SESSION 1

Development of Guidance Documents

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PHARMA COMMITTEE
TECHNICAL EXCHANGE

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Discussion Overview

- ISTA Pharma Committee Overview & Update – 10 minutes
- PCG-00 – Glossary of Terms Project Overview – 10 minutes
- Ambient Temperature Profile (ATP) Best Practice Guideline Overview – 20 minutes
- Performance Qualification/Verification Best Practice Guideline Overview – 20 minutes

This is meant to be an interactive session - attendee participation is encouraged!

ISTA Pharma Committee Overview

- The ISTA Pharma Committee is an Ad Hoc Technical Committee comprised of individuals from both **supplier partners and Life science end-user organizations** involved in the supply chain for temperature-sensitive products.
- The committee's goal is to develop and publish **peer reviewed technical guidance** that addresses relevant needs of the industry as well as provide a forum for industry members to **collaborate and share best practices.**
- This guidance will **define a representative standard and drive standardization** to address specific topics for the advancement of the industry.
- Organizations from each part of the supply chain are members to provide **differing perspectives and develop comprehensive technical content**.

Committee Activity Overview

- The ISTA Pharma Committee will sponsor different types of activities including:
  - Best Practice Guidelines
  - Short Technical Papers
  - Benchmarking Discussion Groups
  - Presentations
  - Articles
  - Data Sharing
  - Technology Evaluations
  - Industry Conference Discussions

Committee Activity Status

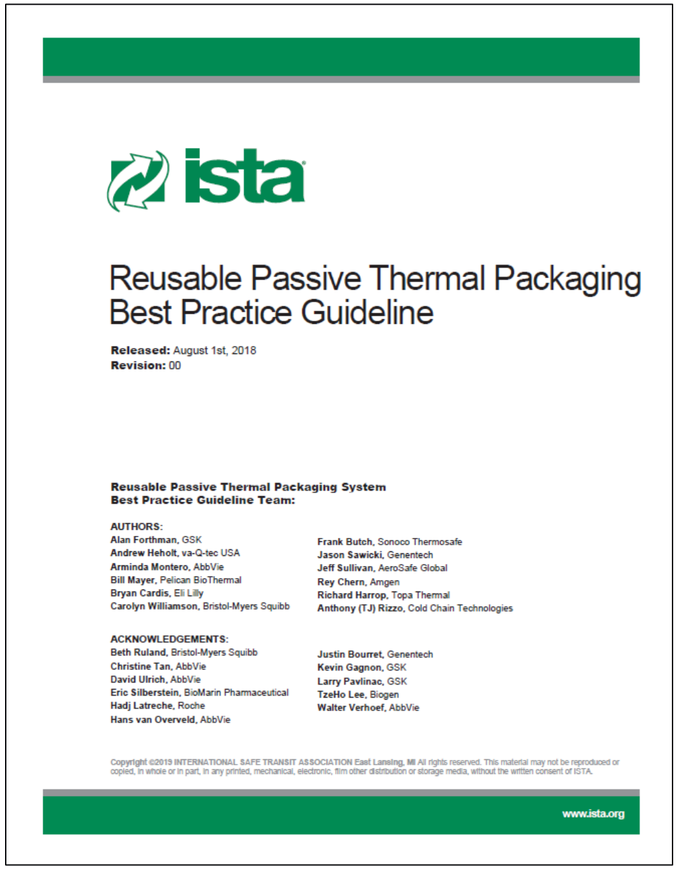
Completed

1. “PCG-01: Reusable Passive Thermal Packaging System Best Practice Guideline” published August 2018
2. “PCG-02: Passive Thermal Packaging System Operational Qualification Best Practice Guideline” – published November 2020

In Process

1. Performance Qualification/Verification Best Practice Guideline (final title to be determined) – estimated completed in Fall/Winter 2021
2. Ambient Temperature Profile Best Practice Guideline (final title to be determined) – estimated completed in Fall/Winter 2021
3. PCG-00: Glossary of Terms

PCG-01: Reusable Passive Thermal Packaging System Best Practice Guideline



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Reusable Passive Thermal Packaging Best Practice Guideline

Released: August 1st, 2018
Revision: 00

Reusable Passive Thermal Packaging System Best Practice Guideline Team:

AUTHORS:
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Released: August 2018

Purpose

- Increased demand for reusable passive thermal packaging systems has led to a wide variety of ways to qualify, return, refurbish, and manage these types of shipping solutions. Setting an industry best practice, as well as expectations for these aspects, will increase the quality of the systems and services and ultimately lead to increased product quality and solution innovation.

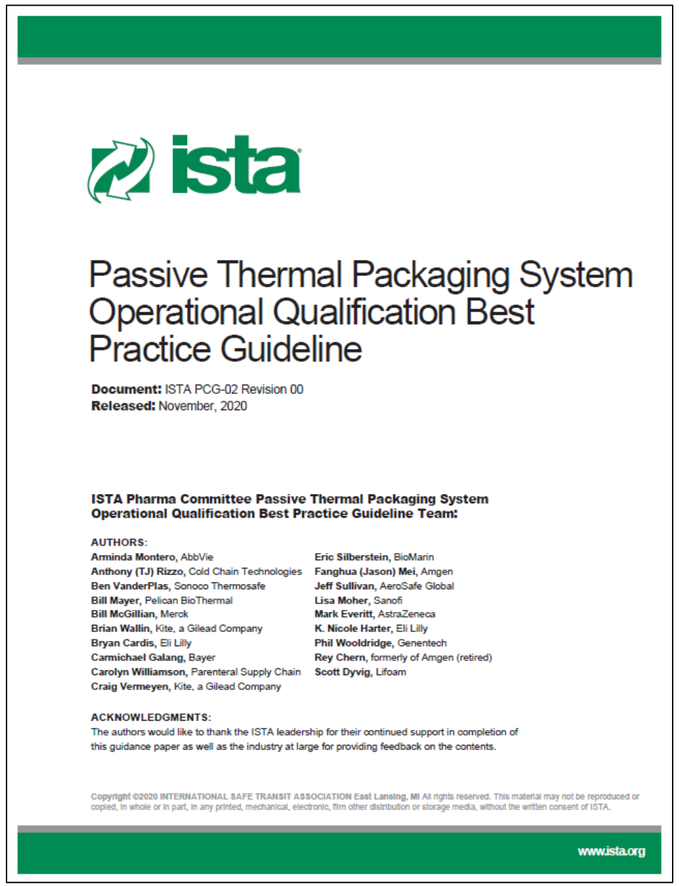
Objectives

- To provide a set of principles and examples, distilled from industry best practices, for the implementation and management of reusable passive thermal packaging systems

Guideline Areas Covered

- Process for Qualifying a Reusable Shipping Solution
- Refurbishment and Replacement Service
- Refurbishment and Replacement Inspection Details
- Appendices:
  - Examples on Common Defects
  - Examples of Executed Reuse Programs

PCG-02: Passive Thermal Packaging System Operational Qualification Best Practice Guideline



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Passive Thermal Packaging System Operational Qualification Best Practice Guideline

Document: ISTA PCG-02 Revision 00
Released: November, 2020

ISTA Pharma Committee Passive Thermal Packaging System Operational Qualification Best Practice Guideline Team:

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ACKNOWLEDGMENTS:

The authors would like to thank the ISTA leadership for their continued support in completion of this guidance paper as well as the industry at large for providing feedback on the contents.

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Released for Comment: November 2020

Purpose

- To simplify the process for end-users to comparing solutions on the market and ensure they meet testing expectations. Also, to standardize the expectations from end-users to streamline the operational qualification and review process for solution partners.

Objective

- To develop a guideline on the passive thermal packaging operational qualification process that defines the minimum requirements and drives standardization among packaging providers and life science companies alike. Collaboration between end-users and solution suppliers to develop mutually beneficial and harmonized requirements.

Guideline Topics Covered

- Equipment
- Test Plan & Methodology
- Documentation
- Implementation Considerations
- Appendices: Best Practice Examples

Future Topics of Interest

- Lane Qualification
- Thermal Blankets/Covers
- Risk Assessment associated with Selecting temperature-controlled packaging
- Thermal Modeling
- RFP/URS Development
- Sustainability
- Real-time monitoring
- Mechanical testing best practices: Bulk versus Parcel and Single Use versus Reusable
- Total Cost of Ownership
- Continuous Monitoring Strategies
- Qualification of Active ULD Solutions
- Temperature Monitoring Strategies
- Validation of Refrigerated trailers
- Ambient temperature lane data capture project
- Shipper Orientation
- Design Qualification
- Gene Therapy Strategy
- Ocean Freight
- Dry Ice Shippers
- Anti-counterfeiting and Product Security
- Long duration (>7 day) passive PCM and dry ice shippers
- Clinical, phase appropriateness testing strategy

How to Get Involved

- We are looking for more involvement from all areas of the supply chain including:
  - Medicinal product manufacturers
  - Suppliers of passive thermal packaging
  - Active thermal solution/service providers
  - Transportation monitoring solution providers
  - Logistic service providers
  - Wholesalers
  - Distributors
  - Specialty pharmacies
  - Industry subject matter experts
  - and any other interested party.

- If you would like to join a specific project team or participate as an extended team member, please contact ISTA at ista@ista.org and include the Pharma Committee in the title.
- All new members will be added to the extended team and asked to provide peer review of all committee work.
- There will be further opportunities to join the leadership or core team and participate in new activities in early 2022.

PCG-00: Glossary of Terms Project Overview

Overview of Project

- Develop a centralized glossary that all guidance documentation will reference
- Set up an annual review to align with the release of new guidance documents
- Benchmarking current definitions PDA, WHO, ISTA, and USP publications

Example – Definition of “Qualification”

ISTA PCG	ISTA SD-0014	PDA TR39	PDA TR58	PDA TR72	WHO Supplement 14 Annex 9	USP <1079>	USP <1058>	USP <2750>
Documented testing that demonstrates, with a high degree of assurance, that a process or system will function to meet its predetermined acceptance criteria.	The establishment of documented evidence, which provides a high degree of assurance that equipment, system or subsystem works correctly and actually leads to the expected results	Documented testing that demonstrates, with a high degree of assurance, that a process or system will function to meet its predetermined acceptance criteria.	Qualification is documented testing that demonstrates with a high degree of assurance that a specific process will meet predetermined acceptance criteria.	Documented testing that demonstrates, with a high degree of assurance, that a process or system function will meet its predetermined acceptance criteria.	Action of proving that any premises, equipment and supporting systems work correctly and actually lead to the expected results. The meaning of the word validation is sometimes extended to incorporate the concept of qualification.	Qualification is the assurance that systems or equipment meet predetermined acceptance criteria. This process typically focuses on equipment and utilities such as refrigerators and HVAC systems, as well as packaging. There are several different types of qualification, and an organization should determine which to use and when. Some of these include design qualification, installation qualification, operational qualification, and performance qualification	Action of proving that any instrument works correctly and delivers the expected results; demonstration of fitness for purpose	Action of proving and documenting that equipment or ancillary systems are properly, work correctly, and actually lead to the expected results. Qualification is part of validation, but the individual qualification steps alone do not constitute process validation.

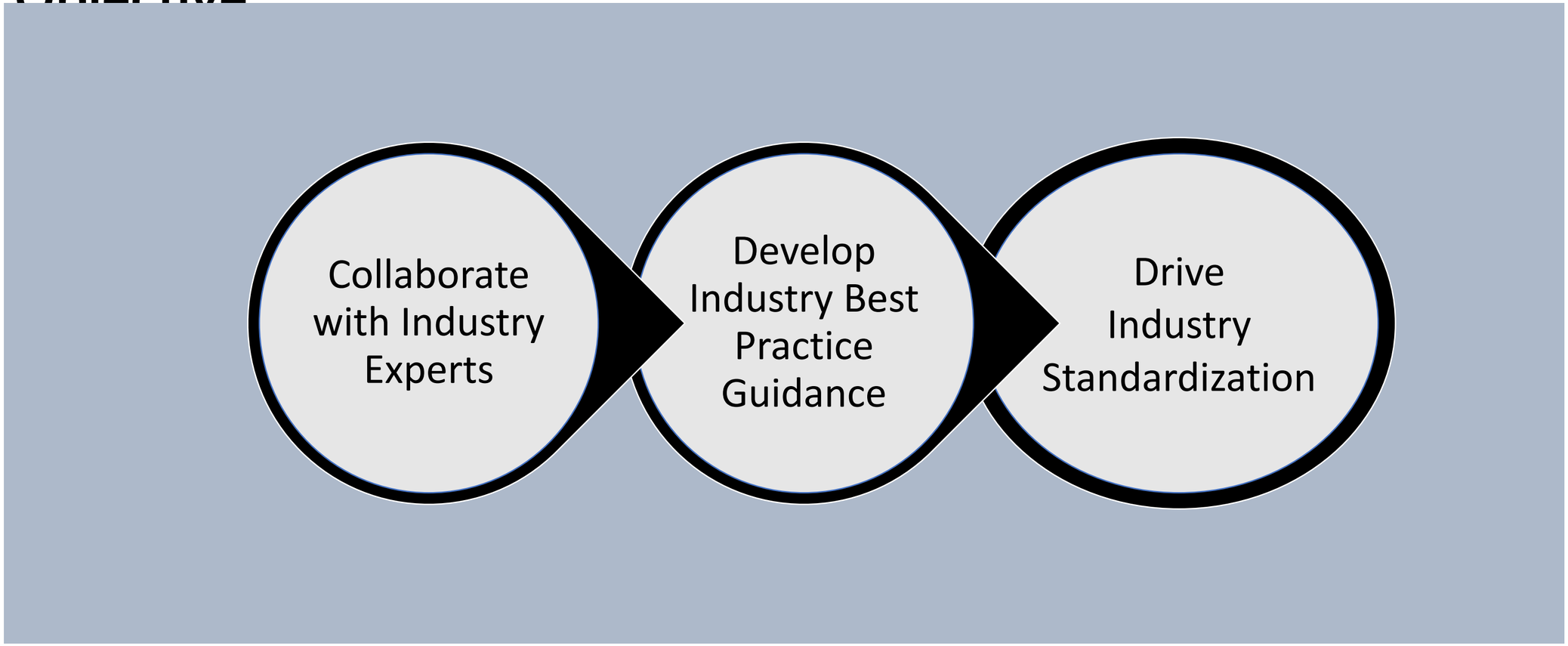
Next Steps

- October/November 2021: Working team to review differences and make recommendation to the committee on a standardized definition
- December 2021: Release for peer review to the industry
- Q1 2022: Publication aligned with the release of the current committee activities
- Q4 2022: Annual review of glossary

Audience Questions?

Ambient Temperature Profile (ATP) Best Practice Guidance

ISTA Ambient Temperature Profile (ATP) Team Mission and Objective



- Drive standardization from an approach & methodology standpoint – not focused on driving one standardized ATP
- Identify and balance the needs from both suppliers and end users
- Provide useful information for new and experienced Cold Chain professionals

The ATP Core Team:

- Suppliers of packaging and peripherals
- Industry consultants
- End users

Team participants are subject matter experts with real-world working knowledge

Andrew Klasek, EFP Corporation
Anthony (TJ) Rizzo, Cold Chain Technologies
Arti Roth, Edwards Lifesciences
Ben VanderPlas, Sonoco ThermoSafe
Bernard McGarvey, Eli Lilly (Retired)
Bill Mayer, Peli/Pelican BioThermal
Carolyn Williamson, Parenteral Supply Chain
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Jeff Sullivan, AeroSafe Global
Karen Greene, Network Partners
Lisa Moher, Sanofi
Mark Maurice, Sensitech
Michael Scipione, TemperPack
Scott Dyvig, Lifoam Industries
Thomas Heckard, Csafe Global
Tiffany Hughes, Merck

Progress TimeLine

Team Selection (Oct – Dec 2020)

Scope Definition/ Outline (Jan – Feb 2021)

Content Development & Review (Mar – Nov 2021)

Peer Review (Dec – Jan 2021)

Estimated Publication (Feb - Mar 2022)

Background/Objective/Scope – ATP Team

Background	• There are various approaches taken today by end users, industry consultants and suppliers when creating or selecting an Ambient Temperature Profile for DQ and OQ activities. • There are various industry ATP's and procedures available today but no central reference source
Objective	• Determine the various approaches companies are following to select, create and/or evaluate ATP's and develop guidance to drive standardization of best practices across the industry. • Balance the needs of suppliers and end users • Create useful content for both new and experienced Cold Chain professionals • Emphasis is on ensuring the ATP you use is appropriate for the application!
Scope	• Overview of currently available industry ATP's and procedures • Provide guidance on a process for developing a custom ATP • Provide guidance on ATP evaluation and comparison • Provide guidance on a risk-based approach to defending a particular ATP • OUT OF SCOPE: Driving the industry to using a single universal set of ATP's → WHY?

Complete

ATP Document Outline

In-Progress

ATP Outline	Status
1 Introduction	X
2 General Overview of ATPs	X
3 Overview of available industry ATPs & procedures	X
4 Development of ATPs	X
4.1 Risk assessment/control/review	X
4.2 Types of ATPs	X
4.3 Application of ATPs	X
4.4 Supply chain/distribution analysis	X
4.5 Sources of data for ATP creation	X
5 Data analysis methods for ATP creation	X
6 ATP Evaluation and Comparison	X
6.1 Key steps and relevant characteristics	X
6.2 ATP risk analysis	X
7 Impact of modeling and simulation	X
8 Conclusion	X
9 Appendices	X

Audience Questions for ATP Team?

How many companies use an industry standard ATP? How many create their own?

What are your biggest challenges related to ATPs?

How does your company currently compare ATPs?

Do you think industry collaboration to develop best practice guidance document for ATPs will help your company? Why/Why Not?

What types of real-life examples would be useful to include?

If creating your own ATP, what type of source data do you use?

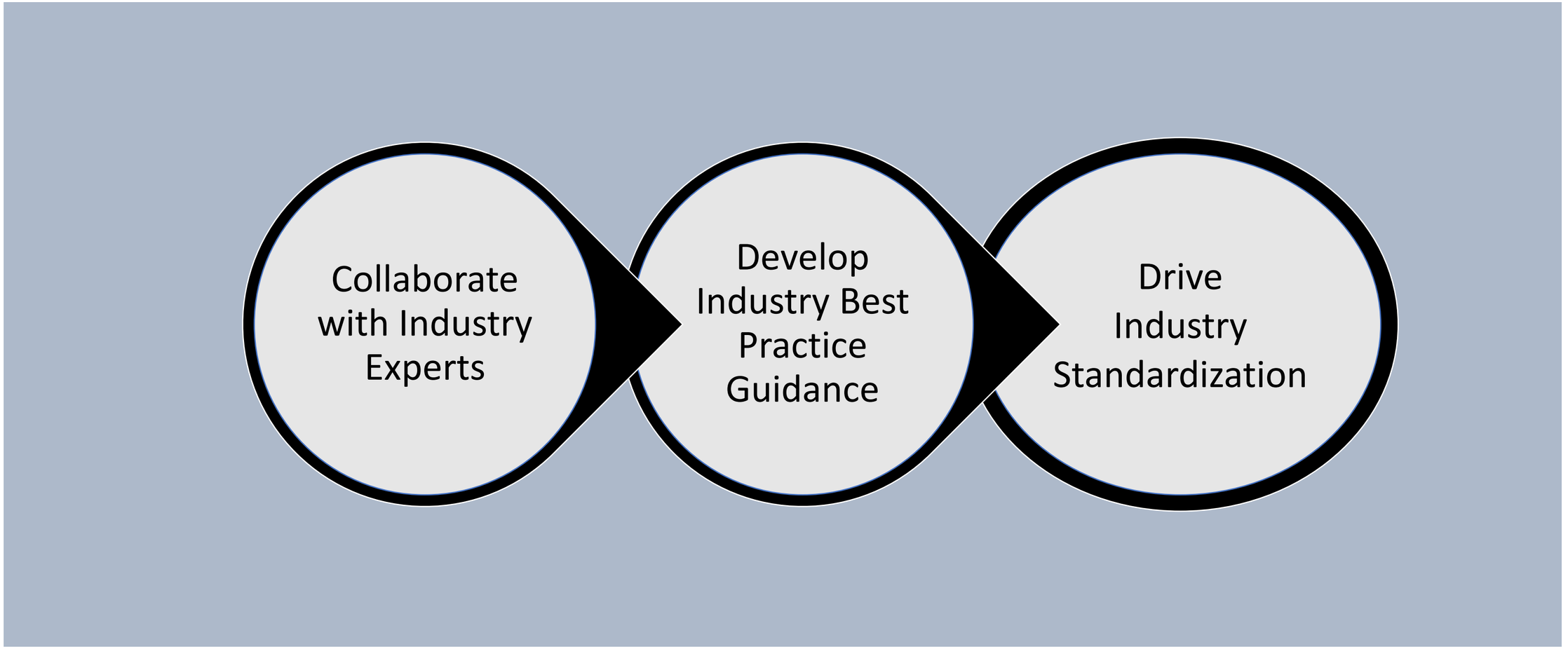
How do you currently defend your ATP(s) chosen for OQ activities?

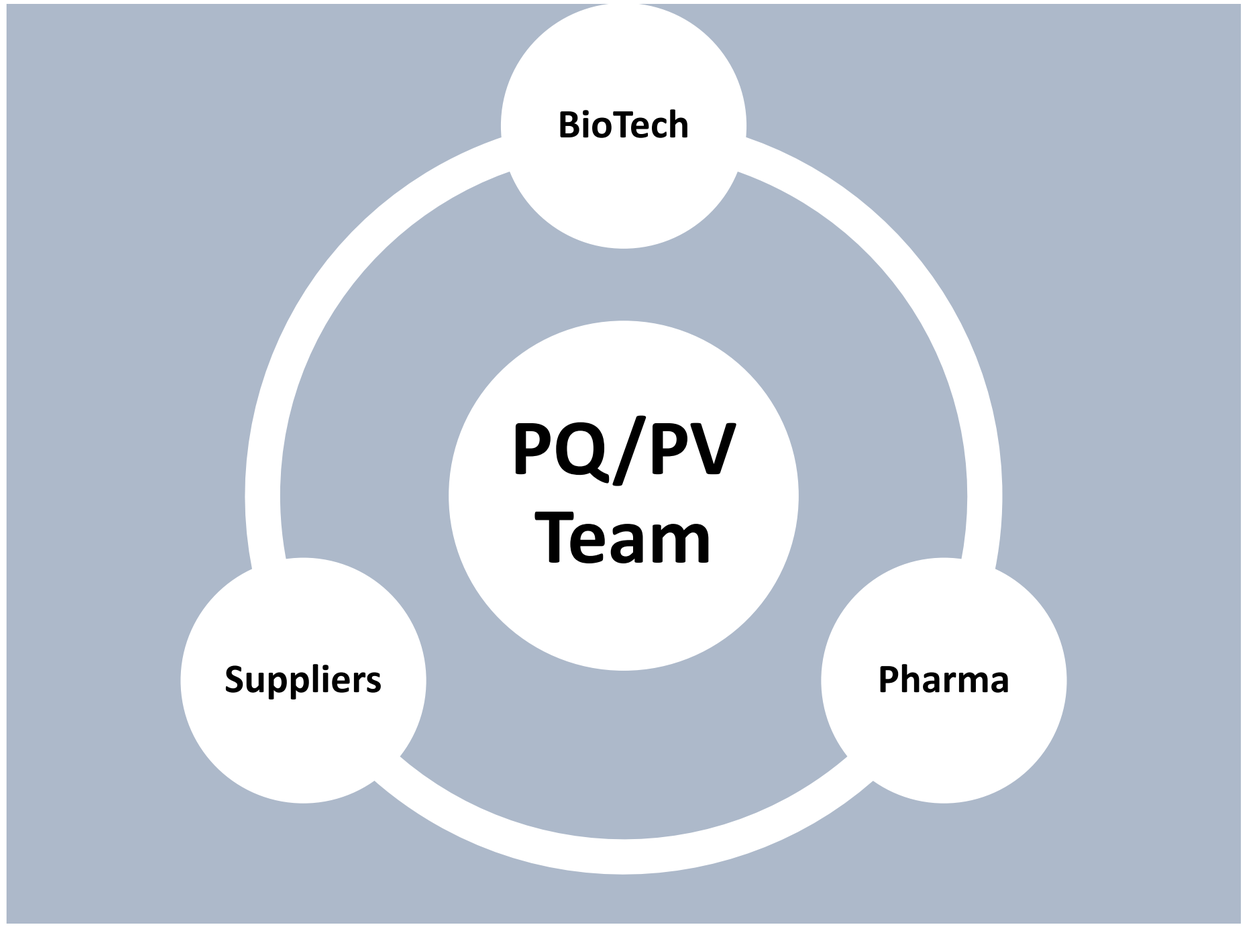
Any major scope topics missing in the current guidance draft?

Questions?

Thermal Shipping System: Performance Qualification (PQ) and Performance Verification (PV) Best Practice Guidance

ISTA PQ/PV Team Mission and Objective





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Progress TimeLine

Background and Objective

Background	**There are various guidance documents and multiple qualification and verifications terms in use pertaining to the transport of temperature-sensitive products (such as ISPE, ISTA, PDA, USP, WHO) but what are the best practice approaches medicinal product companies are following to ensure product temperatures are within the pre-defined specifications during transport and to demonstrate in submissions and audits that temperature-sensitive product shipping processes are appropriate and in a state of control.**
Objective	**Determine the various qualification/verification approaches medicinal product companies are following to implement and maintain compliant temperature-controlled shipping processes and develop guideline to drive standardization of best practices across the industry.**

Complete

PQ/PV Document Outline

In-Progress

PQ-PV Outline	Performance Qualification	Performance Verification
1 Introduction	X	X
2 Definitions	X	X
3 Prerequisites	X	X
4 Change Management (high-level section)	X	X
5 Risk Management (high-level section)	X	X
6 Process SOPs	X	X
7 Performance Qualification	X	N/A
8 Temperature Monitoring Program	X	X
9 Implementation	X	X
10 Exception Management	X	X
11 Performance Review	X	X
12 Periodic Review	X	X
13 Re-Qualification	X	N/A
14 Performance Verification	N/A	X
15 Conclusion	X	X
16 Appendices	X	X

Audience Questions?

How many companies perform PQ vs PV? Alternative Approach?

When/Why is PQ vs PV performed?

Is PQ vs PV performed for a specific type of thermal system? Active/Passive/Hybrid Owned vs Leased?

Do you think industry collaboration to develop best practice guidance document for PQ/PV will help your company? Why/Why Not?

When executing a PQ/PV, how many test runs are required?

How often is PQ/PV completed for a thermal shipping system?

Is PQ/PV required for thermal shipping system implementation?

How do you determine the shipping lanes for PQ/PV?

Summary

Additional questions or comments?

- Send them via email webinar@ista.org

Calendar of Events

- October 2021: Virtual Technical Exchange October 5th and 12th
- Q4 2021: Peer review of current activity work
- Q1 2022: Committee Member Nominations
- April 11-13, 2022: ISTA Forum TransPack & TempPack in San Diego, CA
- Q2 2022: Kick of new committee activities
- Q3/Q4 2022: Virtual Technical Exchange