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The Business Imperative for Cost-Effective Quality Patient Care"

# BIOTECH SUPPLY CHAIN ACADEMY



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## Overcoming the Hurdles in Emerging Markets, a Panel Discussion





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## INTRODUCTIONS





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## Panelists

- Jamin Eberhart – Moderator – Director, PwC's PRTM Management Consultants
- Matthew Blume – Sr. Director, Packaging and Logistics, Aptuit
- Nathan Kohner – Distribution Project Group Manager, Almac
- Diana Vazquez – Sr. Manager Global Supply Chain and Logistics, Onyx Pharmaceutical





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Key Challenges in Emerging Markets

## PRIMARY QUESTIONS







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**What are the primary clinical supply chain challenges that your companies are dealing with in emerging markets like China, India, and Brazil which differ from those of more developed countries?**





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## Q & A





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China Challenges and Solutions

## PRIMARY QUESTIONS







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**What are the unique import and export regulations in China, including duties, taxes, and other potential challenges? What is the typical timeline to get drug into China?**

- High Customs and VAT rates
- IP testing by SFDA
- Regional import requirements vs. China-wide
- Longer regulatory review period
- SFDA may request potential changes to protocol, which could impact global studies
- Higher documentation requirements than average
- Reach of premium carriers vs. consolidators varies





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**How does the cycle time for shipping drug - once at a depot in country - vary in China versus other parts of the world? Does this cycle time affect shipping configurations, especially for temperature controlled shipments?**

- Transit time of 1-3 days
- Use premium courier service
- Often use internal flights
- Shipping control similar as for other locations
- Potential for extremes of temperature





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**What visibility is there into shipment status (depot-to-depot and direct to site) while clinical materials are in transit? Any issues with alarm frequency, reporting, or investigations for temperature controlled shipments?**





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**What is China's stance on expiry dating vs. date of manufacture labeling? How does this affect your labeling and clinical trial preparations?**





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How have companies best managed the distribution of standard-of-care materials in conjunction with a trial? Where should the inventory be held?







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## Q & A





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Brazil Challenges and Solutions

## PRIMARY QUESTIONS





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**What are the unique import and export regulations in Brazil, including duties, taxes, and other potential challenges? What is the typical timeline to get drug into Brazil?**

- Import license requirements
  - Pitfalls – Quantity and unit of measure must match exactly to shipment. Otherwise, product could be held in customs indefinitely
- High Vat/Customs rates
- Average cycle time from shipment to customs clearance 5-7 days
- Importers of Record must be electronically registered



– Who will be your importer of record – Sponsor, CRO, carrier?





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**How does the cycle time for shipping drug - once at a depot in country - vary in Brazil versus other parts of the world? Does this cycle time affect shipping configurations, especially for temperature controlled shipments?**





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## Q & A







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India Challenges and Solutions

## PRIMARY QUESTIONS





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**What are the unique import and export regulations in India, including duties, taxes, and other potential challenges? What is the typical timeline to get drug into India?**

- Long cycle time to obtain Import license (average 12-14 weeks), although could take 6-8 weeks
- Usually valid for a year or six months
- Extensive paperwork required
- Usually shipped to local depot
- VEC letter required
- NOL is quantity based
- Customs generally quick turnaround (2 days)





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How does the cycle time for shipping drug - once at a depot in country - vary in India versus other parts of the world? Does this cycle time affect shipping configurations, especially for temperature controlled shipments?

- DCGI must approve labels and witness any relabelling. This make exp update very difficult
- Calcutta needs separate NOL





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## Q & A





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Other Emerging Markets

## PRIMARY QUESTIONS







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What are some of the countries on the next frontier of emerging markets (e.g., what is the next China, India, and Brazil)? What unique challenges are companies facing in these markets?

- Russia
  - Import duties and VAT variability and changes
  - Local depot is necessary
- Ukraine
  - Import duties and VAT variability and changes





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## Q & A





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## CLOSING REMARKS





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**What final, key takeaway messages do you have for the audience in 30 seconds or less?  
Any topics that we did not have time to cover?**





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## Q & A







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# THANK YOU

