



B S M A

Bio Supply Management Alliance

2024 Annual Conference
March 20 and 21, 2024

DAY TWO

Clinical and Commercial Supply Chain Execution:

**Logistics, Import/Export, Regulatory
Compliance, and Process Excellence**



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WELCOME ADDRESS

Bill Coakley

Executive Vice President, BSMA



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UNACCEPTABLE REALITIES

- **Cost for Drug Development - \$2.6 billion**
- **Time for Drug Development – 3 to 10 years**
- **Studies Running Late – 70%**
- **Success Rate of Clinical Trials – Less than 10%**
- **Waste – 56% of Products Made for Clinical Trials**

Source: Tufts Center for the Study of Drug Development



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UNACCEPTABLE REALITIES

Industry Average for Wasted/Unused Kits is 76%

Source: McKinsey

Over 90% of Booklet Labels Applied on Clinical Trial Material Were Never Opened

Source: A Major Service Provider

50% of BSMA Members Do Not Track Clinical KPI's, Including...

Forecast Accuracy

Production Plan Performance

Distribution Performance

Patient Service Levels

Raw Material Availability

CMO Performance

Inventory

ERP/IRT System Performance



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STAKEHOLDERS OF CLINICAL TRIALS

- **Drug Developer/Manufacturer (Internal Departments)**
- **Contract Manufacturing Organization (CMO)**
- **3rd Party Clinical Research Organization (CRO)**
- **Label & Packaging Service Provider**
- **Storage and Distribution Provider**
- **IRT and Data Analytics Provider**
- **Regulatory Agencies**
- **Patient Care Providers**
- **Patients**



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WHAT IS THE PROBLEM?

- **Most Stakeholders are siloed**
- **Lack of end-to-end visibility**
- **Lack of “real time” data**
- **Manual systems**
- **Inability to make “informed decisions”**



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BSMA's RESPONSE

Steering Committees & Work Stream Groups

- **Clinical Supply & Demand Planning**
- **Moving Beyond Excel and Point Solutions**
- **Transitioning from Clinical to Commercial: Ensuring a Successful Product Launch**
- **Global Logistics & Trade Compliance**



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TODAY'S AGENDA

- Art vs Science: Clinical Supply Planning Strategies
- Waging a War on Clinical Supply Waste
- Navigating Through the Complexities of GDP in a Global Supply Chain
- The Final Countdown: Navigating a Successful Study Close-Out
- Debate: Should a Company Have 1 Combined or 2 Separate Supply Chain Departments for Supporting Commercial and Clinical Products?
- Overcoming the Achilles Heal Valuating Products for Importers & Exporters
- SCM Excellence Awards

Remember to visit our Exhibitors!



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CALL TO ACTION

- **Challenge Status Quo**
- **Let Us Collaborate**
- **Challenge Business Assumptions**
- **Establish Efficient Business Processes**
- **Integrate Systems – Internally & Externally**
- **Achieve Visibility – End-To-End**
- **Conduct Data-Driven Trials**
- **Utilize Generative AI, Machine Learning & Blockchain**
- **Become engaged with your peers and solution providers in at BSMA**



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THANK YOU!

LET THE DELIBERATIONS BEGIN!