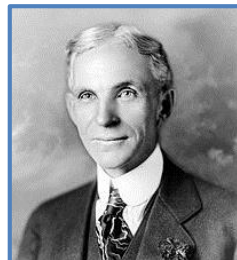
### KEY WORKSHOP OUTCOMES:

- Industry temperature check
- Clarified common pain points
- Documented recommendations for improvement
- 7-page summary report shared with workshop participants

# IP Accountability, Returns & Reconciliation

## ISPE & GCSG Working Together to Drive Improvement

- ISPE and GCSG are Joining Forces!
- More workshops are happening this week
  - ❑ WS1: *IP Accountability, Returns & Reconciliation*
  - ❑ We are building on the 2016 workshop outcomes
- Joint Task Team on IP Returns and Destruction
  - ❑ Goal is to deliver a *Good Practice Guide* for the industry
  - ❑ Will include membership from both ISPE and GCSG



*"Coming together is a beginning;  
Keeping together is progress;  
Working together is success."*

*Image Source: [https://en.wikipedia.org/wiki/Henry\\_Ford](https://en.wikipedia.org/wiki/Henry_Ford)*

# Ask Me About Reverse Supply Chain



***I'M HERE ALL WEEK***

I'd love to have you in one of my workshops:

**WS1: Drug Reconciliation,  
International Returns & Destruction**

*We are making things happen this week!*





# GLOBAL

## CLINICAL SUPPLIES GROUP

*30<sup>th</sup> Anniversary • Albuquerque, New Mexico*

# Thank You!

The ISPE Update Team:

