CLINICAL TRIAL SUPPLY NEW ENGLAND 2024

GlobalData.

ARENA INTERNATIONAL EVENTS GROUP

Clinical Trial Supply New England 2024

Boston, Massachusetts

9th -10th April 2024

www.arena-international.com/ctsnewengland/

REGISTER HERE

Arena will be returning to the Westin Waltham for our 2024 Clinical Trial Supply, New England conference. The event will showcase talks from top industry players, unrivaled networking opportunities and the chance to find cutting-edge solutions in the exhibition hall.

Speakers 2024:

- **Anthony Thomas,** Consumer Safety Officer, **FDA**
- **Stephen King,** Compliance Officer, **FDA**
- **Sean Smith,** Biological Threat Exclusion Coordinator (BTEC), **US Customs and Border Protection**
- **Paul Larochelle,** Director, Global Clinical Supply Chain, **Takeda**
- **Sydney Reynolds,** Postdoctoral Fellow - Global Clinical Supply Chain, **Takeda**
- **Amanda Murphy,** Senior Director, Data Intelligence & Solutions, **Global Data**
- **Scott Sutton,** Senior Director, Clinical Supply Chain, **Constellation Pharmaceuticals, a MorphoSys company**
- **Rajiv Panwar,** VP, CMC, Technical Operations and Clinical Supply Chain, **Disc Medicine**
- **Jessica Vieira,** Global Value Chain Environmental Sustainability Strategy Lead, **Takeda**
- **Sarah Mandlebaum,** Lead, Global Environmental Sustainability & Life Cycle Assessment, **Takeda**
- **Rakibou Ouro-Djobo,** Global Clinical Supply Chain & Logistics Lead, **Bill & Melinda Gates Medical Research Institute**
- **Gilad Beck,** Site Head, Operations and Manufacturing Director, **Orgenesis**
- **Agnes Jung,** VP, Head of Clinical Development and Operations, **Bridge Biotherapeutics**
- **Jamie Myers,** Senior Manager Clinical Supply Chain, **Takeda**
- **Lisa Kaufman,** Associate Director, Quality, Process and Risk Management, **AstraZeneca**

CLINICAL TRIAL SUPPLY NEW ENGLAND

APRIL 9TH & 10TH | BOSTON, MA

DAY 1 – TUESDAY APRIL 9TH

8:15	**Registration and refreshments**
8:50	**Chairperson's opening remarks** **Amanda Murphy,** *Senior Director, Data Intelligence & Solutions,* ***Global Data***
9:00	**Importing FDA regulated Biological Products** • Entry Screening/Admissibility • FDA Regulatory Requirements for CBER Regulated Products • Making ACE Work for You: Importing Biological Products **Anthony Thomas,** *Consumer Safety Officer,* ***FDA*** **Stephen King,** *Compliance Officer,* ***FDA***
9:30	**Reserved for N-Side**
10:00	**Optimizing forecasting: size-phase appropriate approaches** • Implementing forecasting techniques tailored to the specific size and phase of the project. • Discussing strategies for dynamically adjusting forecasting methods as the project progresses through different phases • Exploring how size-phase appropriate forecasting can enhance risk management and improve decision-making in diverse project scenarios **Scott Sutton,** *Senior Director, Supply Chain,* ***Constellation Pharmaceuticals, a MorphoSys company***
10:30	**Morning refreshments and networking**
11:00	**Modernizing the way drugs are made: a transition to continuous manufacturing** • Exploring batch vs continuous manufacturing • Pinpointing benefits of continuous manufacturing- reduced manufacturing costs, particularly over the long term, shorter production times, improved quality • A challenging but worthwhile transition revamping industry infrastructure **Rajiv Panwar,** *VP, CMC, Technical Operations and Clinical Supply Chain*, ***Disc Medicine***
11:45	**Reserved for Mercalis**

REGISTER HERE

Sales Enquiry
Jarvinder Sidhu
Senior Sponsorship Sales
T: +44 (0)207 9472755
E: jazsidhu@arena-international.com

Speaker Enquiry
Ralitsa Pashkuleva
CTS Portfolio Manager
E: ralitsa.pashkuleva@arena-international.com

Marketing Enquiry
Haida Amirzadah
Marketing Manager
E: Haida.Amirzadah@arena-international.com

CLINICAL TRIAL SUPPLY NEW ENGLAND

APRIL 9TH & 10TH | BOSTON, MA

12:15	**State of the biopharma industry: the outlook for drugs, trials, and manufacturing** • What's coming in the pharma pipeline? • Drug manufacturing for clinical trials • Emerging trends: gene therapy, mRNA, and AI • Opportunities for contract development and manufacturing organisations (CDMOs) **Amanda Murphy**, *Senior Director, Data Intelligence & Solutions,* ***Global Data***
12:45	**Lunch and networking**
1:45	**Optimizing drug utilization: strategies to tackle drug waste in healthcare** • Exploring how precision medicine and personalized dosing can be leveraged to minimize drug overuse and reduce waste, considering factors such as patient variability and therapeutic response. • Discussing improvements in supply chain management to prevent overstocking and expiration of medications, emphasizing collaboration between healthcare providers and pharmaceutical suppliers to streamline inventory and reduce waste. • Highlighting the importance of patient education and adherence initiatives in reducing unnecessary drug consumption, and explore how healthcare professionals can work with patients to enhance understanding and compliance, ultimately minimizing medication waste **Lisa Kaufman,** *Associate Director, Quality, Process and Risk Management,* ***AstraZeneca***
2:15	**Reserved for Boostcode**
2:45	**A greener future for patients: the pharma supply chain's journey to net-zero** • Starting sustainability • Discovering continuous manufacturing as a way to generate 80% less carbon emissions • Exploring new technology to entirely replace natural resources with a fermentation-based method • Reducing carbon emissions caused by cold chain shipping by investing in greener fuels and energy sources for transport vehicles **Jessica Vieira**, *Global Value Chain Environmental Sustainability Strategy Lead,* ***Takeda*** **Sarah Mandlebaum**, *Lead, Global Environmental Sustainability & Life Cycle Assessment,* ***Takeda***
3:15	**Afternoon refreshments and networking**
3:45	**Investigating the necessities surrounding the import and export of biological materials** • Emphasizing the critical role of thorough preparation • What relevant authorities to contact in advance to avoid unnecessary complications • CBP One – an application that allows scheduling inspection appointments in advance for biological products upon their air arrival into the U.S.

REGISTER HERE

Sales Enquiry
Jarvinder Sidhu
Senior Sponsorship Sales
T: +44 (0)207 9472755
E: jazsidhu@arena-international.com

Speaker Enquiry
Ralitsa Pashkuleva
CTS Portfolio Manager
E: ralitsa.pashkuleva@arena-international.com

Marketing Enquiry
Haida Amirzadah
Marketing Manager
E: Haida.Amirzadah@arena-international.com

CLINICAL TRIAL SUPPLY NEW ENGLAND

APRIL 9TH & 10TH | BOSTON, MA

	• Understanding what Importer of Record is and how to become a registered one **Sean Smith,** *Biological Threat Exclusion Coordinator,* ***US Customs and Border Protection***
4:15	**Reserved for event sponsor**
4:45	**PANEL DISCUSSION** **Discovering the evolution in the clinical supply chain** • Exploring the role of emerging technologies, such as blockchain, IoT, and AI, in revolutionizing the clinical supply chain and discuss how these innovations enhance visibility, traceability, and efficiency. • Discussing the evolving regulatory landscape and its impact on the clinical supply chain, focusing on how industry players are navigating compliance challenges and ensuring alignment with changing regulations. • Examining the shift toward patient-centricity in clinical trials and its influence on the supply chain, emphasizing how personalized medicine, decentralized trials, and direct-to-patient models are shaping the evolution of clinical supply strategies. Moderator **Amanda Murphy,** *Senior Director, Data Intelligence & Solutions,* ***Global Data*** Panelists **Gilad Beck,** *Site Head, Operations and Manufacturing Director,* ***Orgenesis*** **Agnes Jung,** *VP, Head of Clinical Development and Operations,* ***Bridge Biotherapeutics***
5:30	**Chairperson's closing remarks**

END OF DAY 1 AND NETWORKING DRINKS

DAY 2 – WEDNESDAY APRIL 10TH

8:15am	**Registration and refreshments**

REGISTER HERE

Sales Enquiry
Jarvinder Sidhu
Senior Sponsorship Sales
T: +44 (0)207 9472755
E: jazsidhu@arena-international.com

Speaker Enquiry
Ralitsa Pashkuleva
CTS Portfolio Manager
E: ralitsa.pashkuleva@arena-international.com

Marketing Enquiry
Haida Amirzadah
Marketing Manager
E: Haida.Amirzadah@arena-international.com

CLINICAL TRIAL SUPPLY NEW ENGLAND

APRIL 9TH & 10TH | BOSTON, MA

8:50am	**Chairperson's opening remarks**
9:00	**PROBLEM-SOLVING ROUNDTABLE DISCUSSIONS** *During the roundtable discussion session, the conference hall will be divided into three 'zones'. Delegates can choose which zone they would like to join. Each zone will be led by a table moderator and will focus on a different challenge within clinical supply chains. After 45 minutes, delegates will have the opportunity to swap and choose a different table, and each roundtable will run twice.*
	ROUNDTABLE 1: **A Q&A session examining U.S. Customs and Border Protection – help with any questions about how to import or export biological materials to or from the U.S.** **Sean Smith,** *Biological Threat Exclusion Coordinator,* ***US Customs and Border Protection***
	**ROUNDTABLE 2:** **Effective strategies for strengthening the relationship with CDMOs** **Rajiv Panwar,** *VP, CMC, Technical Operations and Clinical Supply Chain*, ***Disc Medicine***
	ROUNDTABLE 3: **Exploring Effective Strategies for Small Sponsors to Select the Right Vendor and Ensure High Quality Output**
	ROUNDTABLE 4: **Understanding Impacts of New EU Clinical Trial Regulation on Supply Chain**
10:30	**Morning refreshments and networking**
11:00	**Understanding strategies for preventing shortages and enhancing resilience in supply chain** • Delving into the importance of building resilient clinical supply systems, exploring technologies and methodologies that enhance agility and responsiveness to prevent shortages in the face of unforeseen challenges • Discussing strategies for effective comparator sourcing, addressing potential bottlenecks, and exploring partnerships or alternative sourcing approaches to ensure a stable and consistent supply of comparators for clinical trials • Explore considerations and approaches for removing comparators from the free market, examining the potential impact on supply stability and discussing measures to mitigate market-related risks, ensuring a reliable and sustainable clinical supply chain **Rakibou Ouro-Djobo,** *Global Clinical Supply Chain & Logistics Lead,* ***Bill & Melinda Gates Medical Research Institute***

REGISTER HERE

Sales Enquiry
Jarvinder Sidhu
Senior Sponsorship Sales
T: +44 (0)207 9472755
E: jazsidhu@arena-international.com

Speaker Enquiry
Ralitsa Pashkuleva
CTS Portfolio Manager
E: ralitsa.pashkuleva@arena-international.com

Marketing Enquiry
Haida Amirzadah
Marketing Manager
E: Haida.Amirzadah@arena-international.com

CLINICAL TRIAL SUPPLY NEW ENGLAND

APRIL 9TH & 10TH | BOSTON, MA

11:30	**Reserved for event sponsor**
12:00	**Exploring how decentralized manufacturing can enhance clinical trial supply** • High level overview of decentralized manufacturing – understanding what it means, the approach and how it's done in practice • Recognizing how decentralized manufacturing can improve resilience of clinical trial supply • Maximizing upstream and downstream clinical supply efficiency through a decentralized framework • Envisioning the future of decentralized manufacturing and exploring its potential **Gilad Beck,** *Site Head, Operations and Manufacturing Director,* ***Orgenesis***
12:45	**Lunch and networking**
2:00	**Fostering a Dynamic Team Culture for Talent Development** • Cultivating collaborative team dynamics • Emphasizing the value of diverse thinking for problem-solving and creative solutions • Implementing ongoing training programs to upskill team members and address skill gaps • Providing mentorship and coaching opportunities to nurture individual growth **Paul Larochelle,** *Director, Global Clinical Supply Chain*, ***Takeda*** **Sydney Reynolds**, *Postdoctoral Fellow - Global Clinical Supply Chain*, ***Takeda***
2:30	**PANEL DISCUSSION** **Harmonizing temperature excursion management: navigating conflicting policies at investigative sites** • Addressing the challenges of integrating site-specific temperature excursion policies with the sponsor's requirements and proposing effective strategies for alignment. • Emphasizing the importance of open communication between sponsors and investigative sites to identify and resolve conflicts in temperature excursion management procedures. • Exploring the implementation of standardized procedures that accommodate both site-specific policies and sponsor requirements, ensuring effective temperature excursion management while respecting local protocols Moderator **Amanda Murphy,** *Senior Director, Data Intelligence & Solutions,* ***Global Data*** Panelists

REGISTER HERE

Sales Enquiry
Jarvinder Sidhu
Senior Sponsorship Sales
T: +44 (0)207 9472755
E: jazsidhu@arena-international.com

Speaker Enquiry
Ralitsa Pashkuleva
CTS Portfolio Manager
E: ralitsa.pashkuleva@arena-international.com

Marketing Enquiry
Haida Amirzadah
Marketing Manager
E: Haida.Amirzadah@arena-international.com

CLINICAL TRIAL SUPPLY NEW ENGLAND

APRIL 9TH & 10TH | BOSTON, MA

	Rakibou Ouro-Djobo, *Global Clinical Supply Chain & Logistics Lead,* ***Bill & Melinda Gates Medical Research Institute*** **Jamie Myers,** *Senior Manager Clinical Supply Chain,* ***Takeda***
3:00	**Chairperson's closing remarks**

END OF CONFERENCE

REGISTER HERE

Sales Enquiry
Jarvinder Sidhu
Senior Sponsorship Sales
T: +44 (0)207 9472755
E: jazsidhu@arena-international.com

Speaker Enquiry
Ralitsa Pashkuleva
CTS Portfolio Manager
E: ralitsa.pashkuleva@arena-international.com

Marketing Enquiry
Haida Amirzadah
Marketing Manager
E: Haida.Amirzadah@arena-international.com