Supply, Capacity and Quality in the Virtual Pharmaceutical Supply Chain

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President and CEO
TraceLink Inc.
TraceLink is revolutionizing the Life Sciences Business Network by bringing point and click collaboration and information exchange to teams working across multiple enterprises.
Session Topics

- Factors driving the shift from a vertical business model to a virtual execution model
- Business issues and operational challenges created as production is outsourced
- Taking a network approach to life science supply collaboration
- The required collaborative business network architecture for visibility, accountability and control
- Opportunities to improve supply, capacity and quality control in a collaborative supply network
Supply, Capacity, Quality Issues
Out of Stocks

New Drug Shortages (US)

- Product Quality
- Shipment Delays / Capacity Constraints
- Discontinuation
- Raw Materials (API) Issues
- Loss of Manufacturing Site
- Component Problems / Shortage

Source: University of Utah Drug Information Service
Supply, Capacity, Quality Issues

Product Recalls

Product Recalls in US

- Manufacturing (temp, contaminants)
- Manufacturing (cGMP)
- Packaging Issue (labeling)
- Adverse Event

*Through 2Q2011

Source: FDA

*Not including Advantage Dose recall
Supply, Capacity, Quality Issues
Globalization and Diversification of Demand

Global Demand

<table>
<thead>
<tr>
<th>Region</th>
<th>2005</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>US / Canada</td>
<td>43%</td>
<td>33%</td>
</tr>
<tr>
<td>Europe</td>
<td>27%</td>
<td>19%</td>
</tr>
<tr>
<td>Japan / S. Korea</td>
<td>12%</td>
<td>13%</td>
</tr>
<tr>
<td>Pharmerging (Brazil, Russia, India, China)</td>
<td>12%</td>
<td>19%</td>
</tr>
<tr>
<td>Rest of World</td>
<td>6%</td>
<td>7%</td>
</tr>
</tbody>
</table>

$605B $1,080B

Product Type Demand

<table>
<thead>
<tr>
<th>Type</th>
<th>2005</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brand</td>
<td>70%</td>
<td>53%</td>
</tr>
<tr>
<td>Generics</td>
<td>20%</td>
<td>39%</td>
</tr>
<tr>
<td>OTC / other</td>
<td>10%</td>
<td>8%</td>
</tr>
</tbody>
</table>


Source: IMS Market Prognosis May 2011
### Regulatory Actions

<table>
<thead>
<tr>
<th>Year</th>
<th>Country(s)</th>
<th>Regulation/Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>US, Italy, Belgium, Greece, Turkey</td>
<td>Pre-existing regulations in force</td>
</tr>
<tr>
<td>2011</td>
<td>US FDA</td>
<td>Track and Trace Workshop</td>
</tr>
<tr>
<td>2011</td>
<td>France</td>
<td>CIP13 labels; 2D barcode</td>
</tr>
<tr>
<td>2011</td>
<td>EU</td>
<td>Serialization directive vote</td>
</tr>
<tr>
<td>2011</td>
<td>Turkey</td>
<td>Phase 2 full aggregation</td>
</tr>
<tr>
<td>2011</td>
<td>India</td>
<td>Export barcoding; Domestic serialization guidance</td>
</tr>
<tr>
<td>2012</td>
<td>China</td>
<td>Phase II Essential Drug List</td>
</tr>
<tr>
<td>2012</td>
<td>UK</td>
<td>NHS supplied products with GS1 identifier on package</td>
</tr>
<tr>
<td>2012</td>
<td>Canada</td>
<td>GTIN-based labeling</td>
</tr>
<tr>
<td>2012</td>
<td>Brazil</td>
<td>Reg 11.903 serialization (expected)</td>
</tr>
<tr>
<td>2012</td>
<td>South Korea</td>
<td>KDC labels on all Rx (except orphan drugs)</td>
</tr>
<tr>
<td>2013</td>
<td>Canada</td>
<td>National Product Registry live</td>
</tr>
<tr>
<td>2013</td>
<td>China</td>
<td>All locally produced drugs (expected)</td>
</tr>
<tr>
<td>2014</td>
<td>US</td>
<td>CA Phase 1</td>
</tr>
<tr>
<td>2014</td>
<td>EU</td>
<td>Serialization implementation across members states</td>
</tr>
<tr>
<td>2015</td>
<td>US</td>
<td>FDA (expected)</td>
</tr>
<tr>
<td>2016</td>
<td>Canada</td>
<td>National Product Registry live</td>
</tr>
</tbody>
</table>

### Industry Requirements

<table>
<thead>
<tr>
<th>Year</th>
<th>Country(s)</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>Italy, Belgium, Greece</td>
<td>Gov't reporting</td>
</tr>
<tr>
<td>2011</td>
<td>France</td>
<td>Gov't authentication</td>
</tr>
<tr>
<td>2011</td>
<td>Turkey</td>
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</tr>
<tr>
<td>2012</td>
<td>China</td>
<td>Gov't authentication</td>
</tr>
<tr>
<td>2012</td>
<td>Brazil</td>
<td>Gov't reporting</td>
</tr>
<tr>
<td>2013</td>
<td>Canada</td>
<td>Product registry synchronization</td>
</tr>
<tr>
<td>2013</td>
<td>CA</td>
<td>Product serialization and ePedigree</td>
</tr>
<tr>
<td>2014</td>
<td>EU</td>
<td>EQDM authentication</td>
</tr>
<tr>
<td>2015</td>
<td>FDA</td>
<td>Authentication</td>
</tr>
</tbody>
</table>
The Result: Complexity and Risk in the Supply Chain Strategy, Planning and Execution

What Issues Impact Your Supply Chain Strategy, Planning and Execution?

- More products being produced in smaller lots and shorter production runs (58%)
- Increased product line complexity due to targeted therapies and new markets (66%)
- Increased operational / IT complexity due to mergers, acquisitions and inherited programs (71%)
- Increased packaging complexity due to regulations, serialization and other mandates (76%)
- Greater risk due to globalization of supply (78%)

Source: 1st Annual NC State / TraceLink Executive Study on Supply Network Performance in Life Sciences

Tight cash flow is all well and good when you have high forecast accuracy and consistent demand. But, in the last 5 years, our portfolio has increased to ten different SKUs per product line with massive expansion into new markets that have poor forecast accuracy and considerably smaller sales volumes.

Top 10 PharmaCo
Outsourced Production is Growing in Response
Flexible Capacity, Market Access, Increased Capabilities

By 2012, 32% of pharmaceutical manufacturing output is expected to be produced by third parties.

Hussain Mooraj – Managing VP

* Expected Contract Manufacturing CAGR (11%) is 3x that of Rx (3.5%)

Source: PharmSource research (2010 numbers)
Availability of Timely and Accurate Data for Outsourced Production Management is Lacking

The reality today is that manufacturing and supply chain process data is infrequently shared.

Level of Information Sharing in the Supply Network

- Production Status
- Incident and Change Control Quality Items
- Batch Record Rev Status
- Inventory
- Production Forecasts
- API/RM Supply PO's
- Material Receipt Conf.
- Production PO's
- Advance Ship Notices
- Invoice Tracking

Percent of Partners Receiving/Sending Frequent Data Updates

Source: 1st Annual NC State / TraceLink Executive Study on Supply Network Performance in Life Sciences
As a result, there is a significant barrier to supply network collaboration across the industry. Process and Transaction Collaboration is Limited. Source: 1st Annual NC State / TraceLink Executive Study on Supply Network Performance in Life Sciences.
Ensuring Supply, Capacity and Quality Requires a Network Approach

- Dozens of interconnected processes (orders, production runs, quality reviews, inventory management, distribution...)
- Between tens of thousands of companies (material suppliers, CMO/CPO, pharma/bio, distributors, pharmacies/clinics...)
- With data flowing between millions of links (forecasts, orders, production status, inventory levels, product flows, ID authentications...)
- For billions of products moving between nodes (pharmaceuticals, OTC drugs, clinical kits, bulk materials, packaging supplies...)

The right approach must be easy to adopt, support interoperability and enhance business process collaboration.
Approaches for Improving Supply Network Connectivity and Collaboration

1. Add More People
   - Poor integration with core systems
   - Manual data entry
   - Low data exchange frequency
   - No collaborative view
   - Labor intensive

2. Push Data into Portals
   - Partial integration with core systems
   - Manual data entry
   - Low data exchange frequency
   - No collaborative view
   - Increased partner complexity, work

3. Expand Point-to-Point Integration
   - Integrated with core systems
   - Complex, translated data integration
   - High exchange frequency
   - No collaborative view
   - IT intensive (per-partner setup, mgmt)

4. Integrate Once With a Business Network
   - Integrated with core systems
   - Native data integration
   - High exchange frequency
   - Collaborative view
   - Single set-up, self-managed
The Required Collaborative Business Network Architecture

Connectivity • Visibility • Collaboration • Measurement

1. Simplifying integration to a company’s entire business network through a single connection
2. Interoperable Information
3. Multi-Enterprise Collaboration
4. Real-Time Analytics

- Providing real-time analysis of all product, production and channel performance
- Enabling virtual teams from multiple companies to collaborate across business activities
- Delivering visibility and timely business data for a company’s business network activities
- Simplifying integration to a company’s entire business network through a single connection
The Collaborative Architecture Provides Monitoring, Measurement and Control of Outsourced Production

Life Science Company

Collaborative Supply Network Dashboard

Collaborative Team Workspaces

On-time Delivery  Prod. cycle time  Instrumented KPI Dashboards  Right-first-time  Inv. levels, expiry

Production  Materials  Integrated Business Processes  Quality  Inventory

Notes  Connected Communication Trail  Docs

IDoc  QDoc  Integrated Data Exchange  X12  XML

CMO-US  CMO-EU  CPO

FluMed fm1234 fm4567 122 276889 PharmaCo CMO-US
FluMed fm4567 122 276889 CMO-US

AllergyMed am1234 am4567 122 276889 PharmaCo CMO-EU
AllergyMed am4567 122 276889 CMO-EU

SleepMed sm1234 sm4567 122 276889 PharmaCo CPO
SleepMed sm4567 122 276889 CPO

CMO-US 92.5%
CPO 96.6%
A Collaborative Business Network Improves Control Over Supply, Capacity and Quality

Estimated % Improvement with a Collaborative Supply Network

- Manual Data Entry: 41%
- Order Fluctuation Response: 31%
- Customer Satisfaction: 30%
- Inventory Reduction: 27%
- Stockout Reduction: 26%
- On-time in full Working Capital Improvement: 41%
- Production Cycle Times: 31%
- Batch Record review: 30%
- Right time first quality: 27%

Source: 1st Annual NC State / TraceLink Executive Study on Supply Network Performance in Life Sciences
Supply Collaboration Equals Direct Financial Gain

Example: Quality Review Collaboration for One Product Line

Better Visibility into Current Batch Record Review Status

Reduced Delay in Reviewing and Approving Documents

Faster Product Release

Greater Production Capacity Available

One Extra Product Batch Produced / Month

=$9M Additional Revenue (yr)
TraceLink Network
Network Application for Connection, Data Sharing and Collaboration

Supply Partners
Life Science Partners
Distribution Partners

KPI Dashboard: On-Time Delivery, Order Fulfillment Cycle Time, Avg. Inventory Levels, Right-First-Time...

Collaboration: User-Managed Workspaces, Notes, Documents, Alerts, Free Text Search...

Business Objects: POs, Work Orders, Materials, Production Status, Inventory, Quality, Serialization, ePedigree...

Transactions: XML, SAP IDoc/SNC, EDI (X12, EDIFACT), QAD QDoc, CSV, EPCIS Events...

- Information exchange platform providing single point of integration, transaction management and data sharing for all supply relationships
- Integrated, cross-linked business objects providing visibility across the production lifecycle and throughout the distribution channel
- Collaborative workspaces connecting users, improving communications and providing access to data on status, activities and performance
- Per-partner KPI dashboards providing real-time information about on-time delivery, production cycle time, etc.

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Questions