



Global Forum

15TH ANNUAL

Temperature Controlled
Life Science Supply Chains

Moving the Industry Forward

850+ Attendees | 120+ Speakers | 120+ Sponsors & Exhibitors



15TH ANNUAL

SEPTEMBER 25-29, 2017 | CHICAGO, IL



The industry is changing...

Personalized medicine is likely to grow 11.8% between 2014 and 2022.⁽¹⁾ Drones can now get drugs into the hands of people who are off the grid. Virtual Reality can now test your entire supply chain digitally to ensure consistent temperature. Projections estimate that in five years, 80% of companies are expected to have a digitized supply chain in some form.⁽²⁾

(1) <http://www.supplychaindive.com/news/personalized-medicine-cold-chain-logistics-growth/434060/>

(2) <https://www.strategyand.pwc.com/reports/digitization-in-pharma>



**With such exciting innovations,
we decided WE NEEDED TO EVOLVE TOO...**



Our Commitment To The Future Of The Industry:

The need for a robust, streamlined temperature controlled supply chain has never been more in demand.

With an influx of temperature sensitive products entering the supply chain, companies must revisit their logistics, packaging, quality, and security processes to ensure they are keeping pace with this exponential growth.

How do teams make sure they utilize new techniques, implement better technology, keep costs low & quality high, while remaining compliant to global regulations?

They gather at Global Forum to hear from leading experts, share ideas, challenge each other's processes, gain insight into the newest solutions on the market, and maintain a next generation mentality.

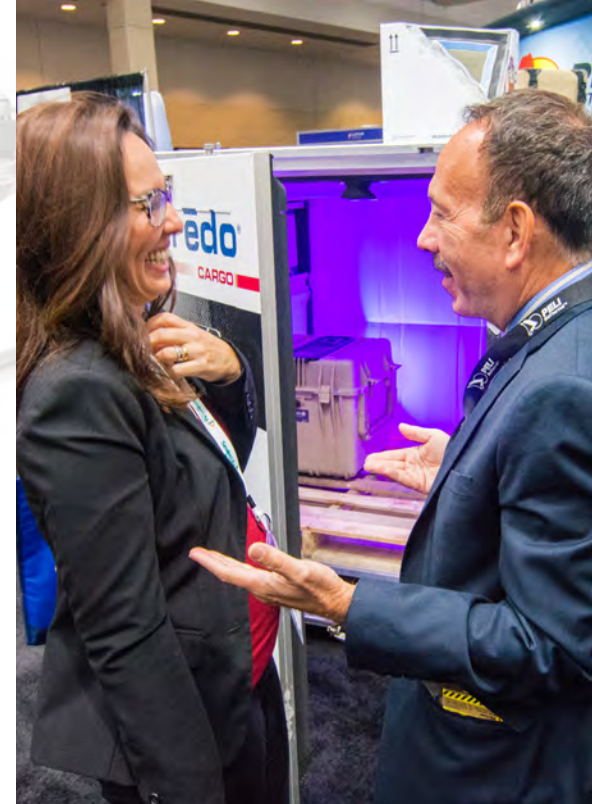
Come see what's possible!

Sincerely,

The Global Forum Team

Jody Tropeano
Program Director

Claudia Rubino
Divisional Director - Life Sciences



New City, New Look, Same Quality Event...



The World's Largest Event On Temperature
Controlled Life Science Supply Chains Is In
Chicago For 2017!



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Agenda at a Glance:

MONDAY SEPTEMBER 25TH	TUESDAY SEPTEMBER 26TH	WEDNESDAY SEPTEMBER 27TH	THURSDAY SEPTEMBER 28TH	FRIDAY SEPTEMBER 29TH
8:30am Conference Opens	8:00am Pre-Conference Workshop Day	7:45am Main Conference Day One Opens	7:45am Main Conference Day Two Opens	8:00am International Focus Day Begins
9:00am- 5:00pm MASTER CLASS DAY- Temperature Assurance Packaging Certification Program	8:30-10:30am Workshops A&B	7:45am Expo Hall Opens with 100+ Exhibitors	8:45am 2 Industry-led Keynotes on Innovation & Security	9:00am- 12:30pm Sessions on US, EU, Canada, Middle East
	11:00am- 1:00pm Workshops C&D	8:45am Opening Keynote from IBM on Big Data	10:15am Annual Global Forum Excellence Awards Presentation	1:30-5:00pm Sessions on LATAM, MENA, Africa & India
	1:30-3:30pm Workshops E&F	8:45am-6:00pm Food Fresh Day Sessions	11:00am Demo Drive Kick Off in Expo Hall	5:00pm Conference Closes
	4:00-6:00pm Workshops G&H	10:30am Morning Networking Break	12:00pm 10 Interactive Roundtable Discussions	
	1:00-3:30pm Site Tour at LifeSource Blood Center	12:45pm Break the Ice Luncheon	1:50pm Track Sessions Begin	
	6:00pm 2017 Welcome Reception	5:15pm 10 Sip & Learn Roundtable Discussions	1:50pm Track Sessions Begin	
		6:00pm Annual Cocktail Reception in Expo Hall	3:15pm Annual Prize Drawing in Expo Hall	





Global Forum Strategy Team



Rafik Bishara Ph.D.
Technical Advisor &
Former Director QKMTS
Eli Lilly & Company



Arminda Montero
Global Supply Chain QA Manager
AbbVie



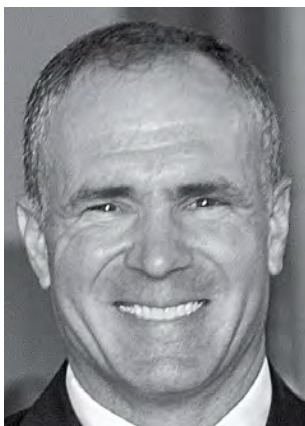
Alan Kennedy
Founder
TEAM-UP Global



Jim Bacon
Vice President
AeroSafe Global



**Courtney
Becker-James**
Strategic Marketing Manager
ELPRO



Brad Elrod
Former Global Supply Chain
Security Director
Pfizer



Michael English
Associate Director,
Engineering
Merck & Co.



Geoffrey Glauser
Senior Consultant Supply
Chain
HHS/ASPR/BARDA



Mark Walls
Director, Clinical Supply
Operations and Logistics
Tetraphase Pharmaceuticals



Mary Foster
Chair, Packaging and Storage
Expert Committee
United States Pharmacopeia



Jeffrey Beck
Head of Supply Chain
North Americas Sanofi



Global Forum Strategy Team



Robert Heinrich
Senior Traffic Administration Advisor
Novartis Pharmaceuticals



Jay Johnson
Regulatory Compliance Manager
Inmark



Russell Grissett
VP of ThermoSafe
Sonoco ThermoSafe



Carolyn Williamson
Principal Packaging Engineer
Bristol-Myers Squibb



Karl Kussow
Manager of Quality and Validation
FedEx



David Martin
Director for Logistics Management
Zogenix



Bernard McGarvery
Senior Engineering Advisor
Eli Lilly & Company



Dan Mirica
Former Head of Global Logistics
Lonza Biologics



Les Sparrow
Technical Support & Analytical
Service Manager
World Courier Inc.



TJ Rizzo
Senior Vice President
Cold Chain Technologies

A man with glasses and a beard, wearing a dark suit and a patterned bow tie, is speaking at a clear acrylic podium. He is gesturing with his right hand. The background is a blue curtain. A quote is overlaid on the image.

“If your actions inspire others to dream more, learn more, do more and become more, you are a leader.”

- John Quincy Adams

MEET OUR GLOBAL FORUM THOUGHT LEADERS ►



Global Forum's 2017 Keynote Speaker



PAUL ZIKOPOULOS

VP of Competitive and BigData Analytics Teams
and Future Trends Expert

IBM

- **Big Data. Big Impact.** Named one of the “50 Big Data Twitter Influencers” by SAP.
- Paul will predict the industries ripe for disruption and identify potential new products that will change the way we work and live.
- Paul has authored 19 books and over 350 articles on data and analytics.
- Paul breaks apart the roles of data collection and decision making for executives seeking the opportunities for disrupting their industry and leap-frogging the competition.

“Digitization is quickly moving from hype to reality. It’s time to start eating this elephant, one bite at a time.”

<https://www.forbes.com/sites/kevinomarah/2016/11/17/digitization-in-supply-chain-five-key-trends/2/#a7d20985c9a7>



Featured Speakers



Wesley Schmidt

Vice President of Quality Systems
AbbVie

Educating the industry to better reach underserved patients' globally



John Brownstein PhD

Chief Innovation Officer & Professor
Boston Children's Hospital & Harvard University

How innovation is transforming the way in which people access care



Bradford Stewart

Global Security Operations Center Manager,
Securitas and Former Chief of Staff to the
President's Daily Brief

Opening our eyes to the global threat landscape and its potential impact on the pharma supply chain



2017 Thought Leaders



Ben Romero
Director Logistics Temperature Control
Bristol-Myers Squibb



Lisa Wyman
Head of Quality Compliance & Data Analytics
Shire Pharmaceuticals



Marla Phillips, Ph.D
Director, XavierHealth
Xavier University



Dan Marasco
Head of Packaging Materials & Medical Device Sourcing
Bristol-Myers Squibb



Rey Chern
Director, Engineering
Amgen



Tonino Antonetti
Executive Director, Regulatory Affairs, Quality Management, Safety & Health and Environment
Roche Diagnostics Canada



Henrik Fröjdh
Associate Director Supply Chain Management
Merck & Co.



Rick Calabrese
Global Director of Corporate Quality Systems
Sartorius Stedim North America Inc



Ravi Kalyanaraman
Associate Director, Global Analytical Technology, Manufacturing, and Supply
Bristol-Myers Squibb



Rakesh Shah
Director Supply Chain-APAC (Sub Region II), India and Frontier Market
Merck Serono



Ropah Hove
Director, Pharmacy Services
Ministry of Health and Child Care



Rami Arafat
Supply Chain Director
Hikma Pharmaceuticals



Lisa Sykes
Director of Quality Operations and Sterile Network
Merck



Jeremy Cress
Director of Operations
Fibrocell Therapeutics



Matt Sample
Sr. Director, Secure Supply Chain
AmerisourceBergen Corp



Rita Karam, Pharm.D., Ph.D.
Quality Assurance of Pharmaceutical Products
Program Director
Lebanese Ministry of Health



Michelle Southall
Industry Engagement Director
GS1



Viliam Kovac
Head of Global Supply Quality
Roche Diagnostics GmbH



Ed Treacy
Vice President, Supply Chain Efficiencies
Produce Marketing Association



Vally Helgadóttir
Director of Customer Service
Distica



Lisa Forian
Senior Director, Product Quality Management
Johnson & Johnson



Mike Broughton
Director, Global Logistics
Eli Lilly and Company



Mary Foster
Chair, Packaging and Storage Expert Committee and Head of Quality
United States Pharmacopeia, Xellia Pharmaceuticals



William Crates
VP QRA
Cardinal Health



Thomas Scalone
Associate Director Logistics Supply Chain
Celgene



Catherine Coppage
Supply Chain Planner - Personalised Medicine
Kiadis Pharma



Jason Lu
Associate Director, Logistics
Hello Fresh



Gopal Nadadur
Senior Manager, Global Markets Team
Clinton Health Access Initiative (CHAI)



2017 Thought Leaders

Ashley McAdams
Global Supply Chain Manager, End-to-End
Operations
GlaxoSmithKline

Italo Costa
Global Transportation and Cold Chain Leader
Zoetis

Mike Sweeney
Senior Director, Global Service Development
World Courier

Dustin Roller
VP of Innovation Product Development
ASD Healthcare

Glenda Womack
Director of Client Relations & Business Development
ASD Healthcare

Alan Forthman
Supply Chain Solutions Manager, NPI
GlaxoSmithKline

Regis Gautier
Director of Global Packaging Technology
Bristol-Myers Squibb

David Martin
Director for Logistics Management
Zogenix Inc

Christelle Fransawi
Technical Member
Lebanese Ministry of Health

Felipe A. Gomes Sales
Gerente/Manager - GIMED/GGFIS
ANVISA

Mike Auerbach
Editor-in-Chief
**American Pharmaceutical Review, Pharmaceutical
Outsourcing**

Mark Walls
Director, Clinical Supply Operations and Logistic
Tetraphase Pharmaceuticals

Rafik Bishara
Technical Advisor & Former Director QKMTS
Eli Lilly and Company

Arminda Montero
Global Supply Chain QA Manager
AbbVie

Javier Gomez-Contreras
Supply Chain BGx LATAM- OE Latina-Mid East Africa-
India & Asia Pacific Lead
GSK

Alan Kennedy
Founder
TEAM-UP Global

Carolyn Williamson
Principal Packaging Engineer
Bristol-Myers Squibb

Dr. Kelvin Lee
Director of the National Institute for Innovation in
Manufacturing Biopharmaceuticals (NIIMBL)
**Gore Professor of Chemical Engineering at the
University of Delaware**

Dana Dallas
Cold Chain Program Manager
Defense Logistics Agency

Bernard McGarvey
Senior Engineering Advisor
Eli Lilly and Company

Saheed O. Muhammed
Supervisory Import Specialist Pharmaceuticals,
Health & Chemical Center
U.S. Customs & Border Protection

Claude Jolicouer
Director Regulatory Affairs, Corporate GMP officer
McKesson Canada

Bryan Cardis
Consultant, Distribution Platform Stewart
Eli Lilly and Company

Steve Epperson
Consultant, QA Material and Operations
Eli Lilly and Company

Harrison Weisberg
Specialist, Clinical Supply Management,
Neurodegenerative Therapeutic Area, Clinical Drug
Supply
Biogen

Lisa Moher
Head Of Distribution Packaging
Sanofi

Tim Corbridge
Facilitator
BPOG - BioPhorum Operations Group

Jeremy Peters
Associate Scientist
Bristol-Myers Squibb

Octavio Ulloa
Director of Supply Chain
BPL Plasma

Samantha Betancourt
Vice President of Supply Chain
BPL Plasma

Dip Parikh
Associate Director, Supply Chain
Biogen

Francia Bocanegra Aleman
Warehousing and Distribution Head Central America
and Caribbean
GlaxoSmithKline

Dan Mirica
Former Head of Global Logistics
Lonza Biologics

Ingrid Freeland
Associate Director, Quality Operations
Astellas US Technologies, Inc.

Lin-Mai Malmstrom
Supervisory Agriculture Specialist
U.S. Customs and Border Protection

Mark Grzeszkowiak
Chief Agriculture Specialist
U.S. Customs and Border Protection

Roxanne Tata
Vice President And Chief Quality Officer
Institute For Transfusion Medicine

Leo Vaytsman
Supply Chain Security Specialist
Takeda Pharmaceuticals

David Bailey
Director of Trade Relations
VitaMed/ Therapeutics MD

Justino Hurtado
Senior Logistics Analyst
Sanofi

F. Scott Fein
Supply Group Manager
Robinson Fresh

Steve Zontek
Quality/Sustainability
The McDonald's Supply Center of Excellence

Jim Bacon
Vice President
AeroSafe Global

Taylor Clark
Vice President of Marketing and Sales
RNC

Frank Butch
Director of Engineering
Sonoco

Ben VanderPlas
Global Product Manager
Sonoco

Tom Meier
Senior Project Manager Distribution Systems
Henry Schein, Inc.

Ron Devitt
Managing Partner
Despir

Margaretha Laseen
Director, Cargo Customer Solutions & Airline
Partnerships, Americas
Cathay Pacific Cargo

Larry Knorr
Applications Development
DuPont

Yasuhiro Suzue
Team Leader of PCM Business Promotion Team
Kaneka Corporation

Cyril Winkler
Team Leader, Product Management
ELPRO

Teresa Parayil
Global Account Manager
ELPRO

Stefan Braun
Senior Software Developer
Smart CAE

John Carr
Managing Partner
Despir

Penny Basso
Security and Compliance Manager
Despir

Dave Malenfant
Executive Vice President,
Industry Liaison and Talent Development
BSMA (Biotech Supply Management Alliance)
Director, Center for Supply Chain Innovation
Texas Christian University

Kathy Phee
CLS Compliance COE
Johnson & Johnson

Elaine Merritt
Sr. QA Manager Transportation
and Temperature Control
Johnson & Johnson

Dr. Rasha Salama
Public Health Advisor for Public Health Policy &
Licensing Sector
**Ministry of Health and Prevention - United Arab
Emirates**

David Pasnuk, DVM, MS
Senior Staff Veterinarian
USDA, APHIS, VS



New Look, New Program, New Themes...



Next Generation Medicines

track with industry-lead case studies on emerging treatments entering the supply chain



Blue Sky Room

focused on Innovative Technology with Hands-on Activities

A focus on collaboration & standardization within your global organization and across the industry



Keynotes

focusing on the hardest hitting topics affecting your operations: Disruptive Technology, Supply Chain Security Threats, Globalization & Patient-centricity



A brand new Food Fresh Day

dedicated to maintaining quality & efficiency in the perishable food supply



20 in-depth discussion lounges

connecting you to the top thought leaders in a candid dialogue on the hottest topics



Global Forum's Unparalleled Expo Hall Experience

100+
Exhibiting
Sponsors

ANNUAL
Themed Cocktail
Reception

Demo Drive
& Incubation
Lab

Presentation Theater
featuring Top
Speakers & Content

And much,
much, more...

A background image showing three men in business attire smiling. The man on the left is older with grey hair, wearing a dark suit and tie. The man in the center is bald with glasses, wearing a dark suit and light blue shirt. The man on the right is younger, wearing a light-colored suit and checkered shirt. They are all smiling and looking towards the camera.

The 2017 Global Forum Excellence Awards

Awarding the Brightest Minds in the Industry

Supply Chain
Transformation
Award

Collaboration
Award

Customization
Award

Technological
Innovation Award

Learn more about the awards and how to apply on www.coldchainglobalforum.com



Words of Wisdom

WHAT OUR GLOBAL FORUM COMMUNITY IS SAYING ▶



Words of Wisdom

“Fantastic selection of topics and speakers. This was one of the best events I have participated in.”

- Johnson & Johnson

“Always the best show of the year.”

- Sofrigam

“I just learned a couple years of information/ experience in the span of 2 days.”

- Bayer

“Great place for forward thinking industry experts to collaborate on hot topics facing logistics for temperature sensitive CTM's and commercial drugs.”

- Ultra Genyx

A group of seven diverse professionals, four women and three men, are smiling and holding bottles of sparkling water. They are standing in front of a trade show booth. In the background, there is a sign for "OLD BOX .COM CONTROLLED CONTAINERS" and a sign for "Station BOSTON" with Arabic text. The image has a semi-transparent white box over the middle with text, and a dark blue curved shape at the bottom.

Maximize your Global Forum Experience by Attending as a Team

"Growth is never by mere chance; it is the result of forces working together."

— James Cash Penny

Team discounts available, contact: Michael.Ringo@iqpc.com



**Fine-tune your skills through a
detailed learning experience**

**LEARN ABOUT OUR EXCLUSIVE
MASTER CLASS PROGRAM ►**



Pre-Conference Master Class

Monday, September 25th

MASTER CLASS: TEMPERATURE ASSURANCE PACKAGING (TAP) CERTIFICATION PROGRAM

PART ONE: Online Course - “Temperature Assurance Packaging Fundamentals”

This self-paced, online course offers training participants a systematic approach to developing a foundational understanding of Temperature Assurance Packaging. Participants completing the ISC Labs Temperature Assurance Packaging (TAP) Certification Program will understand the fundamentals and advanced concepts of temperature assurance packaging so that they can:

- Evaluate different TAP solutions as they relate to the needs of their company
- Contribute knowledgeably to conversations regarding temperature assurance packaging
- Guide their organizations in implementing TAP solutions

PART TWO: Master Class Day- “Temperature Assurance Packaging Professional” Course

This one-day, live and interactive training course conducted by a diverse team of industry experts will provide hands-on instruction. The Professional Course aims to coach the participants through the entire life-cycle of developing a Temperature Assurance Package (TAP) including considerations with regards to regulations, transportation/logistics, ambient profiles, operations, and packaging design. A “Certificate of Professional Course Completion” will be awarded to training participants successfully completing this course.

During this course you will:

- Understand the fundamentals of temperature assurance packaging and be able to evaluate different solutions that best meet the needs of their company
- Guide the implementation of temperature assurance packaging solutions within your organization
- Grasp the key processes, protocols and techniques involved in designing temperature-controlled packaging
- Topics of discussion include considerations for product details, regulatory, transportation, environment, operations, and packaging



Frank Butch
Director of Engineering
Sonoco ThermoSafe



Ben VanderPlas
Global Product Manager
Sonoco Thermosafe

*Delegates must be qualified and pre-approved to attend this session.

A photograph of a man with glasses and a beard, wearing a suit and tie, speaking into a microphone at a workshop. He is seated at a table with papers, a glass, and a coffee cup. Other people are visible in the background, some looking towards him. The image has a blue tint and a white horizontal bar across the middle.

**Be a Part of a New Level of Learning through
Global Forum's Hands-On Workshops**

REVIEW OUR WORKSHOP & SITE TOUR EXPERIENCE





Pre-Conference Workshop Day

Tuesday, September 26th

8:00AM

REGISTRATION WORKSHOP A & B

CLINICAL

Workshop A: Managing Contingencies to Minimize Risk of Highly Sensitive Medications during End-to-End Clinical & Commercial Distribution

When you are managing clinical and commercial supply chains that have strict temperature control demands, you often face the challenge of choosing qualified packaging options that are most practical for your products, projects and transportation lanes.

- Discuss at-home and in-clinic portable 2-8°C and CRT storage, with continuous real-time temperature monitoring and inventory management using RFID technology
- End to end traceability and excursion management leads for efficient QA oversight and release which can be achieved from point of manufacture, packaging through patient treatment
- Review logistical route planning and contingency considerations to minimize risk and loss of highly sensitive medications
- Case studies: Demonstrate successful solutions for the most challenging routes, temperature requirements and complex delivery, including direct to patient and import scenarios
- Technology demonstration of the CubixxCT and cloud based portal
- Group Exercise: Small-group discussions on overcoming case scenarios of global cold chain challenges in collecting and using temperature data

Mike Sweeney

Senior Director, Global Service Development

World Courier

Dustin Roller

VP of Innovation Product Development

ASD Healthcare

Glenda Womack

Director of Client Relations & Business Development

ASD Healthcare

PACKAGING

Workshop B: Intelligent Selection of Passive Temperature Protection for Cargo Based on Real World and Virtual Testing

When selecting passive temperature protection for your cargo, think broadly about the performance requirements you need and how to get the necessary information to help you make an informed decision about which protective option to use. These performance requirements always include temperature control but they should also address other needs or desires such as breathability, tamper evidence, ability to withstand adverse weather, ease of use, and sustainability. Direct testing is the most trusted route to establish performance qualification (PQ), and typically involves significant time, effort, and resources. Modelling continues to advance in its ability to provide insights into expected performance and comparative differences between protection options.

- Evaluate the performance of passive temperature protection options
- What are performance requirements, broadly
- How can you get the information you want
- What are the limitations on the information
- How can you compare your options
- Case Study: Actual testing versus modelling predictions
- Case Study: Comparing protective options using modelling
- Group Exercise: Small-group exercise to select a protective option from alternatives



Lawrence Knorr

DuPont Fellow, New Product and Applications Development

DuPont

8:30AM

10:45AM

REGISTRATION WORKSHOPS C & D (BOXED LUNCH PROVIDED)

DATA MANAGEMENT

Workshop C: Temperature Data Analysis: Your Best Friend in Logistics Optimization and Quality Control

Temperature data management doesn't have to be wading thru spreadsheets for subliminal messages. Setting up your data collection and management system the right way can in fact help you automate processes, letting the system communicate with supply chain stakeholders, providing overall QA support. This workshop will look at how to use temperature data to make cost-saving improvements in your supply chain, while meeting GDP Quality requirements.

- How to enable efficient deviation processing and timely investigations
- Examples of logistics improvements by trending data of multiple shipments
- How to track and release shipments, not just individual data loggers
- Deciding which central repository system works best with your current processes
- Case Study: Customer implementation of a central database
- Group Exercise: Small-group discussions on overcoming case scenarios of global cold chain challenges in collecting and using temperature data

Workshop leaders:



Cyril Winkler
Team Leader, Product Management
ELPRO



Teresa Parayil
Global Account Manager
ELPRO

QUALITY

Workshop D: Fine-tuning your Temperature Ranges to Justify Shipping Outside of Label Claims

- Build a stability budget to justify investment and improvement in your cold chain operations
- Analyzing the trade-offs involved in optimizing different parts of the cold chain
- Review the importance of communication between the stability, packaging, and distribution areas within a company to leverage the budget to support a robust supply chain
- Streamlining how to use the budget to support the supply chain & communicate and respond to excursions
- Address temperature excursions that exceed the time supported in the stability budget: who is responsible, how to communicate, how to determine product disposition

REGISTRATION WORKSHOPS E & F

RISK MANAGEMENT

Workshop E: The Price Tag Attached to Reverse Logistics: Validation and Risk Assessment Techniques to Achieve End-to-End Supply Chain Success for CRT Products

Transparency and control are the keys to success of any end-to-end supply chain, and the global supply chain of life science products is no exception. The storage and distribution of controlled room temperature (CRT) life science products are a costly and complex process, and requires attention at every level from packaging to logistics, monitoring to data. As we enter an age of biologically based medicines, so the need to monitor and control temperature sensitivity is increasing.

- Ensure compliance to the increased regulations for distributing CRT products
- Discuss the trends, issues and successes operating within the CRT arena
- Compare the true pros and cons of reusable vs single-use containers
- Understand the full scope of durability & temp stability for CRT products
- Discuss the price tag attached to reverse logistics and key considerations
- Implement appropriate measures to ensure quality and integrity of products through validation & risk assessments
- Group Exercise: Creating CRT distribution protocols through identifying and understanding all of the exposures that exist along a given shipping lane
- Case Study: Qualification of ambient packaging for a real-life scenario

Steve Winyard
Portfolio Strategies – Life Sciences
Inmark

LOGISTICS

Workshop F: Protecting the Patient: Integrating Technology and Quality Management Systems to Optimize Transportation Security

Not all cold chain cargo is created equally; different products require individual transportation solutions. An effective quality management system creates the framework for integrating the technology and processes necessary to customize shipping strategy for vulnerable products. This workshop will look at how to analyze risk assessment, temperature requirements, and security protocols to optimize secure product supply chains.

- Evaluating the key components of an effective quality management system
- Analyzing actual cost vs. product risk
- Utilizing temperature requirements to establish shipping protocols
- Determining route risk assessment based on security requirements
- Ensuring product integrity through advanced integration of technology
- Group Exercise: Creating product specific standard operating procedures

Workshop Leaders:
Ron Devitt
Managing Partner
Despir

John Carr
Managing Partner
Despir



Penny Basso
Security and Compliance
Manager
Despir

3:45PM

REGISTRATION WORKSHOPS G & H

LOGISTICS

Workshop G: Lane Qualification for your Variety of Products through to the Last Mile

- Interpret the regulations to create standards and validation of equipment
- Get marketing involved to figure out where the customer base is and design a commercial network that best serves them
- Create a plan for active vs passive shipping through the last mile
- Account for variances in global distribution networks to decide what do you need to do in the last mile
- Budget for the last mile by finding the right packaging materials that don't sacrifice quality
- Strategize your use of temp tails for riskier products

4:00PM

PACKAGING

Workshop H: A Case for Reuse - No Excursions, No Exceptions: Uncovering the Mystery of Refurbish, Reuse, and Recovery

Our AeroLoop Reuse Program is a recovery and refurbishment service that enables you to use high performance solutions on a "per turn" cost basis. We'll review how we've made the prospect of owning a high performing solution an affordable one while protecting product integrity and ensuring patient safety.

- Learn how to gain consensus on an internal set of criteria
- Collaborate with partners through DQ, OQ, and a PQ protocol
- Establish a high performance solution that is simply reliable and consistent
- Implement a total cost of ownership model that is efficient and sustainable
- Case Study: Real life client analysis of implementing the reuse program
- Group exercise: Work with your group to determine and rank certain risks and costs for given scenarios

Workshop Leader:



Jim Bacon
Vice President
AeroSafe Global

6:00PM

END OF WORKSHOP DAY

6:15PM

ANNUAL WELCOME RECEPTION





Site Tour Experience: LifeSource Blood Center

Tuesday, September 26th

Location: Rosemont, IL

Departure from Conference: 1:00pm

Departure from Site: 3:30pm

About the Site:

LifeSource is a not-for-profit organization and one of the largest blood centers in Illinois. The group must see hundreds of donors a day to keep pace with the local need for blood. LifeSource currently has 17 community donor centers throughout Chicagoland and several mobile teams that visit businesses, schools, religious organizations and community groups. LifeSource's central building in Rosemont houses the organization's lab where blood products are processed, a blood storage and distribution center, an umbilical cord blood donor bank, a therapeutic hemapheresis area and administrative offices.

Tour includes:

- Onsite presentation and walk-through of each area of LifeSource's Rosemont location
 - Blood lab tour led by Kathy McKibben, manager, product manufacturing
 - Storage and distribution tour led by Joe Nagy, Manager, Distribution Services
 - Therapeutic hemapheresis tour led by Shannon Deluca, RN Specialist
 - Cord blood donor bank tour led by Judy DiSanti MT (ASCP) SBB MBA, Director of Clinical Services Operations
- Discussion and Q&A session

Discussion and Q&A Session Led By:



Roxanne Tata

Sr. Corporate Quality Director, Centralized Quality & Regulatory Services
Blood Systems, Inc.





Exceptional Content Delivered by World Class Speakers

PRESENTING OUR 2017 GLOBAL FORUM AGENDA ►



Main Conference Day One

Wednesday, September 27th

7:45AM

REGISTRATION OPENS – COFFEE AND NETWORKING IN EXHIBIT HALL

8:35AM

Welcome Remarks by IQPC

8:40AM

Conference Chair Opening Remarks

KEYNOTE ADDRESS

8:45AM

KEYNOTE: The Big Data Revolution: Examining the Profound Current & Future Effects of this New Technological Frontier & the Benefit to your Business

- Break down the main business factors disrupting the marketplace and what you can do as a business to succeed in such a time of change
- Predict the industries ripe for disruption, i.e. pharma, and identify potential new products that will change the way we work and live
- Who are future your consumers? Who are your future employees? Make decisions now that will impact your operations in the future
- Review disruptions direct impact to pharma, specifically IoT sensors, blockchain, and the utilization of data to treat rare diseases



Paul Zikopoulos

VP of Competitive and BigData Analytics Teams and Future Trends Expert

IBM

9:45AM

State of the Industry: Addressing the Unmet Medical Needs of Patients' Globally through Industry Collaboration & Supply Chain Innovation

- Review the international landscape of rare disease treatment & new medicines entering the supply chain to treat them
- How have regulations in both the US & abroad impacted the industry's ability to reach patients
- Discuss how new technological innovations and supply chain collaboration can make reaching challenging markets more feasible
- Where is the industry headed next? How is the temperature controlled supply chain an integral part of the future?



Wesley Schmidt

Vice President of Quality Systems

AbbVie

10:30AM

MORNING NETWORKING BREAK IN EXHIBIT HALL

KEYNOTE BRILLIANCE BAR

Didn't get a chance to ask your question this morning? Join our morning keynote presenters in the Exhibit Theater for interactive post-session Q&A!

11:15AM

Putting a Spotlight on Supply Chain Blind Spots to Increase Safety, Improve Quality & Enhance Reliability

- Gain insights into the infamous heparin case and what key takeaways put the Xavier/FDA task force in action
- Review the Pareto and GAP analysis used to identify top risk areas to focus supply chain improvements
- Examine the team’s results and recommendations for good supply practices (GSPs) through a supply-by-design process
- How will the outcomes of this project affect the pharma supply chain? How can the GSPs be adopted across the industry? How to use the regulations to your advantage?



Marla Phillips Ph.D
Director, Xavier Health
Xavier University



Viliam Kovac
Head of Global Supply Quality
Roche Diagnostics GmbH

12:00PM

United States Pharmacopeia Update: Enhancing Quality Assured Processes to Maintain Product and Supply Chain Integrity through Advanced Risk Mitigation Techniques

- Review the increased globalization of the pharmaceutical industry and its impact on the handling, storage, and distribution of products
- Take a life cycle management approach to quality, ranging from material procurement to manufacturing to delivery of a final product to the patient
- Ensure each activity in the distribution of a product is carried out according to the principle of Good Distribution Practices (GDP)
- Identify common risks in the storage and transportation of finished drug products and recommended mitigation strategies for these risks



Mary Foster
Chair, Packaging and Storage Expert Committee, United States Pharmacopeia
Head of Quality, Xellia Pharmaceuticals

12:45PM

“BREAK THE ICE” NETWORKING LUNCHEON

Fostering new connections at Global Forum! Are you onsite without your team? Are you looking to make new contacts?
Find a table with unknown faces, and grab a question from the center of the table to kick off the conversation with new contacts.



Main Conference Day One | Wednesday, September 27th

1:45PM

Transition to Track Sessions

1:50PM

COLLABORATION & STANDARDIZATION

CASE STUDY: Building an Organizational Standard Across your Global Departments to Achieve Resiliency, Agility & Cost Savings throughout your Supply Chain Processes

- Create a global team between quality, supply chain, logistics, and packaging to streamline transportation challenges yielding cost savings
- Implement governance and address the nuances in global GDP regulations by setting an internal standard at the most stringent level
- Complete a GAP analysis of your different product lines to determine where issues may occur
- Collaborate with suppliers to provide visibility on the inbound for raw materials and semi finished goods for PO's throughout the entire life cycle as well as forecast



Dan Mirica
Former Head of Global Logistics
Lonza Biologics

NEXT GENERATION MEDICINES

CASE STUDY: An In-Depth Look at How GSK Successfully Distributed their Breakthrough Malaria Vaccine to African Nations

- Review their plan for exporting this 2-8 degree vaccine from the UK to Nigeria & Kenya to the patients in need
- Hear about their pilot process and the mistakes they made along the way helped create a roadmap to success
- Discuss their container selection process and how they landed on the best one
- How they mitigated last mile difficulties in a challenging infrastructure both politically and geographically to ensure product delivery & quality



Javier Gomez-Contreras
Supply Chain BGx LATAM- OE
Latina-Mid East Africa- India & Asia
Pacific Lead
GlaxoSmithKline

SUPPLY CHAIN MANAGEMENT

Supply Chain Mapping Strategies: Streamlining your Product Life Cycle Management from API to Development to Clinical through to Commercialization

- Refine your forecasting & determine your scale in the clinical stage to manage inventory once commercialized
- Where does the scale up process differ from small molecules to biologics?
- How to get validation, packaging, logistics, and quality team working in sync during this transition
- Determine the best criteria for your vendor selection in the clinical stage

BLUE SKY ROOM: *Industry Think Tanks: Next Generation Of Cold Chain Management*

Simulation Technology: Improving Temperature Controlled Logistics by Using the Virtual Cold Chain

- How to run reliable lane risk assessments & improve decision processes using performance curves
- Collaborate with vendor partners to predict the performance of a specific container on a specific lane
- Examine the cost implications of using this technology & and minimize physical testing requirements
- How to easily integrate the virtual cold chain into your current workflow? Where will this technology take us in the future?
- Discuss the value of accurate and easy to use container simulation technology in temperature controlled logistics - a pharma perspective



Bernard McGarvey
Senior Engineering Advisor
Eli Lilly & Company



Jan Walbrecker
Senior Software Developer
SmartCAE

2:30PM

Track Session Transition

2:35PM	COLLABORATION & STANDARDIZATION CASE STUDY: Root Cause Analysis of an Extreme Refrigerated Product Excursion Case through Increased Testing & Data Analytics - Review their problem of having extreme temp increases for refrigerated products being shipped from California to the Pacific Rim - How they drilled down their issue by tracking data from both the carrier and temperature monitoring devices with the material - Created a plan by thermally mapping their specific transit lanes from CA to each customer in the Pacific to find the worst case within the group - Fine-tuned summer packaging protocols to mitigate issue, but the results were extreme low temperatures instead - Examined their rollout plan to fully solve the issue through pack-out component changes  Dana Dallas Cold Chain Program Manager Defense Logistics Agency	NEXT GENERATION MEDICINES Cold Chain's Crucial Role: Navigating the Clinical & Commercial Logistics Behind Getting Novel Cell & Gene Therapies to Patients in Need - Review the breakthrough therapies both commercial and in Phase I & II trials for treating ultra-rare diseases with orphan status - Strategies for ensuring the viability of the sample is intact when received and the short shelf-life is not in jeopardy - Examine Fibrocell's triage list method of tracking weather patterns to make crucial last minute route decisions - How will cold chain management affect the commercialization of these breakthrough therapies? Will international shipments be possible with a 24 hour shelf life?  Jeremy Cress Director of Operations Fibrocell Therapeutics	SUPPLY CHAIN MANAGEMENT CASE STUDY: A In-depth Look at Johnson & Johnson Pharma's Global Temperature Control Center of Excellence Distribution Initiatives, Successes & Challenges - Review how their stability group, secondary packaging, and data management teams must work in sync to achieve global stability standards down to the SKU level - How does data analysis fit in to their processes? How do they utilize the data collected to its greatest potential? - Discuss their global temperature mapping initiative that marries the region with the proven temp ranges by product - Hear about their pilot program rollout starting in Canada, LATAM & Asia  Lisa Forian Senior Director, Product Quality Management Johnson & Johnson	BLUE SKY ROOM: Industry Think Tanks: Next Generation Of Cold Chain Management Next Generation Drug Delivery: Analyzing the Impact of Drone Technology in your Supply Chain - Review the big adoption curve for drone technology and if there is a place for it in pharma - How do you ensure quality when fully exposed to temperature elements on a drone - Understand the positive impacts this technology can have on getting crucial medicines to patients who rely on them faster - Will this only be applicable for CRT products due to weight challenges of other cold chain products
3:15PM	AFTERNOON NETWORKING BREAK Continue discussing the hot topics as your walk the 2017 Global Forum Expo Hall with over 100 exhibiting companies! Visit the VR corner, check out the job posting board, or meet new contacts in the Wi-Fi Lounge.			

3:45PM

Track Session Transition

3:50PM

COLLABORATION & STANDARDIZATION

PANEL DISCUSSION:
Improving Last Mile Distribution through End-to-End Supply Chain Collaboration from a Manufacturer, Wholesaler, Dispenser & 3PL Perspective

- How can the industry collaborate to get products to patients quicker without sacrificing quality
- Discuss best practice standards that can be easily implemented with patient safety as the end goal
- How will the growth of personalized medicine impact the traditional distribution channels and supply chain as a whole
- Is there a need for further classification of "immediate needs" shipping? Chronic versus temporary meds?



William Crates
VP QRA
Cardinal Health



David Bailey
Director of Trade Relations
VitaMed/ Therapeutics MD



Italo Costa
Global Transportation and Cold Chain Leader
Zoetis

NEXT GENERATION MEDICINES

The New Age of Patient Treatment: Discussion on Cell Therapies & Personalized Medicines Impact on Temperature Controlled Distribution

- Review the new delivery systems that will be required to successfully break into this market
- How to ensure quality in a strict environment where excursions are not an option
- Where is this headed next? How will it impact the drug development of the future?
- Discuss where channel & inventory management fit in to ensure the product is delivered correctly the first time



Catherine Coppage
Supply Chain Planner - Personalised Medicine
Kiadis Pharma



Cheryl Tjon A Tham
Supply Chain Manager
Kiadis Pharma

SUPPLY CHAIN MANAGEMENT

Developing a Bottoms Up Plan for Supply Chain Management: Ensuring Quality at the Patient Level First and Working Backwards

- Utilize patient outcome data to track how your decisions in earlier stages had an impact
- What do your last mile sites need from you to ensure patient safety? How can you take care of them better?
- Collaborate with your supply chain partners to create an action plan for a worst case scenario
- Impact of personalized medicine on creating a more patient-centric supply

BLUE SKY ROOM:
Industry Think Tanks: Next Generation Of Cold Chain Management

Standardizing Shipping Validation Across the Industry to Create Consistent Processes & Quality Results

- Review the BPOG mission to create best practices for shipping lane & equipment qualification
- Understand the specific testing & qualification for passive and active shippers
- What is on the horizon to be standardized next within the cold chain arena?
- How to balance cost with quality when choosing your lanes



Tim Corbidge
Facilitator
BioPhorum

4:30PM Track Session Transition

4:35PM

COLLABORATION & STANDARDIZATION

CASE STUDY: You Work Hard to Get your Data, Now Make your Data Work Hard for You- Exploring BMS & Eli Lilly's Initiatives for Increasingly Effective Lane Data Analysis

- Hear how BMS is characterizing lanes for shipping through gathering detailed shock & vibration data
- Review their goal to eliminate the need to ship actual product PQ
- Switch perspectives to hear how Lilly is using climate data to design containers for the varying seasons through simulations & pilots
- Discuss how to use weather data to come up with test profiles and gather lane data in a targeted way



Carolyn Williamson
Principal Packaging Engineer
Bristol-Myers Squibb



Bernard McGarvey
Senior Engineering Advisor
Eli Lilly & Company

NEXT GENERATION MEDICINES

The Business of Biologics: How the Influx of New Medicines into the Supply Chain are Impacting your Operations

- How will this upward trend towards biologics effect the supply over the next 5 years
- Discuss the complex scale up process for biologics manufacturing and where your cold chain processes fit in
- Collaboration between supply chain partners to cater to this new market and ensure consistent quality
- Streamline decision making for your biologics storing & shipping processes from R&D through to patient



Mike Broughton
Director, Global Logistics
Eli Lilly & Company

SUPPLY CHAIN MANAGEMENT

CASE STUDY: Enabling End-to-End Supply Chain Planning, Visibility, and Decision Making through Standardization and IT Integration Across Global Sites

- Discuss the MSD vision for effective supply chain planning through lowering costs and lead-times concurrently
- Review the transformation initiative spanning global demand planning, global supply planning, distribution requirements planning (DRP) and sales and operations planning (S&OP)
- How they combatted change management issues and internal push back for moving to a new IT system
- Hear about the positive results that have come out of their transformation initiative



Henrik Fröjdh
Associate Director Supply Chain Management
Merck & Co.

BLUE SKY ROOM:
Industry Think Tanks: Next Generation Of Cold Chain Management

PANEL DISCUSSION: The New Age of Pharma Logistics: To Digitize or Not to Digitize- Reviewing the Full Scope of Benefits & Potential Drawbacks

- Digitization can mitigate inventory control challenges and increase the visibility downstream
- Evolution of the supply will allow for more consistent quality and patient safety by creating more consistent results and predictable supply patterns
- Account for the job loss that will occur if the supply becomes fully automated, where do logistics professionals fit in?
- Regulatory hurdles to approve the new processes will be too large

ROUNDTABLE DISCUSSIONS- SIP & LEARN LOUNGUES

Choose the topic most relevant to you and join that table for our extended, interactive discussion with seasoned subject matter experts. Bring your entire team so you can split up and regroup afterwards to share knowledge across multiple departments within your organization!

ROUNDTABLE 1: CRT Product Solutions

Discuss the regulatory landscape across the globe and its effect on your decision making for the distribution of CRT products



Arminda Montero
Global Supply Chain QA Manager
AbbVie

ROUNDTABLE 2: Real-Time Temp Monitoring Pros & Cons

Review the move to cloud computing in temperature monitoring and if the extra cost is really necessary. Can you and should you do something about an excursion if noted in real time?



Tonino Antonetti
Executive Director, Regulatory Affairs, Quality Management, Safety & Health and Environment
Roche Diagnostics Canada

ROUNDTABLE 3: Regulatory Audits

How to best prepare your teams for the inevitable regulatory audits? What red flags to look out for and where should you not waste your time preparing? What sources can you use for researching that preparation?

ROUNDTABLE 4: Serialization & Traceability

Review the global scope of traceability regulations and what the supply chain will look like in a post-serialized world



Claude Jolicoeur
Director Regulatory Affairs,
Corporate GMP officer
McKesson Canada



David Martin
Director for Logistics Management
Zogenix Inc

ROUNDTABLE 5: Last Mile Connectivity

How can the industry collaborate to increase visibility in the last mile? What technology or processes are being used now to make this easier? Do we even need greater visibility?



Tom Meier
Senior Project Manager Distribution Systems
Henry Schein, Inc.

ROUNDTABLE 6: Packaging Validation 101

Consider not just the package, but the shipping practices used to move the package when validating. How to create confidence in your logistics processes through proper due diligence? Mapping the process.



William Crates
VP QRA
Cardinal Health

ROUNDTABLE 7: Modal Shift Discussion

Whether you are already shifting modes or considering it in the near future, what risks should you look out for and what benefits should you expect?

ROUNDTABLE 8: Stability Budget Allocation

How much data is too much? How much should you share your stability data with downstream partners in order to decrease risk without sacrificing security?

ROUNDTABLE 9: Unplanned Temperature Excursions

When an excursion occurs without warning, what should be your first move? How to best work with supply chain partners to create an action plan for a worst case scenario

Kathy Phee
CLS Compliance COE
Johnson & Johnson



Elaine Merritt
Sr. QA Manager Transportation
and Temperature Control
Johnson & Johnson

ROUNDTABLE 10: Taking a Total Cost of Ownership Approach to Packaging

Measure your TCO on both single-use and reusable temperature-controlled packaging to make the best choice. Reexamine current strategies based on the actual costs calculated for shipping & storing.



Daniel Marasco
Associate Director of Packaging Materials & Medical Device Sourcing
Bristol-Myers Squibb

End of Main Conference Day One

2017 GLOBAL FORUM COCKTAIL RECEPTION & NETWORKING

Grab a drink and continue the conversation from your roundtable as you network with industry peers in our Exhibit Hall!



We're Not Just Pharma Anymore...

INTRODUCING OUR INAUGURAL FOOD FRESH DAY ►



Food Fresh Day

Wednesday, September 27th

COFFEE AND NETWORKING IN EXHIBITION HALL

7:45am

8:35am

Welcome Remarks by IQPC

8:40am

Chair Opening Remarks

8:45am

KEYNOTE: The Big Data Revolution: Examining the Profound Current & Future Effects of this New Technological Frontier & the Benefit to your Business

- Break down the main business factors disrupting the marketplace and what you can do as a business to succeed in such a time of change
- Predict the industries ripe for disruption, i.e. pharma, and identify potential new products that will change the way we work and live
- Who are future your consumers? Who are your future employees? Make decisions now that will impact your operations in the future
- Review disruptions direct impact to pharma, specifically IoT sensors, blockchain, and the utilization of data to treat rare diseases



Paul Zikopoulos
VP of Big Data Analytics
IBM

9:45am

Future Outlook of the Perishable Food Supply Chain and GS1 Initiatives Aimed to Move the Industry Forward

- GS1 Retail grocery initiative- developed a partner with industry to identify market challenges and foster collaborative solutions using GS1 standards
- Where is the perishable food supply chain going in the next 5-10 years? How will new technology play into that?
- Building a fresh food management solution that pulls in implementation guides created by those initiatives
- Interactive tool to build a traceability tool internally



Michele Southall
Industry Engagement Director
GS1

10:30am

MORNING NETWORKING BREAK

Join your pharma peers to browse the 2017 Expo Hall where you'll be able to find all the latest packaging/container, transportation, logistics, temperature monitoring, security and data management solutions. The ideal place to meet existing and new partners.

11:15am

Designing a Comprehensive Cold Chain: Optimizing Logistics to Maintain and Enhance Quality for your Varied Products and Destinations

- Breaking down your various products into their optimal temperature zones, while accounting for variances within the zone for product type, i.e. produce
- Build infrastructure to support different temperature zones- balance between simplicity of design and flexibility
- Define your quality program to ensure product integrity has been maintained- specifically, continuous temperature monitoring
- How do you choose the ideal transportation model and distribution channel to support your quality program?
- How best to align your carrier partnership in an optimized, efficient and agile transportation network to meet your quality expectations



Steve Zontek
Quality/Sustainability
McDonald's North American Logistics Council

12:00pm

PANEL DISCUSSION: Reviewing the Food Safety Modernization Act's Implications on the Food Supply and Creating Mitigation Tactics within your Operations

- Understand how different players within the supply chain are handling their compliance to the FSMA
- Where do your third party suppliers fit in and how to best work with them to ensure compliance is met?
- Review the cold chain impact on the FSMA regulations and where the main challenges will occur
- How will small, medium, and larger organizations be impacted differently?
- Industry collaboration to tackle the main regulatory hurdles and create standard practices

12:45pm

“BREAK THE ICE” NETWORKING LUNCHEON

Fostering new connections at Global Forum! Are you onsite without your team? Are you looking to make new contacts? Find a table with unknown faces, and grab a question from the center of the table to kick off the conversation with new contacts.

1:45pm

CASE STUDY: Exploring how Blue Apron's Environmental Chamber Improved Efficiency & Reduced Costs

- Determine whether environmental chambers are right for your business through a cost & need analysis
- Review where hidden auxiliary costs can emerge and how to build them into your initial budget
- Understand the physical needs, maintenance and facility resources necessary to operate a chamber successfully
- Hear the positive impact the environmental chamber has had on operations and expected future results

2:30pm

Optimizing your Global Cold Chain Import & Exports from Farm to Factory to Fork

- Review the global landscape of cold chain distribution and what markets pose the largest challenge with delays in customs
- Determine the ideal temperature to receive your products from the farm or factory in order to decrease waste later in the supply chain
- Discuss how the industry may be affected by upcoming regulatory changes & trade agreements for global food distribution
- How your internal team from logistics to packaging to quality can best collaborate to streamline your global operations



F. Scott Fein
Supply Group Manager
Robinson Fresh

3:15pm

AFTERNOON NETWORKING BREAK

Join your colleagues in pharma again to browse our extensive Expo Hall and meet new & existing partners.

3:45pm

How to Leverage Your Traceability Implementation to Realize Operational Efficiencies

- Hear examples of successful traceability implementations that achieved maximum results
- Review of how Companies have:
 - Benefited from using traceability process to enhance their operations
 - Utilized traceability to identify breakdowns in their cold chain
 - Enabled Supply Chain Transparency & increased visibility between stakeholders



Ed Treacy
Vice President, Supply Chain Efficiencies
[Produce Marketing Association](#)

4:30pm

Advanced Data Driven Decision Making to Allow for an Increasingly Efficient Food Service Supply Chain

- Discuss advanced tracking methods of your supply to collect raw data of all transportation modes
- Analyze historic trends in your data to identify problems within certain geographical areas or with specific customers
- How to best organize data stemming from disparate sources to create one clear picture
- Create a more effective decision making process by having clear evidence to support future choices

5:15pm

INTERACTIVE IN-DEPTH DISCUSSION LOUNGES

Choose from the listed roundtables and participate in a lively discussion. Select your discussion topic and join in to hear from leading industry experts

Last Mile Challenges when Delivering Direct to the Customer

How to best mitigate the uncertainty of product quality in the last mile? What tests can be done prior to delivery?



Jason Lu
Associate Director of Logistics
[Hello Fresh](#)

Ensuring Quality & Food Safety for your Varied Product Temperature Ranges

Discuss the different temperature control challenges that come with various products and how to consolidate your efforts from produce to seafood & beyond

Driving the Industry Toward Sustainability & More Eco-Friendly Cold Chain Operations

Discuss where the industry is headed in order to make it easier for companies to move to sustainability. How to actually reduce your carbon footprint?

6:00pm

END OF CONFERENCE

2017 GLOBAL FORUM COCKTAIL RECEPTION & NETWORKING

Join your peers in our Cold Chain Global Forum Expo Hall for our Cocktail Reception! Networking with industry leaders and discuss the day’s highlights.



2017 Global Forum Cocktail Reception & Networking

The premier venue to meet & network with the world's top minds in temperature controlled life science supply chains



Main Conference Day Two

Thursday, September 28th

REGISTRATION OPENS – COFFEE AND NETWORKING IN EXHIBIT HALL

7:30am

BREAKFAST BRIEFING: IATA Update on Dangerous Goods Regulations for the Transportation of Lithium Batteries

- Review the effects of lithium batteries on air transport and what procedures need to be changed to comply
- What are the differences in battery types and the corresponding labeling required
- How to avoid delays in customs due to labeling mistakes and other red flags
- Discuss how the industry can collaborate to educate all supply chain stakeholders on the risks

8:05am

BREAKFAST BRIEFING B: NIIMBL's Innovative Approach to Manufacturing and Supplying Existing and Emerging Biopharmaceuticals

- Discuss the mission of NIIMBL which was recently funded by the Department of Commerce
- Hear how NIIMBL is working with federal agencies to create manufacturing innovations
- Support end to end optimization for biologic drugs with cold chain delivery as a crucial final link
- Learn what organizations are a part of NIIMBL and how to get involved



Dr. Kelvin Lee

Director of the [National Institute for Innovation in Manufacturing Biopharmaceuticals \(NIIMBL\)](#) and Gore Professor of Chemical Engineering at the [University of Delaware](#)

8:40am

Opening Remarks by Chairman

KEYNOTE ADDRESS

8:45am

KEYNOTE: Bringing Healthcare to People and People to Healthcare: The Future of Clinical Trials & Vaccine Distribution

- Review how innovation is transforming the way in which people access care, whether we are moving people, healthcare, or products
- Discuss forward thinking technology and where the healthcare supply chain is going in the future
- Hear case studies of the Uber Health initiatives for clinical trials & vaccine delivery
- What are future predictions for how new technology can transform the healthcare supply chain?



John Brownstein PhD

Chief Innovation Officer & Professor

[Boston Children's Hospital & Harvard University](#)

9:30am

Protecting Our Assets: Global Security's Use of Intelligence and Analysis to Understand and Combat Threats

- Take an in-depth look at how a Pharma Global Security Operations Center (GSOC) can protect its assets and employees worldwide
- Review the use of extensive open-source tools, investigative capabilities & research methods to provide real-time support to employees in times of crises
- How the GSOC authors a variety of strategic and tactical products to mitigate global security threats
- Analyze the current global threat landscape and its potential impact on the pharma supply chain



Bradford Stewart

Global Security Operations Center Manager

[Securitas](#) and Former Chief of Staff to [The President's Daily Brief](#)

10:15am

2017 COLD CHAIN GLOBAL FORUM EXCELLENCE AWARDS

Creating Cold Chain Sustainability: Reviewing the Return/Reuse of Temperature Assurance Packaging – Considerations to Make it Work

- Review the life-cycle of a returnable shipper as it gets shipped across the supply chain from pharmaceutical manufacturers to healthcare professional and back for reclamation and reuse
- Understand the supply chain needs and key stakeholders to make return-reuse options viable
- Discuss on different financial modeling scenarios where return-reuse will and will not be feasible
- Share best practices to reduce asset loss and reclamation time, and achieve cost savings while being environmentally responsible



Ben VanderPlas
Global Product Manager
Sonoco Thermosafe

10:30am

11:00am

MORNING NETWORKING BREAK

2017 DEMO DRIVES & INCUBATION LAB

Join us in the Expo Hall for live demonstrations of the most innovative products and cutting-edge technology currently available in the industry.

11:55am

Transition to Roundtable Discussions

12:00pm

ROUNDTABLE DISCUSSIONS

ROUNDTABLE 1: Passive VS Active Shippers

Why would you switch from passive to active? What are the benefits of each method? What is the data to support those decisions?



Ben Romero
Director Logistics Temperature Control
Bristol-Myers Squibb

ROUNDTABLE 2: Innovations in Data Collection & Storage

How to manage the new era of data capture through upgrading your systems and educating your team? How to streamline temperature & location monitoring through data?

Ingrid Freeland
Associate Director, Quality Operations
Astellas US Technologies, Inc.

ROUNDTABLE 3: Maintaining Optimal Risk Levels

Discuss how your organization views risk as compared to others. Does your propensity to take more risk depend on the product? How does risk affect your bottom line?



Lisa A. Sykes, MBA, VBF
Quality Operations Director
Merck & Co., Inc.

ROUNDTABLE 4: Challenges and Opportunities for Inventory Management for High Value or Complex Product Supply Chains

Discuss methods for choosing inventory locations & mixing replenishment channels & Distribution Requirements Planning.



Thomas Scalone
Associate Director Logistics Supply Chain
Celgene

ROUNDTABLE 5: Global Supply Chain Qualification Considerations

How to accurately qualify the temperature controlled supply chain to account for regulatory changes, factors outside of temperature and multiple packaging components. Discuss the ideal methods for qualification that keep GxP requirements in mind.



Rafik Bishara Ph.D.
Technical Advisor & Former Director QKMTS
Eli Lilly & Company

ROUNDTABLE 7: Strengthening the Weakest Link in the Cold Chain-Air Freight

Discussing the key steps to mitigate risk when shipping by air. How to best collaborate with supply chain partners to manage expectations. What are the future game-changing trends for air freight?



Margaretha Laseen
Cargo Manager, Western USA
Cathay Pacific

ROUNDTABLE 9: Supplier Qualification & SOP Writing

What do your suppliers need from you and what can they do to ensure your organizational standards are being met? Discuss how there is no one-size fits all model

ROUNDTABLE 6: Shipping Outside of Label Claims

Justify the increased temperature range through proven stability studies. Review the regulatory requirements across the globe



Mark Walls
Director, Clinical Supply Operations and Logistics
Tetraphase Pharmaceuticals

ROUNDTABLE 8: Effective Transitioning from Clinical to Commercial Operations

When to start planning pre-FDA approval for your commercial operations and how to speed up your time to market with little mistakes



Dip Parikh
Associate Director, Supply Chain
Biogen

ROUNDTABLE 10: Customs Documentation Issues for Air & Ocean Cargo

How to avoid unexpected delays in customs for agriculture inspections and paper review. Document review methods and tips.

Mark Grzeszkowiak
Chief Agriculture Specialist
U.S. Customs and Border Protection

Lin-Mai Malmstrom
Supervisory Agriculture Specialist
U.S. Customs and Border Protection

Saheed O. Muhammed
Supervisory Import Specialist
Pharmaceuticals, Health & Chemical Center
US Customs & Border Protection

12:45pm

NETWORKING LUNCH - CONNECT WITH LIKE-MINDED PEERS

Join us for a networking lunch break to grown your network and continue discussing the hot topics from the past 4 days.

Main Conference Day Two | Thursday, September 28th

1:45pm

Transition to Track Sessions

1:50pm

PACKAGING/LOGISTICS

CASE STUDY: Defining the Root Cause for Near -90°C Excursions for Dry Ice Shipments in Passive Parcel Shippers

- Discuss the increased need for <-20C shipment and associated challenges
- Simply filling an insulated box with dry ice is not suitable for keeping your product between -70C and -90 during transportation for >96 hrs or longer
- Dear inspector: This is why occasionally the temperature recorder registers <-85 or even <-90C for a prolonged period of time during transportation regardless of air or ground transportation



Rey Chern
Director of Engineering
Amgen

QUALITY/DATA MANAGEMENT

Controlling Your Cold Chain Through The Last Mile: How a Cloud-Based Solution can Enhance Visibility, and Continuously Optimize your Entire Supply Chain

- Strategies for deploying pre-emptive alerts to prevent damage by intervening before a temperature excursion.
- 24/7 visibility and control of your product throughout the many hand offs to suppliers downstream
- Allow for increased collaboration through seamless sharing of data with supply chain partners
- Opportunities for automation within your supply chain processes.
- Using data analytics to illuminate real-time supply chain performance trends



Vallý Helgadóttir
Director of Customer Service
Distica

SERIALIZATION & SECURITY

The DSCSA's Impact on the Global Supply Chain: A Breakdown of the Regulations, Deadlines, and What the Supply Chain will Look Like in a Post-Serialized World

- Examine the full scope of DSCSA requirements and top international serialization deadlines that are looming
- How can logistics professionals support serialization teams past the 2017 deadline
- What application does serialization technology have for temperature monitoring? Can they work in tandem?
- Predicting how a post-serialized world will affect the pharma supply chain



Matt Sample
Sr. Director, Secure Supply Chain
AmerisourceBergen Corporation

BLUE SKY ROOM: *Industry Think Tanks: Next Generation Of Cold Chain Management*

Creating Industry Standards through End-to-End Integration & Effective Communication Between Key Stakeholders

- Discuss the TEAM-UP initiative to foster a more innovative approach to pharma logistics
- Break the organizational siloes by opening up communication channels between supply chain partners
- Review what is considered proprietary and what could & should be shared openly
- How will increased communication & collaboration between stakeholders better ensure quality at the patient level



Alan Kennedy
Founder
TEAM-UP Global

2:30pm

Track Session Transition

2:35pm	PACKAGING/LOGISTICS CASE STUDY: Making the Case for Ocean: How a Modal Shift from Air to Ocean Freight Resulted in Cost Savings & Increased Quality - Prepare your inventory & demand planning teams to account for the longer timelines for ocean - Hear about the approximate 80% cost savings and decreased packing supply requirements through the move to ocean freight - Discuss the ways ocean freight has significantly reduced their overall carbon footprint - Examine their international rollout of ocean freight and which markets pose the biggest challenge  Steve Epperson Consultant, QA Material and Operations Eli Lilly & Co.  Bryan Cardis Consultant, Distribution Platform Stewart Eli Lilly & Co.	QUALITY/DATA MANAGEMENT Creating Strict Organizational Standards through Increased Supplier Visibility and Strong Quality Agreements in a Heavily Outsourced Environment - Ensure your outsourced operations are meeting internal standards through quality checks & identifying critical vendors - Construct an iron-clad Quality Agreements through clear & effective negotiation, execution, and follow-up - Maintain a consistent process globally by working with solutions-providers that have an infrastructure in place that meets your needs - Conduct frequent evaluations & audits of critical vendors to identify potential compliance issues  Rick Calabrese Global Director of Corporate Quality Systems Sartorius Stedim North America Inc	SERIALIZATION & SECURITY Fingerprinting Pharma: Ensuring Supply Chain Integrity Through Advanced Product Tracking Technologies - Examine how and why this technology emerged in order to fight counterfeit medicine - Small Molecules vs Biologics: Understand the identification and structural characterization (i.e. sample degradation) - What are the implications for serialization & cold chain? What else will be possible through this technology? - Case Studies: See the portable device authentication technology in action  Ravi Kalyanaraman Associate Director, Global Analytical Technology, Manufacturing, and Supply Bristol-Myers Squibb  Jeremy Peters Associate Scientist Bristol-Myers Squibb	BLUE SKY ROOM: <i>Industry Think Tanks: Next Generation Of Cold Chain Management</i> PANEL DISCUSSION: Taking a Patient-Centric Approach to your Temperature Controlled Supply Chain Management - Discuss how the evolution of biologics & specialty medicines have given patients more control over their treatments - Consider the patient-centric impact on all areas of treatment delivery & logistics - Review the potential quality challenges surrounding patients at the helm of extremely temperature sensitive products - Examine the trend for direct to customer deliveries that bypass the wholesaler
3:15pm	AFTERNOON NETWORKING BREAK BINGO CARD WINNERS ANNOUNCED & PRIZE DRAWINGS			
3:45pm	Track Session Transition			

3:50pm

PACKAGING/LOGISTICS

PANEL DISCUSSION: Building Custom Packaging when Out of the Box Solutions are Not the Answer: Effective Co-planning with Supply Chain Partners to Create Specially Designed Packaging for Unique Situations

- Discuss specific products that require specialty packaging solutions
- Review where the custom solution market is heading with the growth of biologics & personalized medicine
- When does off the shelf packaging make more sense?
- What are the cost implications for choosing custom? Do you make back the increase investment down the road with reducing risk?



Taylor Clark
Vice President of Marketing and Sales
R.N.C. Industries, Inc.



Regis Gautier
Director of Global Packaging Technology
Bristol-Myers Squibb

QUALITY/DATA MANAGEMENT

Building an Integrated Risk Management Framework in your Company to Allow for Increasingly Effective Decision Making

- Proactively minimize risks to patients, operations, and supply chain through early identification, detection and mitigation
- End-to-end risk review and control of products throughout the supply chain
- Drive continual improvement throughout the product and process lifecycle to ensure a reliable supply of quality products to patients
- Leverage risk management tools to make risk based decisions in temperature controlled distribution



Lisa Wyman
Head of Quality Compliance & Data Analytics
Shire Pharmaceuticals

SERIALIZATION & SECURITY

Utilizing a Risk-Based Approach to Ensure Global Supply Chain Security & GDP Compliance within a High Threat Market

- Clarify vague international GDP regulations and identify higher risk markets within your global distribution network
- Strategies for auditing supply chain partners to certify that internal security processes are being met
- Work with procurement teams to set strict guidelines ahead of new partnership agreements
- What back up plans do you have if an excursion happens? How do you identify high risk areas & products?

Leo Vaytsman
Supply Chain Security Specialist
Takeda Pharmaceuticals

4:30pm

Track Session Transition

4:35pm

PACKAGING/LOGISTICS

Examining a Innovative Approach to Passive Cold Chain Logistics through Inorganic PCMs

- Review the stability & regulatory challenges of shipping with dry ice specifically to the Chinese market
- Understand the recent manufacturing trends in the APJ market to mitigate the excursions caused through dry ice
- Hear the results of an experiment conducted to transport cells stored in a -80° deep freezer with -50° PCMs
- How can PCMs be better utilized to ship cell therapies & biologics globally? What are the regulatory, quality & risk hurdles?



Yasuhiro Suzue
Team Leader of PCM Business Promotion Team
Kaneka Corporation

QUALITY/DATA MANAGEMENT

Data Optimization: How to Integrate and Analyze Temperature Data Stemming from Various Sources

- How to organize the data deluge to create an easily accessible system for your stakeholders
- Determine what lanes to upgrade first through a risk analysis
- Discuss the new technology available to capture & store temp data and what is on the horizon
- How can you better ensure data security within your various sources? Where does cloud fit it?

5:15pm

END OF MAIN CONFERENCE DAY TWO



Globalization of the Life Science Supply Chain is on an Upward Trend. Learn from your Peers from around the World.

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International Focus Day

Friday, September 29th

8:15AM

REGISTRATION & COFFEE

8:55AM

Opening Remarks by Chairman

KEYNOTE ADDRESS

9:00AM

CASE STUDY: Examining the Impact of Innovation & a Robust Temperature Controlled Supply Chain in Challenging Emerging Market Countries

- Discuss the mission of the Clinton Health Access Initiative (CHAI) and their partnerships with the WHO, Gates Foundation & GAVI
- How this work has supported market growth over the last year to get more high-performing cold chain products to a larger number of emerging market countries
- How advanced logistics are being used to mitigate cold chain challenges in these emerging markets
- How cellular-based monitoring technology is being applied to improve data-based decision-making in these regions



Gopal Nadadur

Senior Manager, Global Markets Team

[Clinton Health Access Initiative \(CHAI\)](#)

9:40AM

CANADA: Understanding the New Regulatory Provisions Outlined in Health Canada Guide-0069

- Review guidelines for products in transit: stability data requirements and temperature mapping
- Discuss the regulatory scope of temperature monitoring for CRT
- Hear recommended approaches for risk evaluation and mitigation and analyze examples of compliance and non-compliance
- Take a look at what Roche implement locally to distribute to our Canadian customers to fulfill the authority requirements



Tonino Antonetti

Executive Director, Regulatory Affairs, Quality Management, Safety & Health and Environment

[Roche Diagnostics Canada](#)

10:20AM

NETWORKING BREAK

10:50AM

MIDDLE EAST: Establishing Effective Supply Chain Operations in the Middle Eastern Market

- Identify the major risk factors when distributing to the Middle Eastern regions
- Set up a supply chain partner network that can handle your unique product lines and routes
- Mitigate potential customs challenges by doing your homework on the regulatory requirements
- Manage excursion risks in the hot climates by having diligent processes in place



Rami Arafat

Supply Chain Director

[Hikma Pharmaceuticals](#)

BRAZIL: Mitigating the Logistical Risk of Storing & Transporting Temperature Sensitive Materials in the LATAM Region

- Review specific guidelines in place in Brazil to help manufacturers, particularly touching on CRT/Ambient products
- Transportation validation requests- Guidelines around how they can be used to guarantee product quality
- How the Brazilian & EU regulations are similar. What has Brazil adopted from the EU?
- Overall regulatory climate in the LATAM region for pharma supply chains

Felipe A. Gomes Sales
Gerente/Manager - GIMED/GGFIS
[ANVISA](#)

AFRICA: Ensuring the Integrity of Medicines and Vaccines for Optimum Patient Care in Africa's Increasingly Stringent GDP Regulatory Landscape

- Review the ongoing vaccine initiatives for increasing vigilance in the last mile through data logger deployments
- Understand the strengthening African GDP landscape through collaboration efforts of regional economic communities (RECs)
- Increased communication between regulators both regionally & internationally to implement appropriate mechanisms when global GDP changes occur
- How can stability data collection and analysis be better utilized to support regulatory efforts & increase quality at the patient level? What else can be done by the industry to ensure the public's health?



Ropah Hove
Director, Pharmacy Services
[Ministry of Health and Child Care Zimbabwe](#)

CENTRAL AMERICA & CARRIBBEAN: Exploring GSK's Journey to Complete a Distribution Risk Assessment for 40 Countries at Once to Fulfill Regional Demand

- How they are managing the complex temperature profiles & tighter regulatory requirements of Ambient products
- Discuss their procedures to mitigate the challenging & varying infrastructures and lead times in the region
- Implement a cohesive Distribution Risk Assessment document to standardize temperature-controlled distribution practices throughout your organization
- Where they have seen cost savings? How to make better negotiations with freight forwarders?



Francia Bocanegra Aleman
Warehousing and Distribution Head Central America and Caribbean
[GlaxoSmithKline](#)

Overlook on the Experience of the United Arab Emirates - MOHAP in the Cold Chain: How Temperature Controlled Supply Chain Management Impacts Public Health

- Shedding light on the overall healthcare landscape of the country- and how does cold chain fit in the healthcare continuum with a review on the economic impacts
- Discuss UAE MOHAP regulatory standards for cold chain adapted from several international guidelines
- Examine the trade elements (Economics for pharmaceutical products import/export to the country) and importance of temp control
- Review different model guidance and methods for utilizing increased quality in the supply chain and temperature control

Dr. Rasha Salama
Public Health Advisor for Public Health Policy & Licensing Sector
[Ministry of Health and Prevention - UAE](#)

NETWORKING LUNCHEON

AFTERNOON COFFEE BREAK

INDIA: Mastering Import/Export and Regulatory Roadblocks for your Indian Distribution Channels

- Review changes in GDP regulations and identify potential road blocks when entering market
- Examine the pilot project with the Central Government to conduct wellness programs in society
- Discover Merck's well-defined process to maintain product quality through to the customer
- Understand the main challenges when controlling the cold chain in India from an end-to end perspective



Rakesh Shah
Director Supply Chain- APAC (Sub Region II), India and Frontier Market
[Merck Serono](#)

LEBANON: Reviewing the Lebanese Ministry of Health's GSDP National Guidelines to Ensure Preserved Quality and Identity of Pharmaceutical Products During Storage & Transport

- Discuss steps to fulfill top supply chain responsibilities to avoid the introduction of counterfeit products into the marketplace
- Address documentation and infrastructure requirements to allow for a Quality Management System for ambient and temperature sensitive products
- Hear the Lebanese MOPH GSDP 3 years certification process details and auditing requirements
- Get an update on the GDP regulatory landscape in the MENA region and what future changes on the horizon



Rita Karam, Pharm.D., Ph.D.
Quality Assurance of Pharmaceutical Products Program Director
[Lebanese Ministry of Health](#)

Christelle Fransawi
Technical Member
[Lebanese Ministry of Health](#)

CONFERENCE CONCLUSION





Sponsors



Explore Chicago

An aerial photograph of the Chicago skyline, featuring numerous skyscrapers and the city's dense urban layout. The Lake Michigan is visible in the background under a clear blue sky. The Willis Tower is prominent on the right side of the image.

“Eventually, I think Chicago will be the most beautiful great city left in the world.”

— Frank Lloyd Wright

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