Lane Qualification VS Continuous Monitoring
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Pharmaceutical Supply is laced with stringent control requirements.

In this highly regulated space, suppliers must ensure “...medicines are obtained from the licensed supply chain and are consistently stored, transported and handled under suitable conditions...”(1)

Any compliance reports that fall short of requirements can lead to further investigations and potentially significant consequences - license refusal or suspension.

The approaching 13th Annual Cold Chain GDP & Temperature Management Logistics Global Forum will dissect two dominant risk management methods in the cold chain industry: Lane Qualification and Continuous Monitoring. In light of this oncoming discussion, this Cold Chain IQ e-book will analyze these diverse areas and their latest innovations.

I hope you enjoy! If you have any feedback, please feel free to get in touch

Chanice Henry
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Definitions

Some have argued that the concept of lane qualification requires standardization, with the terms validation and qualification often being used interchangeably, contributing to market confusion on occasion.

The Parenteral Drug Association (PDA) declares that the definitions for the two terms are as follows:

**Qualification:** “A documented testing that demonstrates with a high degree of assurance that a specific process will meet its pre-determined acceptance criteria.”

**Validation:** “A documented testing performed under highly controlled conditions, which demonstrates a process consistently produces a result meeting pre-determined acceptance criteria.”

A dominant difference between the two concepts is lane validation’s use of ‘highly controlled conditions’.

Industry perspectives

In addition to increased cohesion with cold chain definitions, industry figures have called for market consensus upon the certain risk assessments that a lane qualification should contain.

Brian Wallin Principal of Modality Solutions provides a general snapshot of the sufficient requirements: “… test standards, thermal profiles, and verification shipments for transport lane qualification … [allow] an organization to have confidence in the qualification of critical components and equipment delivering product safely to patients.” (3)

Raw data collected for a lane qualifications can present challenges for some suppliers, in regards to the usability of data and analytical capabilities. Micalyn Harris of ELPRO mentioned some of these obstacles saying that once data is collected “…. it’s often not in a usable format, or maybe the format of the data is difficult to handle. They need to have the right tools to analyze the data and look for trends. Internally, they may not have the expertise or resources to conduct the analysis on their own.”
To begin we did a risk assessment which was International. So first we developed it internally for our regions. [This] means Europe, Asia and Africa and then we worked with our colleagues from US to do [this] very globally.

We evaluated approximately 150 different lanes. Each lane got a score and then we chose from three groups. One [being] …. shipments from Europe to Australia. The second group is shipments from Europe to the Middle Eastern countries and the third group is our shipment within Europe.”

“...If I go more into detail for the risk assessment, we had 5 different criteria: the high temperature, the low temperature, the time needed for the shipment, the type of product, and then the route complexity. In the route complexity for example you have if it’s by plane or by truck. We looked at the countries we crossed, the number of Customs we have to pass or the number of transits if it was by plane also the risk: the seismic risks, the risk of having problems in the country like war or political problems.”

“So all the countries that we chose for the validation cover the different criteria, meaning low temperatures, high temperatures, by truck, by plane, different sorts of countries, even politically unstable countries like Syria and Lebanon.
Being Cost Effective qualification/validation:

According to Emilie Deglise, it’s important to analyze the size of shipments in question and consequently select the appropriate number of loggers for your lane. Place too little and you could jeopardize the complete shipment if you lose data loggers. A high number of data loggers will lead to a larger volume of information however, it doesn’t always guarantee additional data content.

A change in data loggers can also expose new opportunities to save time and costs.

Don’t always expect the worst conditions

Informed decision making can ensure that you don’t over exert your resources unnecessarily. It is important to know where temperatures are more extreme and are more likely to occur so precautions can be applied, and these efforts can be scaled proportionally in relevance to the environment in question.

Keep your standards high

Save time, money and stress by working with GMP and GDP qualified partners. On this matter Emilie Deglise notes: “I think it’s important when you choose your partners to work with, to work with partners which are trained where you have the whole confidence that they can handle such a validation.”

Also utilize the test material and know how from the partners you choose to work with.
A recent report on the “Integration of Vaccine Supply Chains with Other Health Commodity Supply Chains” pondered the idea of innovating the cold chain landscape via the integration of vaccine supply chains with selected health commodity chains. Although, this would have to be conducted diligently and with similar products, the report deems this integration could greatly enhance the effectiveness of supply chains in resource constrained environments. (10)

**Lane Qualifications and Extreme conditions**

A topic of much discussion within lane qualification is temperature profile selection which entails the testing of a thermal shipper in a laboratory environment to assess performance in extreme conditions. (13)

Temperature profile selection data is expected to contain the product type in question, the effects that occurred, technology used, duration and mode of travel.

One challenge faced in temperature profile selection is ensuring the extents of extreme conditions are fully represented.

Recommended steps to take include the application of standard temperature profiles, the evaluation of the cold chain’s infrastructure and real data from shipments.

Due to the lack of global industry standards for qualifying product containers, firms choose to qualify containers to worst case conditions, accounting for performance when containers are mishandled or even malfunctioning.

Karin Torvenius from Envirotainer notes that it is more economical to qualify products for global shipments rather than individual trade lanes.

**GOLDEN RULES FOR COLD CHAIN RISK ASSESSMENTS**

- Know your shipment solutions.
- Know your processes.
- Know your risks.

Hear more from *Karin Torvenius*, Envirotainer on the topic of Qualification vs Continuous Monitoring at the 13th Annual GDP Temperature Management and Logistics Global Forum.

Who’s doing it best?

This year, global supply chain solutions provider Marken won Best LIFE Science Logistics Service Provider for the second time in two years at the Annual BioPharma Asia Industry Awards. The firm also offers shipment lane qualification services. (12)

Also, Camille Madelon of Envirotainer was crowned as Cool Chain Europe’s 2015 Supply Chain Innovator of the Year.
Continuous Monitoring

The National Institute of Standards and Technology defines continuous monitoring as a risk management technique used to determine if a system’s security controls continue to be effective over time considering the inevitable changes that will occur. (5)

Industry perspectives

On the topic of continuous monitoring, Emilie Deglise of Celegne International noted: “...for some countries we are obliged to do continuous monitoring because of the regulations in place, for example, to Israel, Saudi Arabia or Australia also. As they don’t accept the validation.”

The cold chain is littered with challenges in regards to continuous monitoring. Simple obstacles include: getting reports back from receivers or having reports in an organized and searchable format. On this note Micalyn Harris from ELPRO stated: “Another challenge is how to store data and release shipments for a multi-data logger shipment, with the issue being if one of the data loggers alarms but not the others. An example of a more complex challenge is how to monitor and release a multi-component shipment (i.e. clinical shipment with an IMP and comparator).”

Technology

The past few years have witnessed a technology evolution in the cold chain space as firms equip themselves to overcome challenges and abide by necessary compliance parameters.

In today’s cold chain, the accidental freezing of vaccines is seen as a “growing threat” by experts, with sub-zero temperatures being capable of reducing a vaccine’s potency.

This became a prevalent issue within Tunisia, which enjoys a mix of Mediterranean and African climates. According to a 2012 experimental study, Tunisia’s national immunization program equipped its health facilities and districts with domestic refrigerators as opposed to imported pre-qualified cold chain equipment. Tunisia’s intentions to introduce newer vaccines into its cold chain systems which held a high risk of freezing sparked the requirement for an enhancement to its vaccine safeguarding capabilities.

The same experiment concluded that despite the continued use of underperforming domestic refrigerators, continuous temperature monitoring using new technologies, combined with other technological interventions, significantly reduced the accidental exposure to freezing temperatures. (9)
Growth

The increase in temperature sensitive healthcare product sales is expected to fuel a surge in the size of the cold chain industry over the next five years.

Recent research findings from the IMARC Group have forecasted the total size of the healthcare cold chain logistic services market to balloon to nearly US$13.4 billion by 2020.

The group believes the industry currently stands at around US$8.5 billion.

However, technology’s adaptations for the demands of the cold chain industry have not seen a revolution in the type of devices used, but more in how existing tech from other industries is used, like portable wireless data systems being applied to real time temperature monitoring.

Today’s available equipment is lined with capabilities such as GPS tracking, notification transmissions via voicemail, text, or email, live data reviews and ‘Geo-fencing’ route alerts. All of which are ideal capabilities for firms that trust third party carriers with cold chain biopharmaceuticals. (6,7,8)

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Drawbacks

Possible downsides with continuous monitoring technology such as data loggers is that one in five are lost in transit or fail to have their data uploaded, according to Cambridge Consultants. (11)

Whose doing it best?

After consulting industry experts, firms like World Courier, QuickSTAT and Berlinger for its data loggers and indicators were pinpointed as industry frontrunners.

Also, Kuehne + Nagel were recently decorated with the Best Temperature Control Logistics Project award for its globally launched KN PharmaChain. The multimodal pharma and healthcare-specific logistics solution claims to offer door-to-door temperature control, In-transit wireless temperature measurement, 24-hour alert and corrective action system.

Aramex’s Biocare was also identified as a leading cold chain solution for moving temperature and time sensitive samples. Cold and ambient temperature ranges are covered by the service, with the use of internal data loggers in boxes to monitor temperature throughout transit.
A necessary partnership?

Some asked whether its imperative to have a combination of lane qualification and continuous monitoring within cold chain risk assessments, or, in fact, are there scenarios where one method could be more suitable than the other?

On this subject David Graaf of Envirotainer said: “I would say it always comes down to the risk assessment that you do before you start your shipment, but I would say that you can’t exchange one for the other. You always need to know in advance that your shipment will be successful, but you also need to work with continuous improvements, once you are up and running with your day to day shipment.

So, continuous monitoring is just as important as doing your homework prior before shipping."

Due to the ongoing and evolving variables encountered in the distribution process, like David Graaf, many experts believe that lane qualification and continuous monitoring should be used together as a two pronged risk management approach. Unforeseen variables can be capable of jeopardizing a qualified lane and cause it to become insufficient in guaranteeing the safety of products.

Hear more from David Graaf, Laboratory Manager, Envirotainer on the topic of Qualification vs Continuous Monitoring at the 13th Annual GDP Temperature Management and Logistics Global Forum.

Hear more from David Graaf, Laboratory Manager, Envirotainer on the topic of Qualification vs Continuous Monitoring at the 13th Annual GDP Temperature Management and Logistics Global Forum.
What do these topics mean for you?

In regards to each approach, cold chain specialists highlighted the following as important considerations:

**Lane Qualification**

**The requirement of trust**

I have heard stories of alleged cold rooms being available in certain airports, but once you go on-site you find there is not even a thermometer installed. If it is a new partner, a new lane, a new process, who should you trust with the data gathering?

If someone in a sub-tropical region of the world, for example, swears to you there are enough electrical outlets to recharge your box, do you take it at face value, ask for evidence, fly in to check it in person?

Would you entrust the truck driver of your shipper, for instance, to perform the on-site inspection to determine the high and low risk elements of the route in question? Does the person have the understanding or know-how to perform such a task?...

Once you have all the relevant data I do agree that doing a proper qualification should be rather straightforward, however, I have yet to see a simple “how to” guide to tackling the nitty-gritty of gathering such information in different countries, involving potentially dozens if not hundreds of partners.

Ultimately, who do you trust?

Eugenio Filippi, Pharmaceutical Logistics Senior Manager. (13)

**The accumulation of data**

A diligent and thorough risk management program will not only allow companies to identify the various exposures and risks to their products during the distribution process but also will provide them with valuable data with which they can use to ship their products in a cost effective manner.

Eric Newman Vice President for Loss Prevention at ProTecht Risk Solutions. (16)
What do these topics mean to you?

**Security in the face of change**

In reference to the collation of shipment data, Cool Pack states that continuous monitoring can help produce ‘the most defendable data’ “accounting for potential changes such as global warming, or changes in the way product is distributed ....” (14)

**Continuous Monitoring**

**The development of real-time control**

Continuous process monitoring and control is critical, and truly predictive tools still need to be developed to model facilities design, information management and automation.

“Processes can then be harmonized as early as possible into the environment required, the information can be monitored and managed, and automation can be established to really achieve real time process control. (15)

*Dr Barry Holtz, President at Holtz Biopharma Consulting*
As regulation requirements increase within pharmaceutical supply, the industry’s focus lays firmly on the compliant risk management methods available, with lane qualification and continuous monitoring falling at the forefront.

In safeguarding product integrity, both the proactive approach of lane qualification and the more reactive continuous monitoring technique can lay significant costs on suppliers in cold chain. This can cause hurdles to arise when supply routes run through countries of low income, low resources and testing climates. As a result, many professionals are left seeking opportunities for measured innovation to be both compliant and cost effective. This notion requires a delicate balance, with serious consequences if wrongly applied.

Despite the enviable intention to reduce the bottom line via economical means, industry consensus does promote the application of a stringent approach within cold chain through the use of both lane qualification and continuous monitoring together rather than adopting one in exchange of the other.
Your industry’s #1 event for temperature controlled supply chains and products

Where Product Integrity Meets Value - Balancing Compliance, Risks and Costs

Talks focused on Lane Qualification and Continuous Monitoring include:
- Qualification vs Continuous Monitoring with Karin Torvenius and David Graaf of Envirotainer.
- Roundtable discussion - Qualification of Thermal Shipping Systems to Meet Global Health Authority Requirements
- Establishing a Global Shipping Qualification, Monitoring and Control Strategy with Bristol Myers Squibb Scientist Carolyn Williamson

Karin Torvenius from Envirotainer notes:
The people attending the workshop will gain higher knowledge of the complexity of the cold chain, but also understand why it’s important to have continuous monitoring in place to improve processes and also to minimize the risks.

Other 2015 program highlights include:
- Expanded use of OCEAN FREIGHT beyond CRT/Ambient products
- GLOBAL GDP updates and best practices from regulatory authorities and industry perspectives
- RISK ASSESSMENT & MANAGEMENT strategies and tools
- EUROPE’s GMP & GDP updates and their impact on the industry
- INTERNATIONAL FOCUS DAY featuring international case studies and speakers from Europe, China, Brazil, India and Middle East
- Global transport of AMBIENT products - From RISK ASSESSMENT to VALIDATION
- Gain competitive advantage by applying DATA ANALYTICS to your temperature controlled supply chain
- Best practice approach to designing stability studies to create a STABILITY BUDGET
- Working towards an industry consensus for LANE QUALIFICATION
- Improved LAST MILE visibility and quality operations
- Proven COST EFFECTIVE best practices and case studies - Balancing compliance, risks and costs
- Comprehensive TRACEABILITY SYSTEM - Prepare for evolving global regulatory mandates
- Proven solutions to help mitigate challenges in your COMPLEX GLOBAL LOGISTICS NETWORK
About Cold Chain IQ

An international resource centre for the temperature control life science professional, Cold Chain IQ delivers insightful, unbiased information about today's hot topics.

Members benefit by reading expert analysis, trend-setting articles, listening to podcast interviews, watching video features and top-rated presentations from IQPCs global temperature control supply chain event series. Cold Chain IQ focuses on all areas of temperature controlled logistics, distribution and quality in pharmaceuticals and biotechnology. Cold Chain IQ, part of IQPC, maintains the largest cool chain pharmaceutical international database, offering strategic partners, members and contributors an unparalleled opportunity to network, share ideas and disseminate best practice information across the globe with peers.

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