COLD CHAIN GDP & TEMPERATURE MANAGEMENT LOGISTICS GLOBAL FORUM SPRING

EXPERT INSIGHT INTO CREATING A FUTURE-PROOF TEMPERATURE CONTROLLED SUPPLY CHAIN

May 22-25, 2017

Hotel Del Coronado, Coronado, CA

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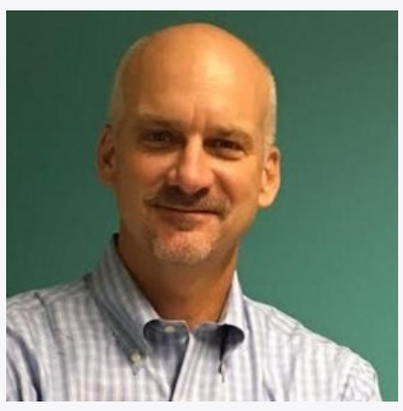
MEET OUR EXPERTS

Ahead of our first ever Spring iteration of the world's largest event on cold chain, we sat down with four of the industry's leading experts to get their perspective on topics specific to each of their areas of expertise. Receive insight on topics that include r**oadblocks and supply chain challenges**, **clinical and commercial operations, validation protocols and many more**. Through this EBook, you'll gather the resources necessary to bring your cold chain to the next level.

Eugenio Filippi
Senior Manager Plasma Logistics & Analytics Europe
Shire Pharmaceuticals

Eugenio leads all European plasma operations, which include logistics, testing (Serological and NAT) and plasma dispositioning, with a passion for cold chain logistics. Eugenio will be leading both an interactive workshop on risk management through taking a total cost of quality approach and a case study on end-to-end process excellence.

William Collingwood
Head of Supply Chain, Biologics
AstraZeneca



William brings 25 years of operations and supply chain experience with both hands-on and leadership roles. William will be leading a plenary session at the Cold Chain Spring event on optimizing the biologics supply chain through effective cross-functional collaboration. He will speak from experience on how to increase efficiency from R&D through to commercialization with improved communication across all departments.

Eden Fucci
Senior Director Drug Product and Supply Chain
Aldeyra Therapeutics

Eden brings a plethora of experience in supply chain, logistics & manufacturing roles from biotech to large pharma organizations. Eden will use his knowledge & experience to lead a plenary session on product launch efficiency that truly bridges the gap between your clinical to commercial operations from validation to inventory planning.

Dave Malenfant
Executive Vice President of Industry Liaison and Talent Development & Director- Center for Supply Chain Innovation
BSMA &Texas Christian University

Dave brings over 30 years of industry experience including the role as Vice President of Global Supply Chain at Alcon Laboratories before joining TCU & BSMA. Dave has vast knowledge of the end-to-end, integrated supply chain and a passion for advancing supply chain theory & innovation, which he will share through leading an in-depth workshop at the Forum on streamlining validation protocols through the last mile.

Eugenio Filippi

Shire Pharmaceuticals

Q: What tips would you give for choosing high quality suppliers with a good balance of cost & risk?

A: "One should always keep in mind that the TCQ (total cost of quality) is what we should be trying to minimize. TCQ is the cost of NOT doing things right the first time, so re-work, corrective actions, CAPAs etc. Selecting high quality suppliers might cost you more short term, but long term you might actually be saving money because their performance ensures fewer deviations, product destruction or even recalls."

Q: What major political and regulatory road blocks would you look out for when shipping cold chain products globally?

A: "One should do a proper PESTL/SWOT analysis before deciding to ship to a given country to assess and understand the cost of this new shipping lane. for example in certain countries like Brazil or Saudi Arabia you might have your goods stuck at customs for 1 week, so your passive box which is validated for 72hrs will not work. This might be appropriate for another lane/country, but highlighting the roadblock such as customs before you start should be part of your risk assessment "

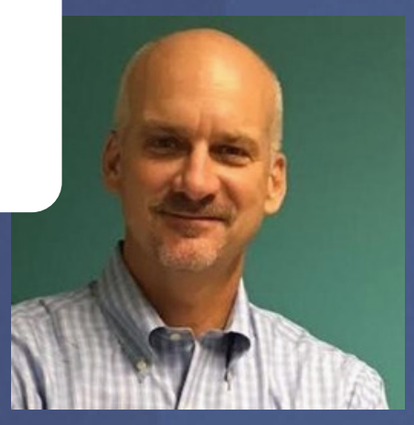
Q: Can you explain what it means to take a “total cost” approach to mitigating risk and ensuring quality?

A: "As mentioned earlier we should not just look at the cost of shipping from A to B but rather understand what level of service we will be getting for this money. If your procurement is only looking at the bottom line price in the given offers, for example, by 3 shipping companies, this is only looking at one element of cost. What about their SLA (Service Level Agreement) and their KPIs (Key Performance Indicators), can they guarantee a 98% delivery, 95% or 90%, for instance, and over thousands of shipments how many are going to be out of specs and how much will this cost?
Is your business high value and low volume or vice versa? "

Q: What most excites you about the Cold Chain event this Spring? What are you looking to gain from the conference?

A: "Having attended a large number of conferences in Europe over the last couple of years I am of course very interested to see what type of topics and pain points are relevant in America, and although there is probably a large overlap, I look forward to learning something new!"

"Selecting high quality suppliers might cost you more short term, but long term you might actually be saving money because their performance ensures fewer deviations, product destruction or even recalls." - Eugenio Filippi



William Collingwood

AstraZeneca

Q **How can the various departments within an organization best collaborate to increase efficiency in the biologics supply chain?**

A **"Collaborating to define the value stream for an end to end supply chain is a key exercise for an organization in creating a common understanding of how material flows from the start of production to delivery to a customer. Using the value stream map to target efficiency (increasing the value add in eyes of the customer) is one of the "secret sauces" of high performing organization. Leaders need to set the expectations to collaborate and drive improvement in the value stream, reward team successes and continue to emphasize high customer service and high value add from supplier to customer both across departments who serve each other and from an entire supply organization to an end customer."**

Q **What tips would you give a smaller organization for communicating between clinical & commercial teams to streamline the scaling up process?**

A **"Leveraging the concepts of "design for six sigma" and Toyota operating model principles, research and product development teams need to partner with manufacturing operations and commercial teams for an all-inclusive "product design" activity. This is a thoughtful, iteractive exercise that continues to monitor the potential forecast for the product, informs the scale of the manufacturing operation and supply chain design, and ultimately, the overall technical process design which needs to be supported by research & development. It is highly collaborative "1 (customer focused) company" process. I believe the industry needs to embrace these concepts in order to establish an efficient/scaleable supply process that starts with an understanding of the customer demand and how that demand is most efficiently satisfied. We can avoid years of continuous process change and global regulatory filing costs if we organize the integrated process much earlier in the life cycle of a molecule."**

Q **What are the main logistical challenges that biologic supply chains face that may not be an issue on the small molecule side?**

A **"The final miles of delivering biologics can be the hardest – temperature, light, vibration sensitive and expensive products require high rigor in logistics execution. Details not often considered for small molecule distribution models are critical to understand and plan for in order to run a high right first time logistics process for biological (and vaccine) supply chains – not only is the product expensive in the final mile, but the pack out costs are also high so there is a double cost to not doing things right the first time. Time to replace damaged or lost shipments can be long, so typically the industry buffers with safety stocks. This is also a significant cost to the business. Extremely high RFT execution in logistics is paramount to running a high quality, lowest possible landed cost supply chain."**

Q **What most excites you about the Cold Chain event this Spring? What are you looking to gain from the conference?**

A **"I am excited to share ideas and collaborate with industry partners in tackling our similar challenges – many of our products are life saving with treatment regimens that cannot be interrupted- the challenge of continuing to balance high service and low cost is why I come to work every day. Benchmarking, sharing ideas and benchmarking, leveraging (without treading on competitive advantages) is a critical component of making us all good at the end of the day and events like this Cold Chain Conference enable the live exchange that keeps innovation in our segment of the industry fueled."**

Eden Fucci

Aldeyra Therapeutics

How can the various departments within an organization best collaborate to increase efficiency in the biologics supply chain?

"One of the biggest challenges during the transition from clinical to commercial, especially for smaller biotech companies, is underestimating the amount of effort required to ensure you have identified, qualified, and fully implemented the right shipping solutions based on the supply chain network, shipping conditions, product characteristics, and ultimately business drivers."

How can clinical, commercial, and regulatory teams best work together to ensure product quality through the last mile?

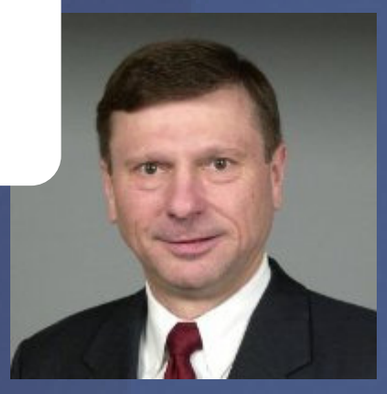
"Having some experience in this area, and coming from a smaller company, it takes a lot of educating up front from supply chain and logistics to get the different parties invested in the criticality of ensuring the last mile is appropriately qualified and ready for commercial distribution. Most clinical phase companies have little to no commercial distribution exposure or experience, so educating upfront helps bring the groups together."

In regards to getting FDA-ready before product launch, what main road blocks should companies look out for?

"As long as you have been open in your communications with the FDA, there should not be many logistics surprises from the FDA - in terms of acceptance of data or post-marketing commitments. Most roadblocks will come internally, and again coming from a recent launch at a small company, they typically revolve around appropriately planning supply chain activities well in advance for launch and decision making in the face of imperfect forecast data. For example, do you look to implement non-optimal shipping solutions off the shelf (save time and effort), or do you look to develop customized solutions for launch (more cost and time upfront, but gains in cost or drug security in the future)? Can you launch with the readily available option and redesign once you have enough volume to justify the cost? These are some of the decisions or roadblocks you may encounter coming up to launch."

What most excites you about the Cold Chain event this Spring? What are you looking to gain from the conference?

" I always look forward to learning about what other people are doing in regards to cold chain logistics. Each company and each product has it's own supply chain fingerprint – no two are the same. There is always something new to take away from these events - some new interpretation or implementation of guidelines, some interesting solution to typical challenge, and ultimately I look to assimilate that new found knowledge and apply it to my company's needs."



Dave Malenfant

BSMA &Texas Christian University

In your opinion, what is the best way for companies to streamline validation protocols in the last mile?

"The best way for companies to streamline validation protocols in the last mile would first be to understand their transportation network. Next, would be to map the routes for those areas that need validation because not understanding the routes that need validation will waste a lot of time and duplicate a lot of work. In addition, try to fence the process – worst case and best case."

What current or proposed international regulations pose the biggest challenge to your global distribution network?

"Many countries have different regulations with respect to cold chain/temperature control. These need to be understood. The greatest challenge is the customs/import controls that may delay a shipment and/or open a shipment that needs constant monitoring and/or control."

What challenges do you think small pharma/biotech face regarding validation processes that may not be as big of a challenge to big pharma?

"Small pharma/biotech companies often do not have the infrastructure for validation. This leads them to outsource the entire process which ends up costing much more than they should spend. In addition, the protocols are often made too complex. Big pharma, on the other hand, has standardize validation protocols and practices as well as the required staff."

What most excites you about the Cold Chain event this Spring? What are you looking to gain from the conference?

"Cold chain and the overall subject of temperature control is becoming a wider requirement in the industry. However, the costs to comply can still be troubling especially in an environment where drug prices are being challenged. I'm most excited to see how this conference help pharma and biotechs look at opportunities to efficiently comply with the existing and upcoming regulations in a cost effective, pragmatic way."

"Map the routes for those areas that need validation because not understanding the routes that need validation will waste a lot of time and duplicate a lot of work." - Dave Malenfant

Hear What Our Advisory Board Has To Say!

"The IPQC Cold Chain event is an excellent opportunity to share innovative ideas on how to manage the supply chain within a highly regulated environment that requires end-to-end monitoring of temperature. Through networking, we can share ideas and solutions that can be implemented effectively."
– **Dave Malenfant, Executive Vice President of Industry Liaison and Talent Development for the BSMA and Director- Center for Supply Chain Innovation at Texas Christian University**

“The IQPC Cold Chain event provides an opportunity for collaboration with experts in the field and leads to meaningful discussions about both the history & future of cold chain practices.”
– **Jeff Carrico, Director, Investigational Drug Services and USP Expert Committee Florida Health System and US Pharmacopeia**

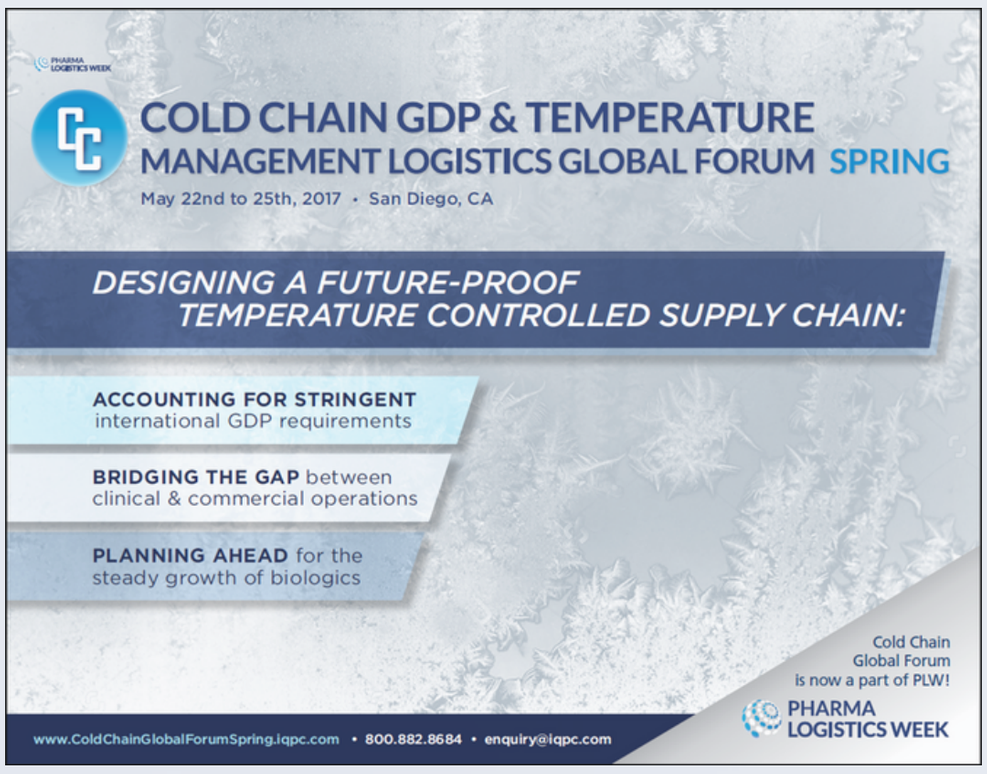
"The Cold Chain Global Forum is a great opportunity for industry practitioners to share innovations and ideas that enable all of us to be great at what we do. The biopharma industry is a highly complex, highly regulated industry, forums such as this are a key part of driving innovation that enables the industry to continue to improve on our mission to deliver high quality, cost effective therapies to our patients.”
- **William Collingwood, Head of Supply Chain, Biologics, AstraZeneca**

"The IQPC cold chain conference offers opportunities for Pharmaceutical professionals to network with industry peers to learn best practices for cold chain supply and DSCSA regulations."
– **Ryan Flaugher, Director, Warehouse Grove City, Tempe and Memphis, Curascript SD**

"The Cold Chain Global Forum Spring event taking place for the first time in California this year is a unique opportunity namely for Biopharma professionals to address some of their key challenges and debate with peers. In a world with more disruptions and where predictability and long term vision have become a challenge, getting this opportunity for us to learn and share knowledge is much appreciated. The event is definitely a must-attend.”
- **Franck Toussaint, Managing Director, BioLog Europe**

"A great opportunity to highlight product and service innovation, stay current on industry trends, and learn how our peers are addressing the evolving challenges for global distribution of temperature sensitive products.”
- **Ben VanderPlas, Global Product Manager, Sonoco ThermoSafe**

"The IQPC event is a timely forum to learn and discuss cold chain improvement opportunities with the industry's thought leaders and practitioners.”
- **Mary Long, Managing Director and Former VP of Logistics & Network Planning, University of San Diego Supply Chain Institute and Domino’s Pizza**



The Cold Chain Global Forum is coming to California!

Join Eugenio, William, Eden and Dave at the inaugural **Cold Chain GDP & Temperature Management Logistics Global Forum - Spring** taking place **May 22-25, 2017** in **San Diego, CA**. Join industry leaders in designing a future-proof temperature controlled supply chain by accounting for increasingly stringent international GDP requirements, the steady growth of biologic based products, and bridging the gap between clinical and commercial operations.

Explore the Agenda to learn more or visit us at www.ColdChainGlobalForumSpring.iqpc.com