

# Strategy for Temperature Controlled Transportation Validation

BioPhorum Operations Group (BPOG)'s Collaborative Best-practice

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# Agenda



1

**What is BPOG?**

2

Introduction- “The need for Collaboration”

3

Qualification of Transport Systems and Verification of Lanes

4

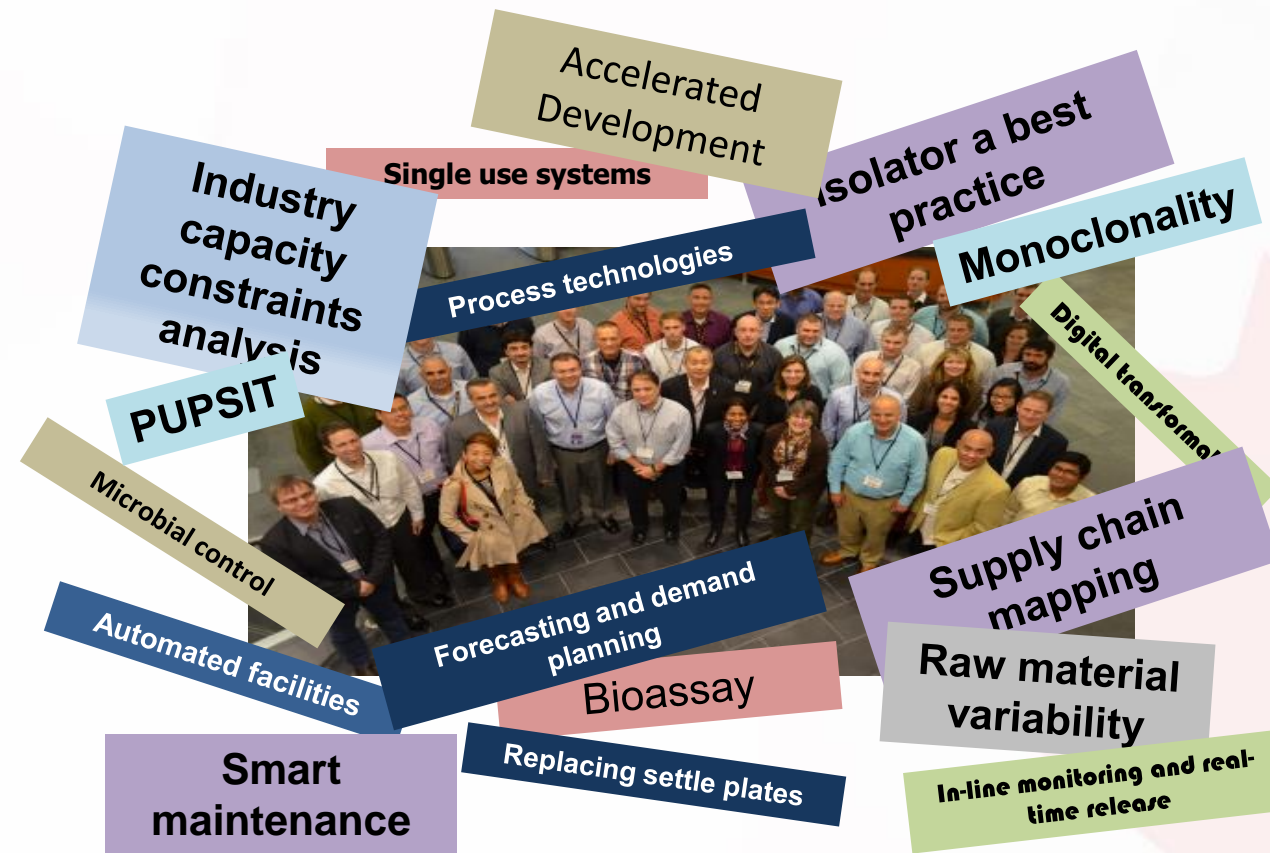
BPOG- Position on Transport Validation

5

Conclusion & Perspective

# What is the BioPhorum Operations Group (BPOG)

- Unique global collaboration
- Powerful vehicle for change
- 6 Phorums
- >50 industry changing initiatives
- Industry leaders and experts working in concert
- Delivers results by pooling knowledge, practices and ideas



<b>53+</b>	<b>2060+</b>	<b>6</b>	<b>1</b>
MEMBER COMPANIES	ACTIVE PARTICIPANTS	THRIVING COMMUNITIES	PHORUM FOR CHANGE

# Workstream: Storage and Transport

## VISION

Globally consistent, industry-wide, patient-centric processes guaranteeing the effective storage and transportation of biopharmaceutical drug substance and product

## MEMBER COMPANIES

- Eli Lilly
- EMD Serono
- Merck MSD
- Pfizer
- GSK
- Biogen
- BMS
- Janssen
- Sanofi
- Abbvie
- Regeneron
- **Novo Nordisk**
- Alexion
- Bayer



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# Introduction & Objective

Providing one-voice: An industry standard to qualification of transport systems and verification of lanes

## Aim/Objective

- Secure compliance to regulatory developments
- Secure a clear and unified approach among BPOG members to key supply chain processes (minimise risk of external findings)
- Network to gain consensus and identify best practices
- Standardize processes to reduce costs (current focus is on transport validation)



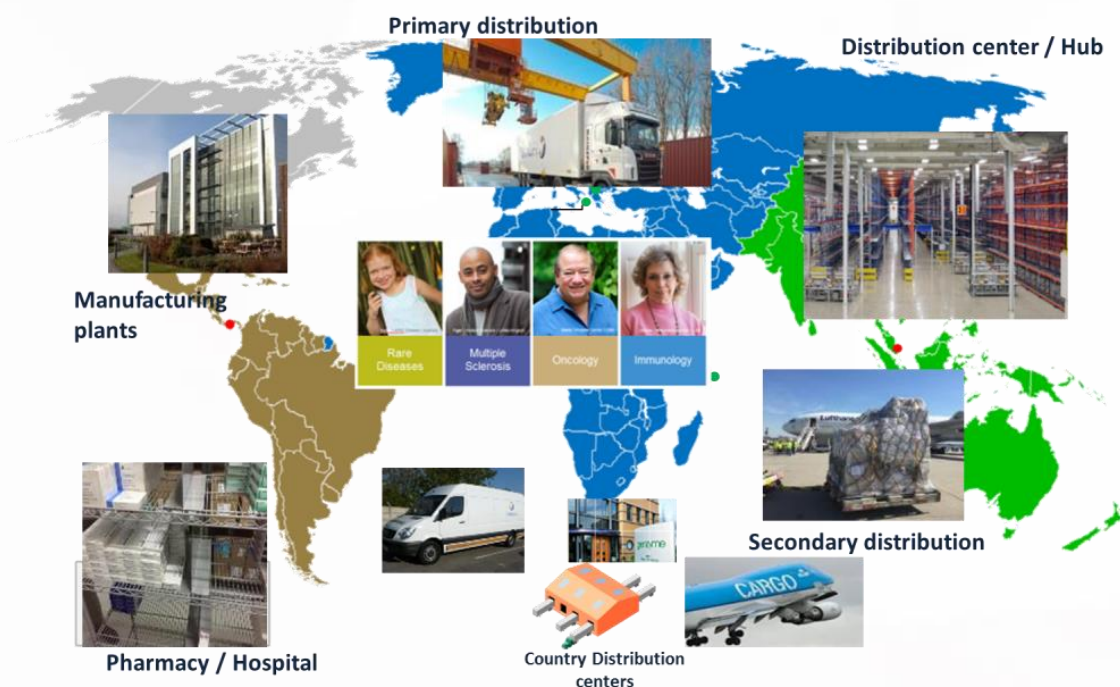
Commitment  
Collaborate  
Benefits (long term)

▶

One strong voice  
Be part of the change  
Reap the rewards



# Complexities in Cold Chain Distribution

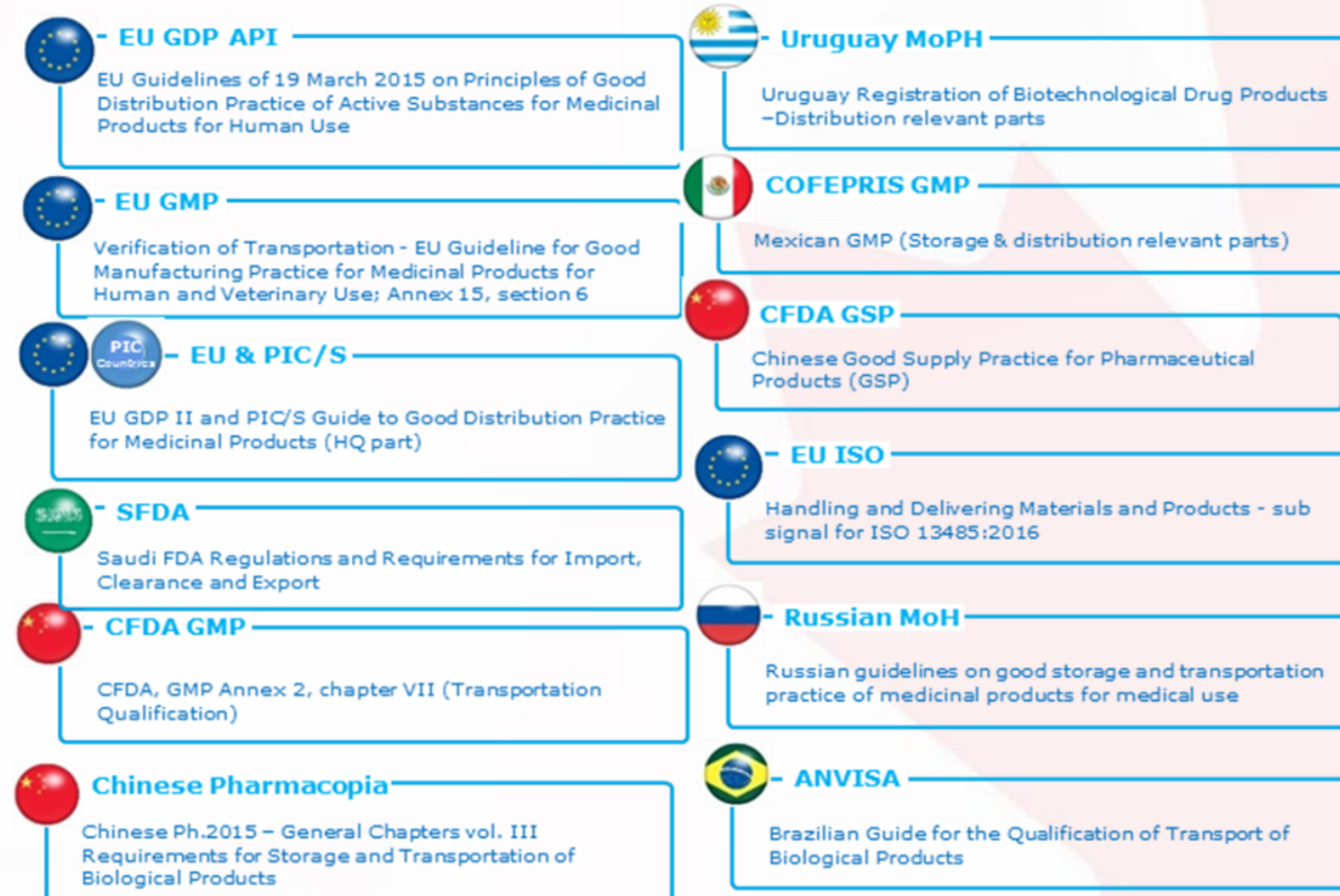


- The cold chain requires application of appropriate transport packaging and equipment
- Larger volumes, vast geographic reach and increasingly specific product requirements
- The cold chain is highly human reliant
- This can make successfully performing transport validations challenging

# Multiple Approaches & Guidelines


## Regulatory requirements and guidelines:

- Huge variety in regulations and guidelines
- The industry struggles to keep up with the pace of new or updated guidelines
- Becoming more and more important to align within the industry – ‘one voice’
- Include and collaborate with suppliers of transport systems and services





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# Qualification & Verification

## Need for a common standard

### Challenges

- Multiple approaches within industry
  - High diversity in regulatory requirements
  - Inconsistent industry interpretation of regulatory requirements
  - Redundant/ repeated and non-value adding work
- Suppliers do not always meet bio-pharma industry's needs

**We are building the Eiffel Tower each and every time we do a validation....**

### Opportunities:

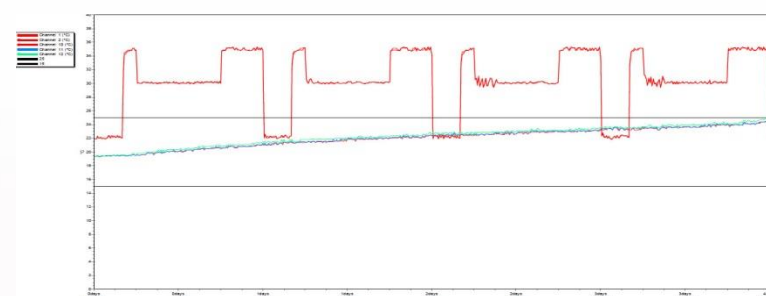
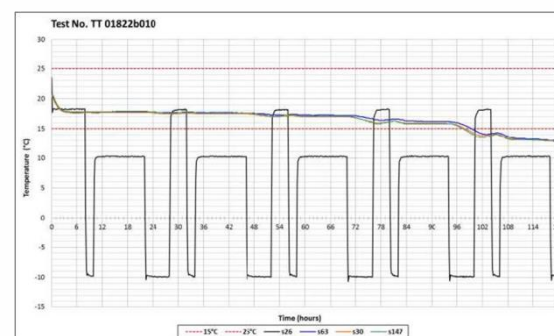
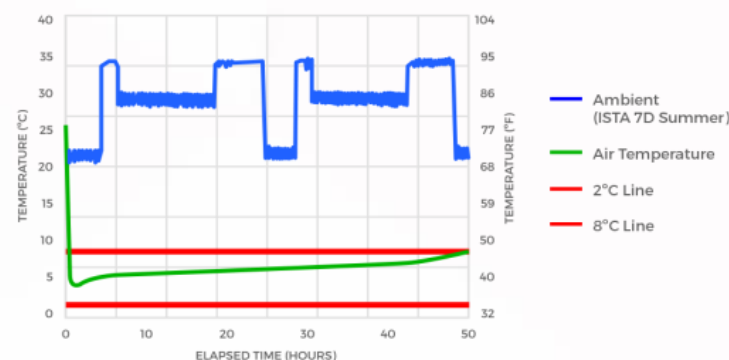
- Comprehensive Operational Qualification (OQ) – chamber studies
  - Alignment with vendors/ service providers
- Reduction of number of Performance Qualification (PQs) (verification shipments)
- Change management of validated process (handling new routes, products without increasing qualification burden)
- Simplify existing shipping solutions
  - Active, Passive, Hybrid




**Simple, robust and dependable strategy**

# Harmonisation in Qualification Approach & Solutions

- Alignment within industry on robust packaging qualification profiles:
  - Pre-set temperature profiles to simulate route/lane i.e. ISTA 7D/7E
  - Upgrade temperature qualification (with vendors)
- Harmonised (passive) container solutions:
  - Potential reduction in number of solutions required by member companies by 50 – 75% (e.g 40 down to 12) equates to savings in terms of time (validation) and resources (man hours) required to qualify
  - FTE (full time employee) requirements reduced
  - Improved rates with container suppliers



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# BPOG: Benchmarking Current Transport Validation Processes

## Operational & Performance Qualification



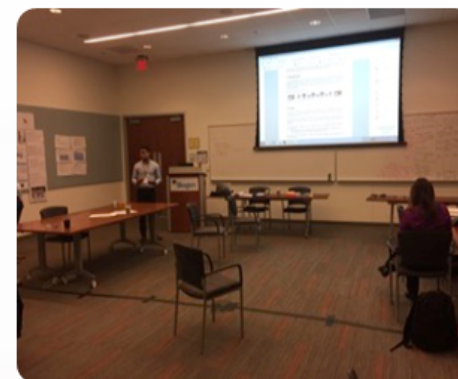
List of key tasks, elements, tests etc.

Test	Company A	Company B	Company C	Company D (API)	Company E	Company F (API)	Company G (API)	Company H	Best Practice
# PQ runs	3	1/site min	1 min	3	3 x 2 (summer & winter)	3/route	Load: 3 Seasons: 2	1	Flexible, min 1
# routes/PQ	1	1	1	1 min	>1	1	Multiple	1	Flexible, min 1
Seasons	No	No	No	No	Yes	Yes	Yes	No	Flexible due to Reg. demands, recommend 1 season

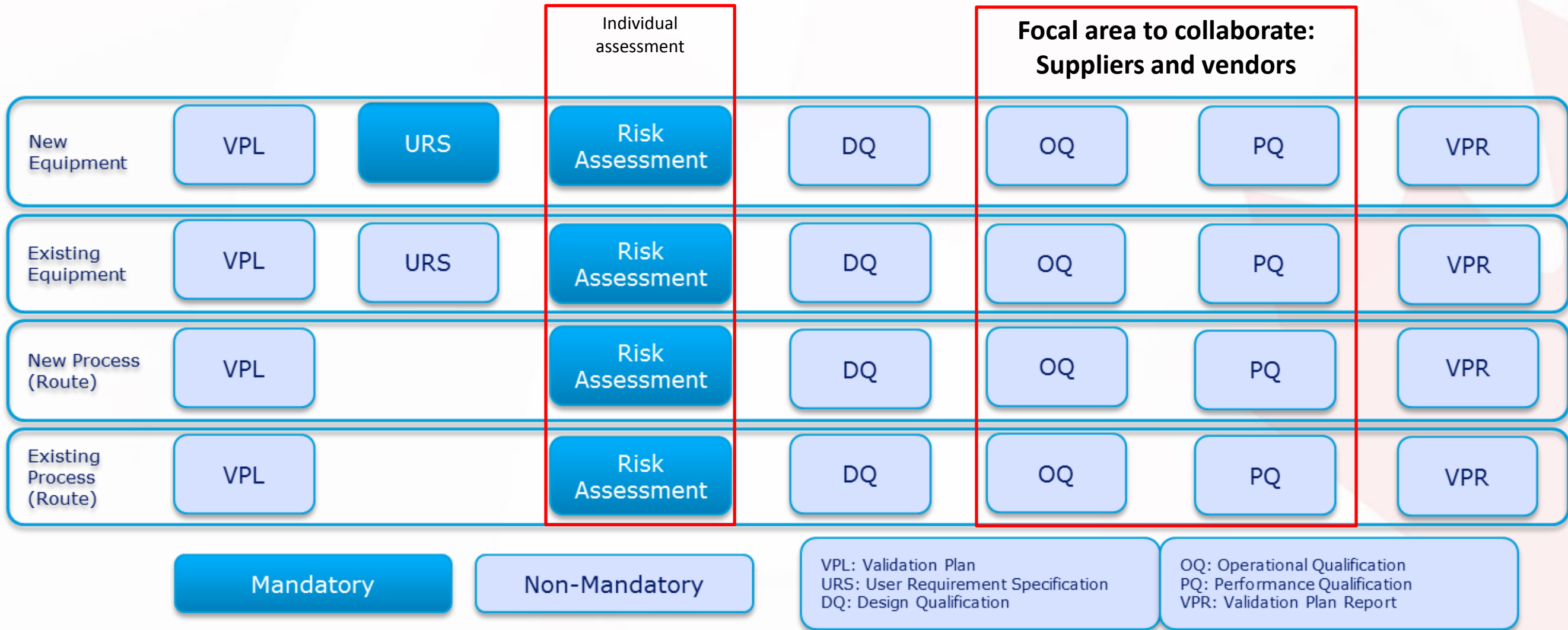
Matrix with input from each company



BPOG recommendation



# Transport Validation Framework



# BPOG Recommendations: OQ & PQ

Test - OQ	Best Practice
Payload (min/max)	Min/Max (load assessment)
External ambient temp	Custom / Industry / Vendor Ideal – BPOG Best practice
Duration	Passive: minimum full route
Orientation	To be agreed
TOR (pack/unpack time)	Yes
Probe inside product	Identify hot/cold spots ; Identify routine location; correlation between routine logger position vs product temperature
Probe routine location	
Probe mapping	

Test - PQ	Best Practice
# of runs	Flexible, min 1
# of routes/PQ	Flexible, min 1
Seasons	Flexible due to Reg demands, recommend 1
Materials (representative or product)	Representative of product
Payload (min/max)	Flexible, recommend no
Worst case	Utilize a Risk Based approach
Acceptance criteria	Temp; Damage; Duration (depending on DQ & OQ)
# routine loggers/unit	1/unit minimum
Extra loggers	0
Placement of loggers	Routine
External loggers (outside)	1 – for info
Shipper- internal loggers	Routine
Inside product loggers	0

# Road Ahead: Harmonisation of qualified solutions and requirements leading improved transport control



**Benchmark and improve processes**

- Standard operation qualification (OQ) and performance qualification (PQ) strategies for shippers and lanes
- Regulatory filing and supplier engagement – collaboration also with BPOG (post-approval strategies)

**Align requirements and reduce costs**

- Regulatory requirements and associated best practice
- Database/ data warehouse of qualified solutions in collaboration with suppliers/vendors (off-the-shelf)


**Network to support internal decisions**

- Transport control in terms of demonstrating control of entire distribution/ transport chain
- Upcoming topics: data analytics, excursion management, distribution risk management and Theft/falsifications of products





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# Conclusion & Perspectives

- Engagement and collaboration are key
- Building an industry standard through collaboration supports all parties (suppliers, manufacturers & regulators)- “one voice”
- Getting ahead and staying ahead of the “Compliance Squeeze” is the ultimate goal while building a more robust and effective supply chain



# Acknowledgement- BPOG

## Work group members

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Beth Ruland  
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Dwight Ricci  
Francois Vivier  
Gabbie White  
Gary Pirozzola  
Gianne Olaes-Denis  
Jennifer Antonetti  
Killian Geraghty

## Company

BMS  
BMS  
Merck MSD  
Pfizer  
Regeneron  
EMD Serono  
Alexion  
GSK  
Sanofi  
Biogen  
Alexion

## Work group members

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Shane O'Connor  
Tim Corbidge  
Zaida Diaz-Rossi

## Company

Bayer  
Novo Nordisk  
Janssen  
Merck MSD  
Novo Nordisk  
Janssen  
Sanofi  
Eli Lilly  
BPOG  
Abbvie



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