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Manufacturing in Emerging Markets; Opportunities and Challenges

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Serving Patients is a Privilege

This Privilege Comes With Significant Responsibilities

The Opportunity of Emerging Markets to Serve Patients

China #3
- Biotech has replaced auto industry as key focus in country's 5-year plan

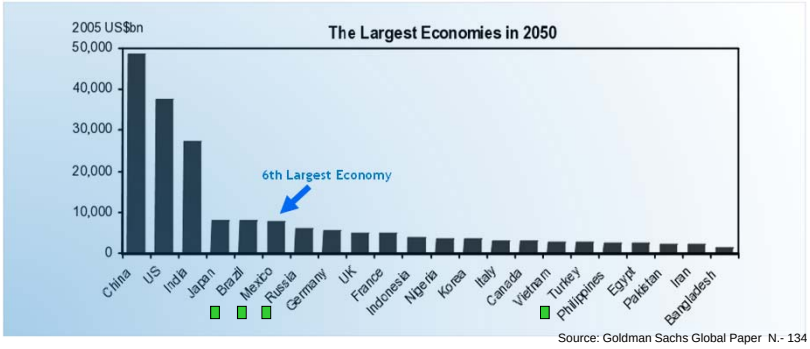
Mexico #6
- Projected to be the 6th largest economy in 2050
- Population of 107M people

Brazil #7
- Investment in universal coverage for 200M people

Russia #11
- Health care agenda 2020 seeking to improve low life expectancy

IMS ranking based on 2010 pharma spends

Mexico's Profile is Similar to Other Markets Expected to Grow Significantly Over Time



Source: Goldman Sachs Global Paper N.- 134

Demographic	Mexico	Brazil	Russia	Turkey
Population (M)*	107	190	142	72
GDP p.c.*	$9,700	$6,900	$9,000	$11,400
Health spend p.c.*	$725	$755	$560	$590
Pharma spend**	$11-12B	$32-40B	$18-22B	$18-22B
'07-'13 CAGR**	6-9%	8-11%	14-17%	14-17%

* WHO ** IMS

Challenges of Emerging Markets

1. Reimbursement/Pricing Squeeze
2. Unique local requirements
3. Current manufacturing models do not work
4. Robust and reliable supply chain

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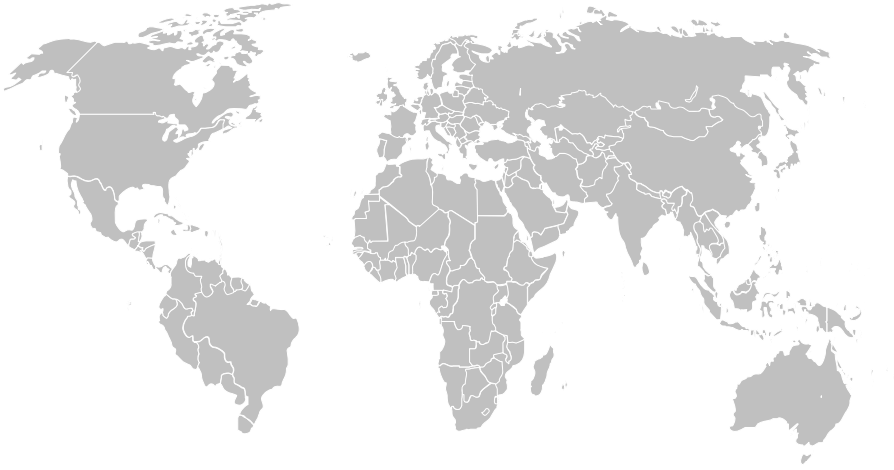
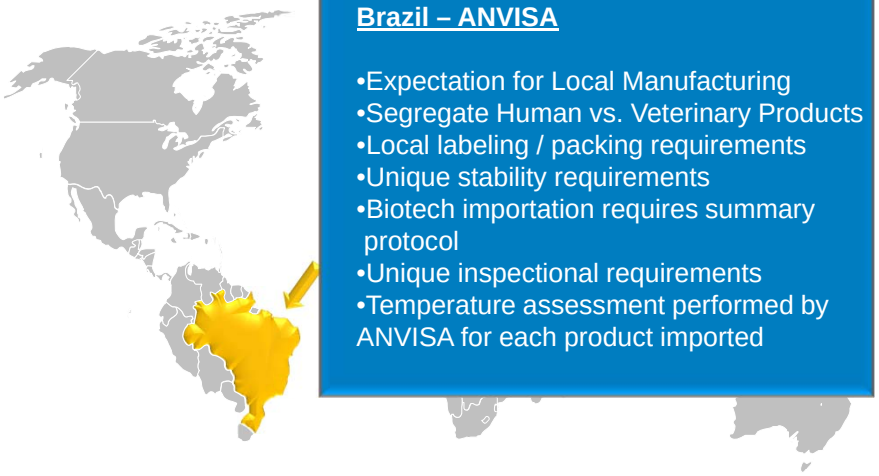
Unique Local Requirements



Unique Local Requirements- Brazil



Brazil – ANVISA

- Expectation for Local Manufacturing
- Segregate Human vs. Veterinary Products
- Local labeling / packing requirements
- Unique stability requirements
- Biotech importation requires summary protocol
- Unique inspectional requirements
- Temperature assessment performed by ANVISA for each product imported

Unique Local Requirements- China

China – CFDA

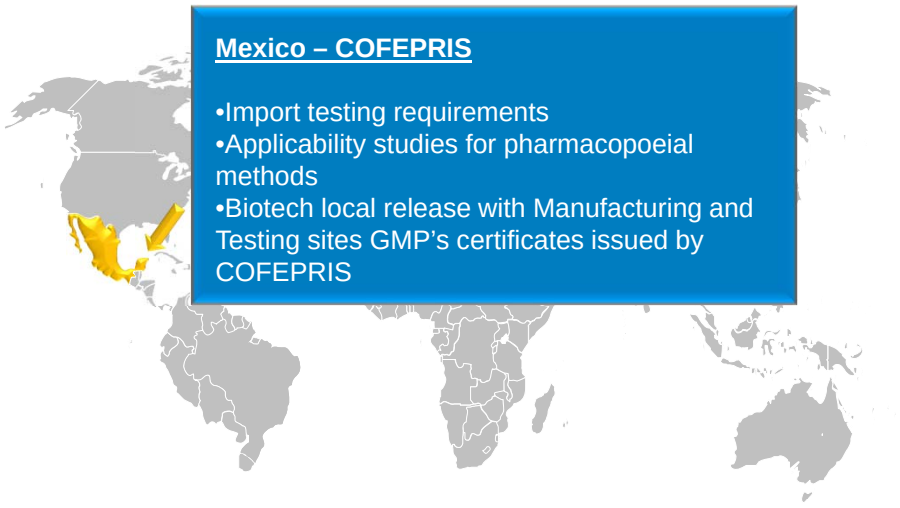
- Expectation for local manufacturing of DS
- Requirements for training on Chinese GMPs
- Restriction on alternative site outside of China
- NIFDC testing of all commercial biological lots prior to release
- Local labeling / packaging requirements

Unique Local Requirements- Russia

Russia

- Expectation for local manufacturing
- Multiple regulatory authorities are involved in registration process
- In country testing requirements from accredited lab
- Regulatory requirements can change quickly with new administrations
- Must reference Russian Pharmacopeia
- Local labeling / packaging requirements

Unique Local Requirements- Mexico



Mexico – COFEPRIS

- Import testing requirements
- Applicability studies for pharmacopoeial methods
- Biotech local release with Manufacturing and Testing sites GMP's certificates issued by COFEPRIS

Are New Technologies the Key to Success for Manufacturing in EM?

Are Communication Technologies Required to Enhance Tech Transfer and Process Monitoring Required?

REMOTE COLLABORATION	REMOTE SENSING	REMOTE VISUALIZATION
Networked, mobile audio-visual tools for high quality global communication between staff	Real-time global network access to operational system parameters	Network cameras embedded within production equipment

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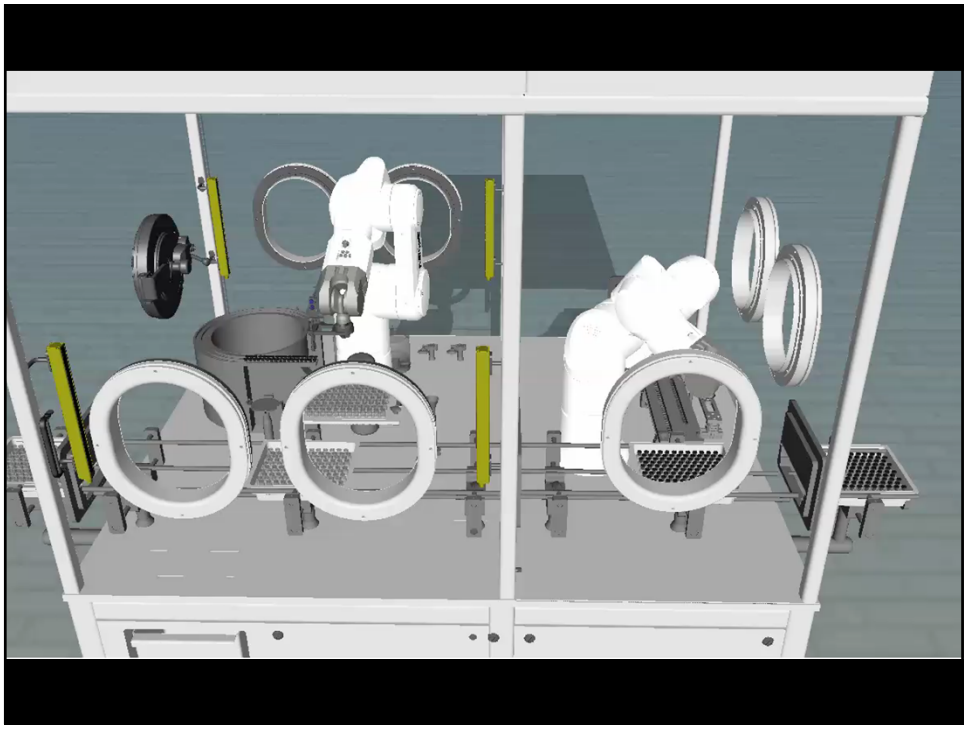

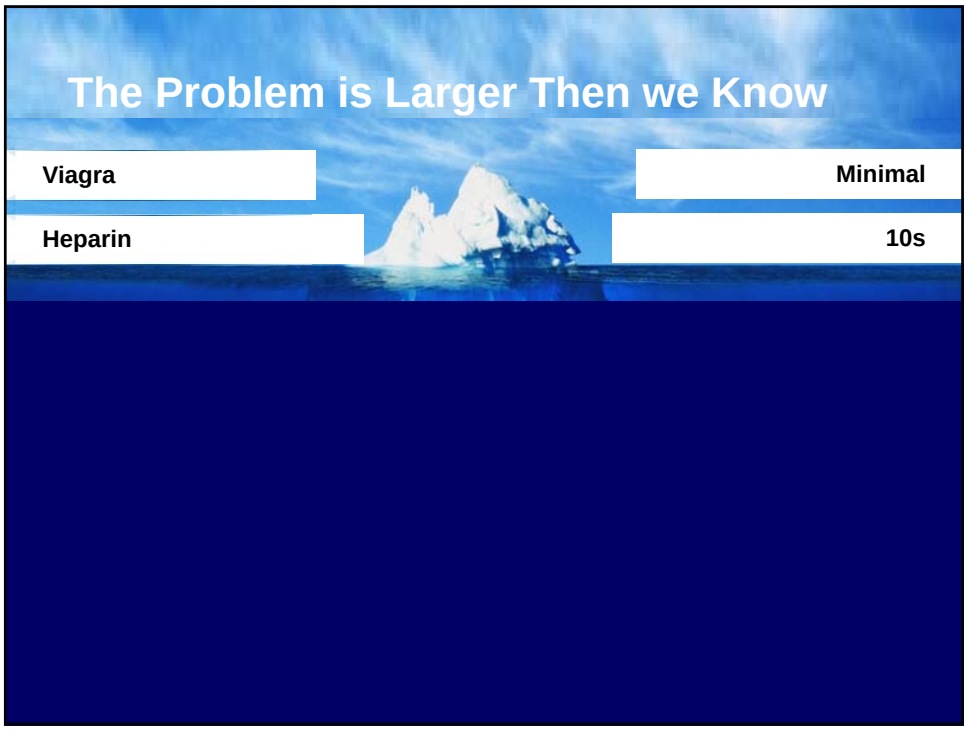
The Problem is Larger Then we Know
Viagra
Minimal
Heparin
10s

Illicit Activity Impacts All Stages of the Supply Chain From…

- Raw materials
- Excipients
- APIs
- Components
- Drug Products
- Packaging & Labeling
- Storage
- Distribution
- Anti-Counterfeiting Technologies

Illicit Activity is Present and Threatens the Safety of Medicines

$1,000 → Counterfeit DVDs → $10,000

Illegal drugs → $100,000

Falsified medicine → $1,000,000

- Criminals are sophisticated
- Weak criminal penalties
- Relatively safe for criminal
- Benign Consumer

Fake Drugs: Causes, Consequences, and Possible Solutions, American Enterprise Institute for Public Policy Research, Roger Bate, Harvard Medical School, March 03, 2010
http://www.aei.org/speech/100125

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To Secure the Supply Chain…Speed up timing

1. Use common sense
2. Embrace best practices
3. Adopt advanced technologies
4. Always collaborate

You know something is worth the effort if it is easy to say but hard to do…

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A Comprehensive Approach is Required to Preventing Drug Shortages

Prevention
- Compliance with cGMP and a robust quality management system
- Operational Excellence
  - Right First Time
- Supply Chain security
- Infrastructure investments
- Business continuity planning

Technology
- Enhance product and process robustness
- Greater focus on characterization
  - Investment in technology
    - Nuclear magnetic resonance
    - HTST (High Temperature Short Time) sterilization
    - Isolators

Inventory
- Quantity of material
- Stage of manufacturing
- Storage location

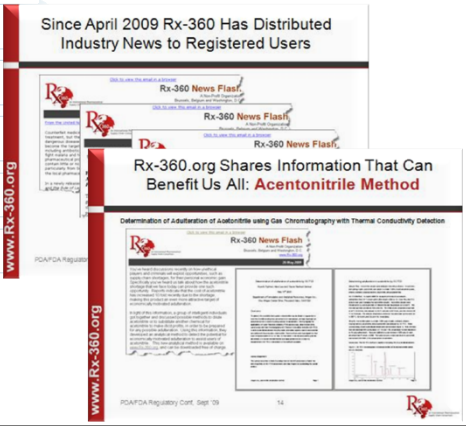
Diversification
- Implement back-up manufacturing capabilities (diversification)
- Enhance existing contract manufacturing capabilities

These four levers are not mutually exclusive and each has an impact on risk, cost, and flexibility

Collaboration is a Game Changer…
Rx-360 Provides that Opportunity

Protect patient safety by sharing information and developing processes related to the integrity of the healthcare supply chain and the quality of materials within the supply chain

1. Educating
2. Sharing Information
3. Standardizing
4. Promoting Best Practice
5. Sharing Audits



Serving Patients Is a Privilege…

We Must Be There For Every Patient, Every Time