Solutions to ensure ground-level excellence in the supply chain

Across three days of workshops, keynote presentations, case studies, interactive discussions and networking, the 19th annual *Temperature Control and Logistics* forum left attendees with strategies, solutions and partners to overcome their most pressing operational challenges

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20TH ANNIVERSARY
TEMPERATURE CONTROL AND LOGISTICS

Contents

"The event is very valuable in terms of networking and finding out the right level of IoT and digital monitoring solutions."

TCL Global Solutions Manager

Pfizer

Transforming the industry in real-time

Every pharmaceutical product has a label specifying the way in which a product needs to be transported – from its temperature, to its stability, to its shelf life. Yet, billions of dollars' worth of pharmaceutical products are still shipped and stored at improper temperatures across the globe, which can make drugs ineffective and potentially harmful to administer or consume.

With the challenges of maintaining a temperature-controlled supply chain spanning across packaging, regulation, manufacturing and drug development, the 19th annual *Temperature Control and Logistics* (TCL) forum honed in on providing solutions for ground-level excellence, ensuring an an uninterrupted chain of product refrigeration, storage and temperate distribution. Across three days in January, top industry facilitators and speakers from big pharma companies such as MSD, Roche, Sanofi, GSK and Teva provided insights on what is required to achieve ground-level excellence and ensure temperature ranges are maintained across the global supply chain.

TCL 2020 dove into the biggest changes happening in the global pharma logistics space, placing a particular emphasis on data management. While containers, blankets and data loggers remain fundamental to building a basic temperature-controlled supply chain, the industry is shifting toward enhancing process development and data utilization through increased use of technologies such as Internet of Things (IoT), real-time monitoring (RTM) solutions, blockchain, lane validation and analytics platforms in the supply chain. With some of these solutions largely considered "future-focused" within the pharma industry, TCL evaluated applications for these solutions, highlighting what the industry is capable of now and where development needs to progress. The discussion was then able to pivot to where the industry is already seeing the value and how to demonstrate return on investment to stakeholders.

Richard Peck, Global Head of Process Controlled Transportation CoE at AstraZeneca and one of the leading facilitators at TCL, said: "From VPs and heads of global supply chains, regional logistics and quality directors and temperature control project managers, TCL 2020's agenda had solutions and strategies for everyone. With the constant pressure on process optimization and cost reduction, there has never been a more important time to engage with the industry's leading experts."

In this post-show report, we explore three key topic areas covered at the event – process implementation, process transformation, and process quality management and compliance – and, if achieved, what it would mean for pharma supply chains now and in the future. The report also provides an exclusive overview of what to expect at TCL 2021.

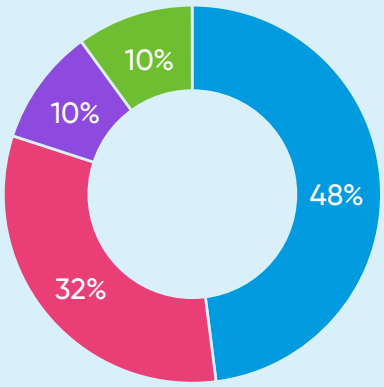
Key discussion topics from TCL 2020

- Incorporating data analytics for real-time supply chain monitoring and process efficiency.
- Improving supply chain visibility, temperature monitoring, demand management and contingency planning.
- Implementing artificial intelligence and IoT as a disruptive force for effective supply chain management.
- Utilizing route simulation and risk management strategies to identify and mitigate against common pitfalls.
- Mapping the growing utilization of sea and rail freight lines: where are we now and what are the hurdles to expansion?
- Examining supply chain sustainability and reverse logistics to minimize our industry footprint.
- Balancing supply chain costs and good distribution practice (GDP) compliance.
- Preparing for success – ensuring compliant and efficient packaging across all product types.

Overview of TCL 2020 attendees

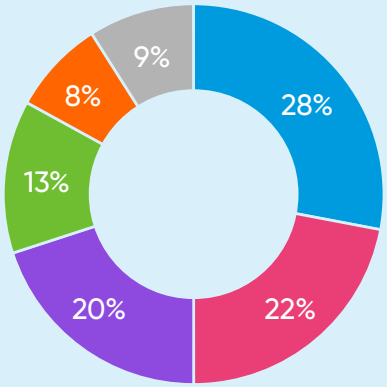
Attendees by sector

- Biopharma/biotech
- Solution provider and consultancy
- Contract manufacturing organizations
- Public sector/Academia



Attendees by industry

- Pharmaceutical large
- Technology
- Pharmaceutical SME
- Biotechnology
- Medical device
- Other



A truly international event, with delegates attending from:

Austria	2	Iceland	4	Luxembourg	5	Switzerland	20	Hong Kong	5
Belgium	24	India	4	Macedonia	1	The Netherlands	32	Mexico	2
Canada	2	Ireland	12	Norway	3	Ukraine	1	Portugal	1
Denmark	10	Israel	5	Pakistan	1	UAE	2	Singapore	2
Finland	3	Italy	7	Poland	4	United Kingdom	226		
Germany	39	Japan	3	Russia	1	United States	38		
Greece	2	Latvia	2	Spain	8	Australia	3		
Hungary	2	Lebanon	1	Sweden	7	Brazil	3		

Process implementation

Focusing on current industry projects, priorities and on-the-ground management, the sessions in the process implementation stream ensured attendees left with new strategies and solutions that can easily be implemented by those working at home or in the office.

By tracking the movement and condition of goods from point of manufacture to point of processing, the industry aims to ensure supply chain risks are minimized. The collection of real-time data and historical data will continue to help decision-makers review and optimize supply chain operations as they uncover inefficiencies. Implementing solutions such as RTM is one way to help companies improve operating effectiveness, drive down the cost of supply and increase data security, safety and fulfillment of environmental regulations.

To ensure you reap the benefits of supply chain analytics and make the right data-driven decisions, Simona Vatzova, Director Transportation EU at Teva, shared how Teva has rolled out a global RTM solution and pinpointed the critical success factors – and what to watch out for – to ensure a smooth roll out.

What to watch for when you decide to implement a RTM solution

Vatzova began her session referencing how the automotive industry has efficiently been able to implement RTM solutions into its operations by closely following the trend of digitalization to improve production processes, worker and plant safety, and reduce energy consumption. She uses the example: "The first vehicle powered by petrol was made in 1880, a century later hybrid car models were released and Tesla continues to showcase its innovation efforts by launching electric cars.

"If the pharma industry took a similar approach to innovate its standard data logger, companies would be able to quickly move away from radio-frequency identification data loggers and toward using real-time data loggers to enhance productivity across the entire supply chain."

In order to successfully implement an RTM solution, Vatzova highlighted three critical factors that need to be considered during the planning stage of any process implementation strategy:

People

- Pharma companies are run by people for people (patients) so operational and performance processes need to be inclusive of people – both its workers and patients.
- All stakeholders should be included at the very beginning of an implementation process. This has proven to increase the success rates of overall supply chains immensely.

Process implementation

Processes

- Understanding how to measure your product quality and IT processes. For example, Teva automates delivery reports to assess the quality of a product (i.e., if a low or high excursion has taken place, Teva can immediately identify the problem and avoid going through a timely investigation process).
- Defining your logistics planning processes. Some customers may need to be notified that real-time data loggers will be used to monitor products as some countries require special licenses to complete transmission functions and to connect to the cloud.

Technology

- Global connectivity is key for transmitting data successfully. The data loggers communicate with different networks but in some cases it will only connect to the strongest signal. In order for the data logger to be strong enough for transport it will need to connect to a number of different signals such as 3G, cloud, 4G, 5G or WiFi.
- In Teva's case, Vatzova says it outsources its technology platforms, with the platforms belonging to the vendor and the data belonging to Teva.

Key takeaways

- Moving from no visibility to full visible, data loggers can have an impact on your logistics, customers and strategies. To overcome these challenges you will need to plan ahead.
- Moving to an agile environment and adapting to new technology takes time. Educating employees on how processes will change when RTM solutions are implemented and what it will mean for them is critical in ensuring transitions are smooth.
- There is almost no difference in cost to implement conventional and RTM solutions, however, from an insurance point of view, costs may decrease as real-time can provide more reliable results.

Process transformation

Designed to look at where we are now, and what the future of logistics and supply chain management heralds, the sessions on process transformation provided insight on how to optimize your end-to-end logistics across internal and external processes.

Building excellence: Looking externally to transform your logistics capability

Drug research and development continues to evolve past traditional chemical-based, small molecule therapeutics and toward more complex and large molecule biologics, drugs which be transported in a temperature-controlledenvironment given that they are increasingly sensitive to temperature, light, vibration and shocks.

Paul Wolstencroft, Director of Global Logistics at Seqirus, noted in his session: "Shipment retention by customs agencies are commonplace, particularly for investigational medical products, so temperature variations must be managed through careful selection of shipping containers and reliable monitoring."

Wolstencroft dived into how to build internal logistical and compliance capability and looked at how hiring from outside the pharma industry can resourcefully build up your supply chain portfolio and help to manage customs clearance of temperature-sensitive material.

Wolstencroft highlighted some of the key challenges, solutions and principles to tackle temperature excursions at custom clearance points:

Challenges

- Delays at custom borders increase the risk of a temperature excursion, increase overall supply chain costs and put companies at risk of receiving penalties from custom authorities.
- For UK companies, applications to get your products across borders will change with new Brexit agreements. According to Wolstencroft, Seqirus initially did not have a good understanding of what needed to happen once the products reached customs. Understanding authorised economic operator (AEO) guidelines are key to successfully transporting products.

Solutions

- Implementing root cause analysis to ensure end-to-end visibility and delivery of products.
- Understand beyond the handover, be part of the solution with your freight forwarders.
- Hire logistics personnel from a non-pharma background to absorb "best practices" thinking and learn from other sectors.
- If you are working in the UK, create a Brexit committee so you can more efficiently integrate AEO guidelines into your processes.

Best ways to move forward

- Redesign inherited logistics networks and implement validated cross-dock facilities.
- Widely adopt 3PL track and trace systems and temperature location tracking systems, which is pivotal for tracking consignments worldwide.
- Educate incoterms, commercial businesses and customers on how to safeguard cold chain products
- Getting the basic logistics right by checking the data that goes through to custom authorities are processed correctly.

Key takeaways

- To increase the speed of shipments and reduce the risk of temperature excursions, supply chains hold greater responsibility for end-to-end logistics activities.
- Hire non-pharma professionals to expand expertise.
- Extend focus beyond company shipments and across the entire supply chain lifecycle.

Process quality management and compliance

Sessions in the final stream of the forum focused on the quality assurance and global compliance aspects of global logistics and supply chain management. The stream was designed to give attendees an in-depth understanding of regulatory and global standards requirements across all underway projects in the industry.

Scaling up specialized supply chains while maintaining GDP compliance

To assess whether products are compliant with GDP laws, data must be provided to demonstrate that the product temperature range has been adhered to across the supply chain. While the pharma market largely understands GDP, achieving it on a shoestring budget remains extremely difficult.

Chris Wallace, Senior Director – Global Supply Chain Operations at Celgene, shared insight on how to preempt the bottlenecks when dealing with controlled or temperature-sensitive products and dove into four foundational capabilities in the healthcare value chain to ensure "high-quality patient care at optimal economic cost" can be achieved.

Four steps to maintaining low cost and GDP logistics compliance

1. **Build up your operations and innovation excellence strategies:**
   A successful culture of innovation can lead to increased revenue, reduced operational costs, as well as a more positive company culture. This culture is key to developing leaders from within and encouraging a company of thought-leaders and disruptors.

2. **Define your business process optimization methodology:**
   Following a standard operating procedure is one way that will allow for the continuous improvement of standards of service and also provide evidence of your commitment toward protecting patients.

3. **Implement cutting-edge technologies to enhance calibration and preventative maintenance procedures:**
   Preventive maintenance programs are essential to prove equipment is working to the correct standard and is being monitored or repaired when necessary. Calibration must also be completed and monitored to eliminate any discrepancies between different equipment's data recording. Implementing technology into this process will help to eliminate time, expense and frustration involved in identifing the causes of bottlenecks in your workflow after-the-fact.

3. **Understand the expected standard of GDP compliance:**
   Standards can vary globally and in some cases can be contradictory. The aim should be to comply with all regulations set by the countries on your logistics route. If this is not possible, ensure that your reasoning is documented and that you are meeting globally established standards. Be aware of changes to regulations and stay up to date with investigations and enforcements. This will also give insight into upcoming areas of focus for regulators.

Key takeaways

- Global and regional demographics and economic dynamics are changing dramatically; the pharma industry focus will have to change.
- Medicine will continue to advance at a tremendous pace, facilitating personalized treatments.
- Patient demands are increasing, especially as populations increase with age.
- Healthcare budgets are evermore restricted and the industry needs to find innovative ways of overcoming this.
- The collective response to these challenges from pharma companies and associated supply chains will be critical to future success.

Temperature Control and Logistics 2021:
A note from the producer

Whether we operate as a digital discussion group or an in-person conference, our industry-leading community comes together to advance the patient paradigm and ensure that every drug is delivered - right place, right time, right temperature.

Our vision for 2021 is to reach new communities while ensuring we remain true to our role in the industry – providing a case study-based conversation on how to practically advance the industry beyond their current hurdles and challenges in order to ensure that pharma is best able to fulfil its critical role: providing patients with life-saving medicines.

For 2021, we will continue to concentrate on the operational and hands-on case study perspectives, picking up from where we left off in 2020 and looking at the impact of Covid-19 on supply chain and logistics management worldwide. Across three days of digital content, we will ensure that the global TCL community continues to reach new audiences and improve the patient paradigm with more flexible, robust and reliable global supply chains.

We look forward to meeting you, wherever you are, in January 2021.

Emily Shirrefs
Senior Conference Director, Pharma IQ

"If it wasn't for this type of event, I think a lot of the innovation in the industry wouldn't be possible."

Technical Director, Softbox