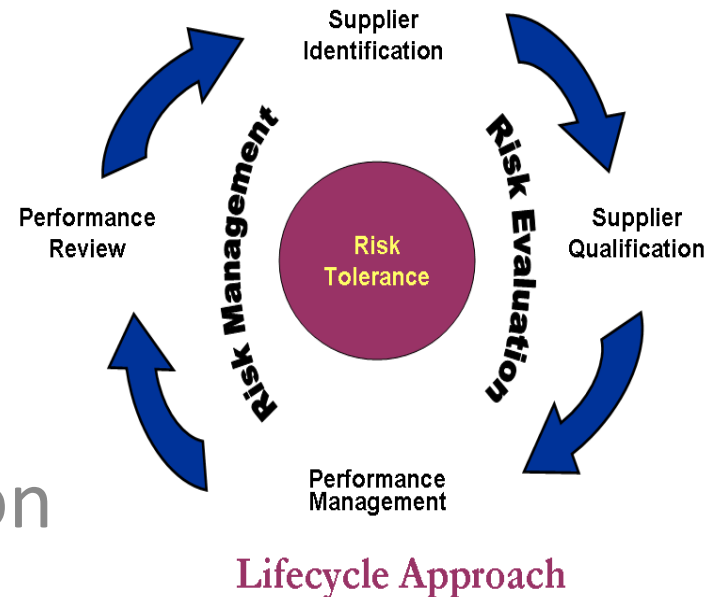


Management of the Supply Chain: Excipients & APIs



Janeen Skutnik-Wilkinson
Director, Quality Strategy
Pfizer

1.8 Quality Manual/Quality Policy

- Pfizer has integrated much of the supply chain Quality elements into its Quality Manual

1.6 Knowledge Management

- How is this concept applied with regard to the upstream supply chain?
 - Supplier Identification and Selection
 - Acquiring knowledge about suppliers, their systems, how they qualify their suppliers
 - Enterprise System for global sharing of suppliers and supplier qualification information
 - Routine monitoring of suppliers
 - Ongoing review of systems, audits, inspections
 - Business intelligence searches for Key Indicators of performance

1.6 Knowledge Management (cont'd)

- Monitoring and engaging in the External Environment
 - Reviewing current events, trends in markets, political regions and extrapolating to potential areas of risk for the company
 - Working with companies, trade associations, professional organizations, governments etc on the gathering and interpreting of knowledge pertaining to the supply chain
 - Usage of on line tools to gather data and information on items that may impact supply chain
 - Google Alerts
 - News reports
 - Trade Press

Melamine Case Study

- >8,000 Pets were killed from Melamine Contaminated Pet Food
- At least 5 infants died from melamine contaminated infant formula
- Melamine intentionally added to boost protein content
- Vulnerabilities in supply chain
 - Transparency/traceability
 - Lack of full knowledge of suppliers/GMPs/GDPs
 - Detection concerns

Melamine (2)

- While pharmaceutical industry was not immediately impacted, same risk was there
- Potential for similar effect, and devastating results
- Industry could not afford “another heparin”
- Case Study for Use of Knowledge Management, Management Responsibility and Management Review

Melamine (3)

- Summer 2008 (prior to FDA development of Melamine Guidance)
 - Based on evaluation of the issue and potential impact Pfizer instituted a company wide CAPA
 - Management notified of the issue and agreed with opening a CAPA
 - Looked at all materials that relied on nitrogen test to detect protein content
 - Assessed supply chain and vulnerabilities
 - Implemented appropriate measures to close gaps and secure supply chain

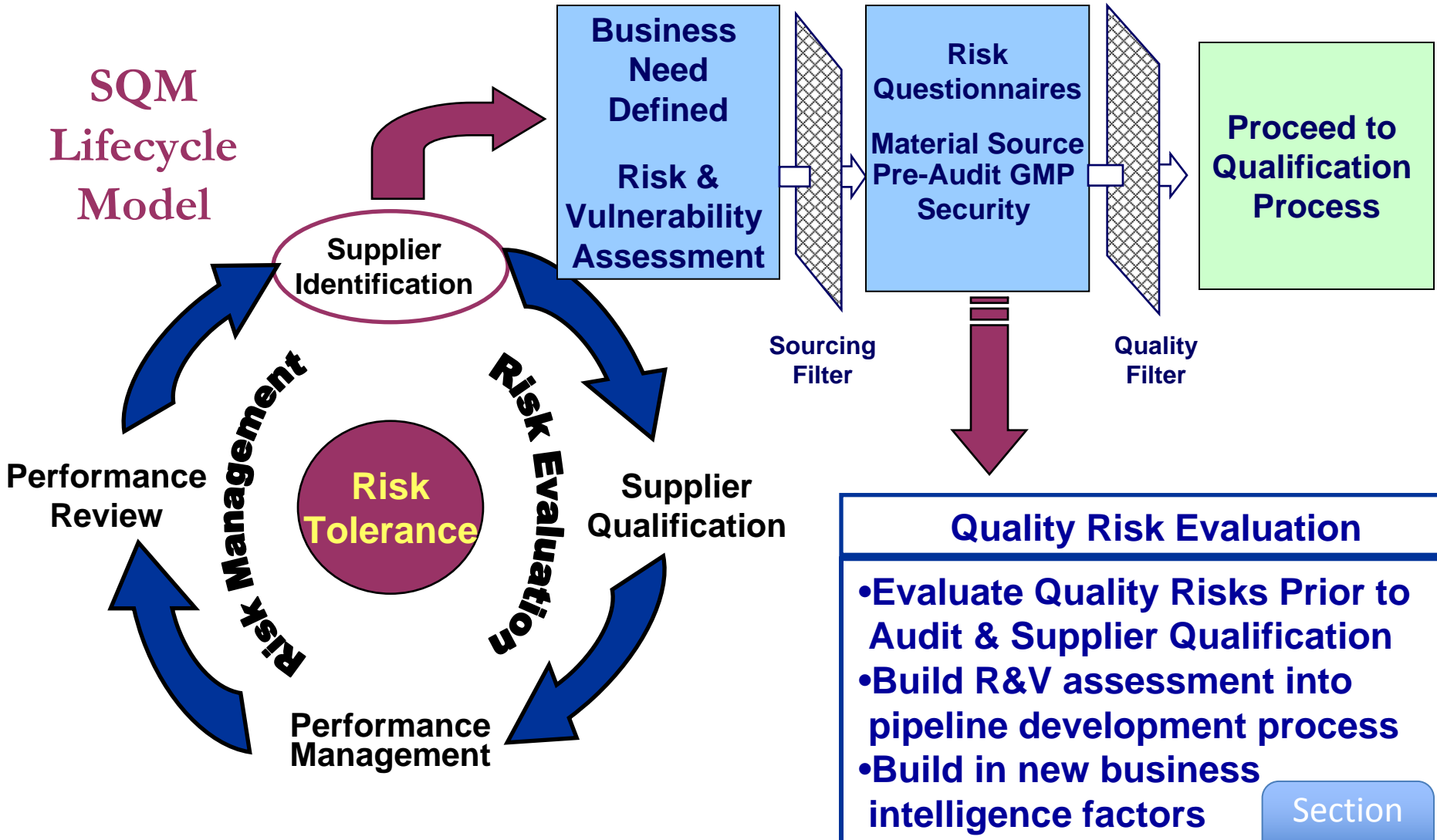
2.7 Management of Outsourced Activities and Purchased Materials

- (a) Assessing prior to outsourcing operations or selecting material suppliers, the suitability and competence of the other party to carry out the activity or provide the material using a defined supply chain (e.g., audits, material evaluations, qualification);
- (b) Defining the responsibilities and communication processes for quality-related activities of the involved parties. For outsourced activities, this should be included in a written agreement between the contract giver and contract acceptor;
- (c) Monitoring and review of the performance of the contract acceptor or the quality of the material from the provider, and the identification and implementation of any needed improvements;
- **(d) Monitoring incoming ingredients and materials to ensure they are from approved sources using the agreed supply chain.**

Supplier Identification Model

Pharmaceutical Quality System (ICH Q10) Conference
October 4-6, 2011 | Crystal Gateway Marriott | Arlington, Virginia
November 14-16, 2011 | Sheraton | Brussels, Belgium

**SQM
Lifecycle
Model**

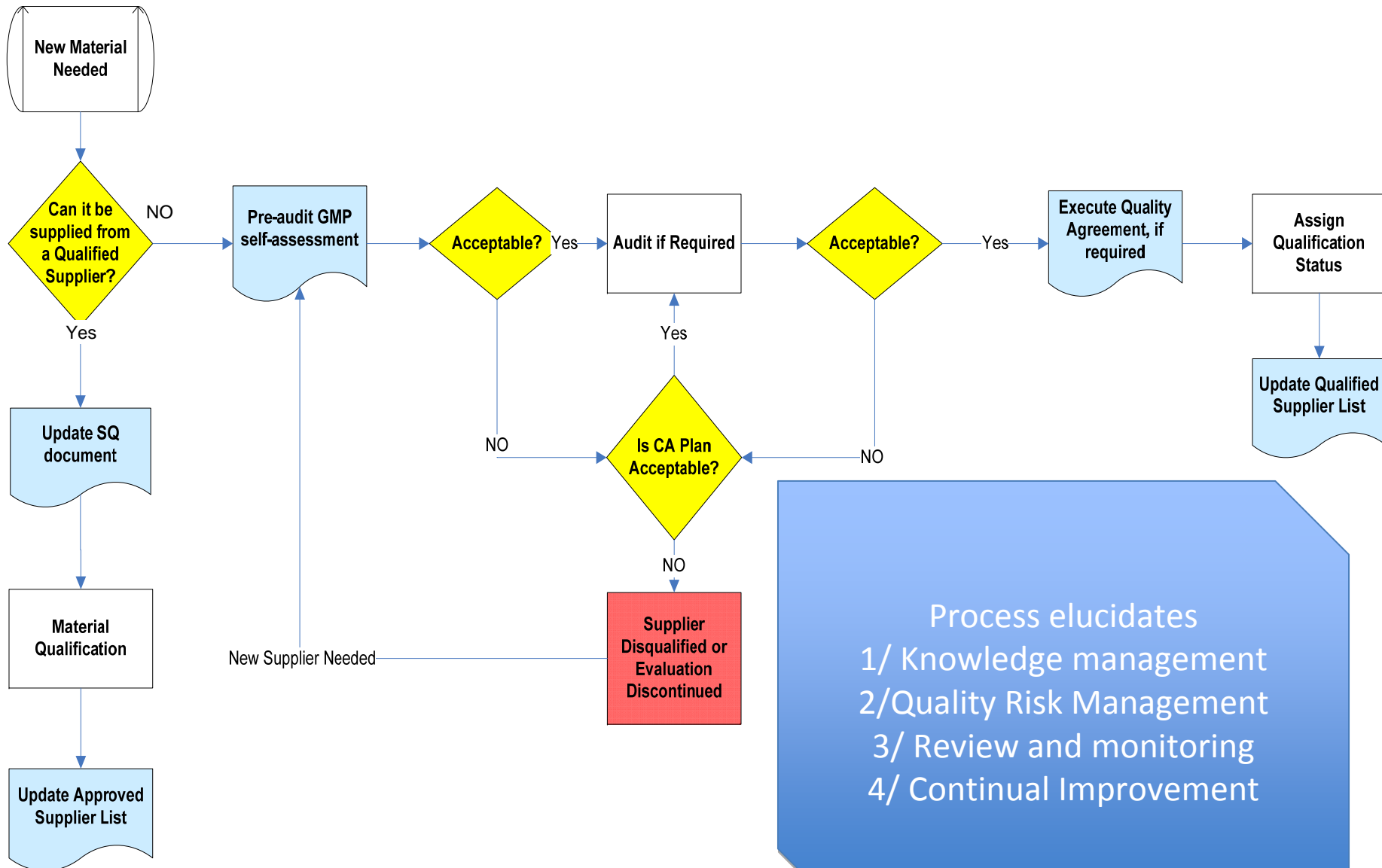


Slide courtesy of Londa Ritchey

Section
1.6.2

Supplier Qualification Process Flow

Pharmaceutical Quality System (ICH Q10) Conference
October 4-6, 2011 | Crystal Gateway Marriott | Arlington, Virginia
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Process elucidates
1/ Knowledge management
2/ Quality Risk Management
3/ Review and monitoring
4/ Continual Improvement

Slide courtesy of Londa Ritchey

Qualification Approach

Pharmaceutical Quality System (ICH Q10) Conference
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Material Qualification and Supplier Qualification - two separate, parallel paths

Supplier Qualification	Material Qualification
<ul style="list-style-type: none">• Lead Site Qualification of Supplier• Qualify Supplier Mfg. by location and material category (not each part #)• Qualify Distributors by the location and role as a Distributor• Shared SQ Summary Reports specify the category for which the supplier is Qualified• One SQ summary can be used to document qualifications of several material categories at the same Supplier location.	<ul style="list-style-type: none">• Each site qualifies materials for process use• Qualify each material part number• Each site maintains material qualification documentation• Each material part # added to site through change management process which should include check of SQ status.• Document the qualification of each material as separate studies• Includes evaluation of specific material supply chain from original mfg to user site

•SQ Summary Document:

- Evaluation of pre-audit risk information (consider cross-functional evaluation)
- Audit review
- CAPA Reviews
- Initiation of Quality Agreement
 - Supplier agrees to enter an agreement
- Review of performance history at User Site (for existing suppliers)

Supplier Qualification Status Declarations:

<p><u>Qualified</u> Supplier/Contractor has been evaluated and found to meet the Pfizer Quality Standards for Suppliers/Contractors</p>	<p><u>Conditionally Qualified</u> Exhibits performance concerns such as continued quality issues. Continued use of materials/services shall be justified through written risk assessment.</p>	<p><u>Disqualified</u> Deemed incapable or unreliable and shall no longer be used.</p>
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Suppliers with these status designations may be used

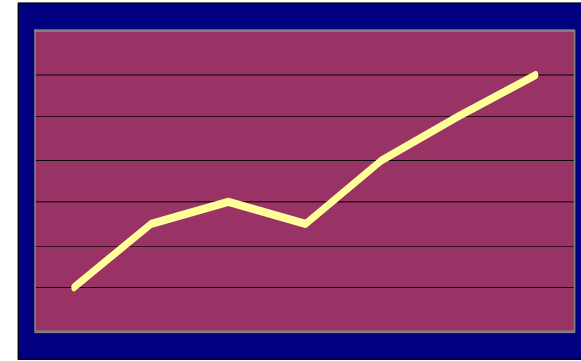


Supplier Quality Performance Monitoring and Q10

- Complaints
 - Timely and adequate responses
 - Identifying trends
 - 1.6 Knowledge Management
 - 3.2.4 Management Review
- CAPA
 - Proactive, preventative, timely
 - 3.2 PQS and 3.2.2 CAPA
- Change Management
 - 3.2 PQS and 3.2.3 Change Management
- Quality Notifications
 - Timely notice and Analysis
 - 2.6 Management Review
 - 3.2.4 Management Review
- Quality Agreement Conformance
 - 2.7

Supplier Qualification and Monitoring is more than just an audit!

Supplier Performance Review



3.2.4 Management review

- Management Review of Supplier Performance

Metrics/Trends

- Knowledge Management Approach to Supplier Re-assessment
- Qualification dependent on:
 - **Critical Quality Event (recall, safety concern)**
 - **Critical Audit Findings**
 - **Scheduled re-assessment frequency based on material category**
- Feedback to Supplier and Goal Setting (SRM) , Scorecard Review

**Allows for an enterprise wide scorecard of supplier,
based on all User Sites**

SCS Development

- Pfizer took a holistic systems approach to Supply Chain Security
 - In the definition of the issue
 - Cargo Theft & Diversion
 - Counterfeiting
 - Economically Motivated Adulteration
 - In development of a cross-functional team
- Used knowledge management, Management review, process performance, monitoring, continual improvement to create new function

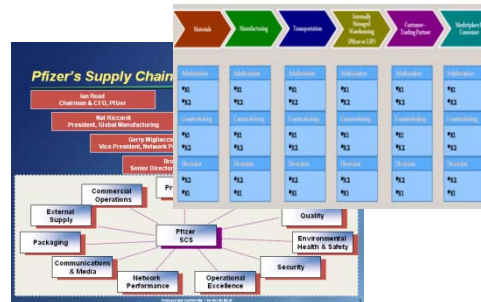
Understanding the threats

- What are the supply chain security threats and how big is the problem?
- What are the key components of the strategy?
- How will we define the supply chain?
- What regions around the world are impacted?



Current / Future State Mapping

- What organizations are involved?
- What are the key processes?
- How do we attack the problem holistically?
- How do our processes integrate?

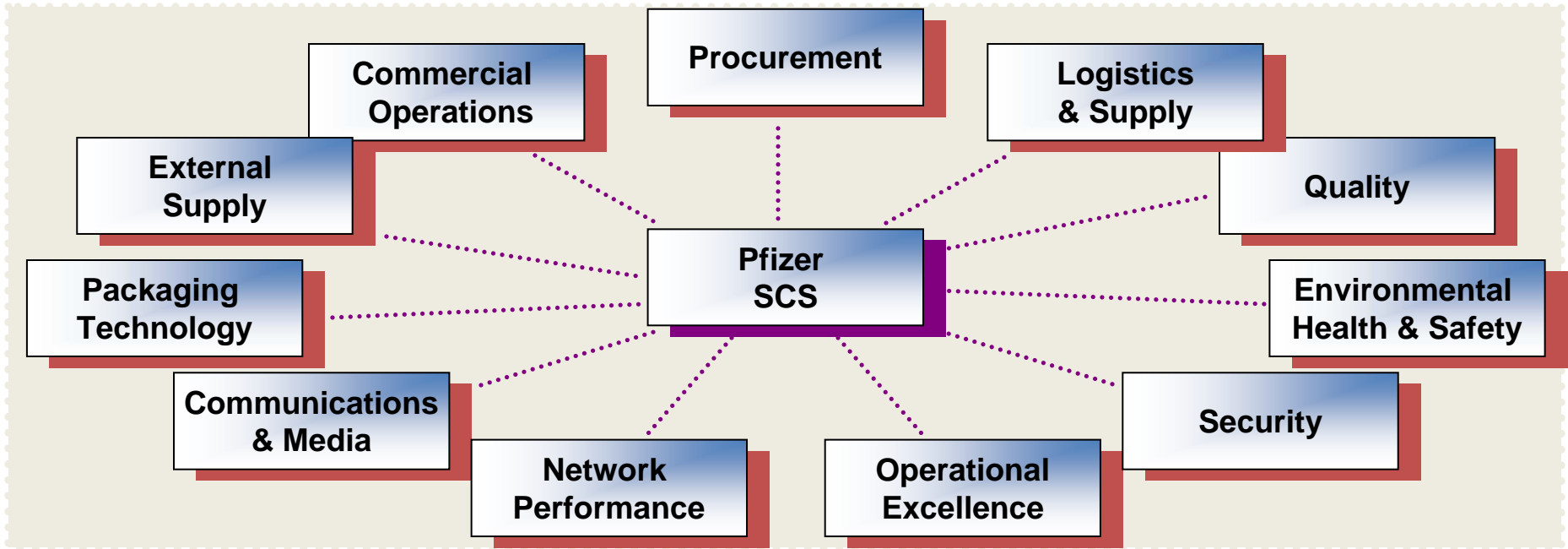
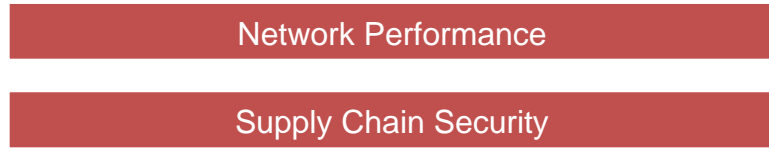


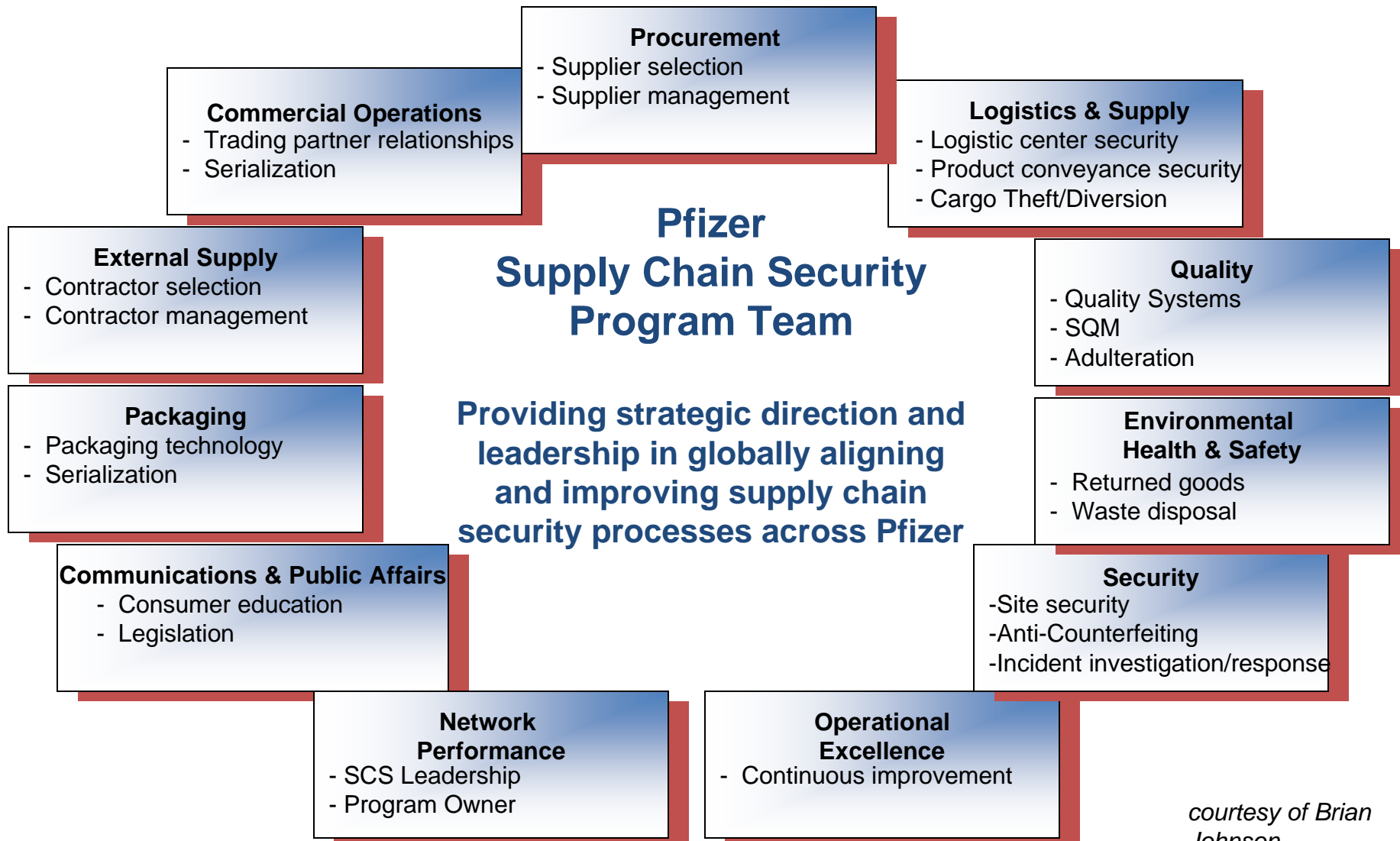
Developing the Strategy

- What is our future state vision?
- What are our opportunities for improvement?
- How do our processes need to change?
- How can we best deliver safe, authentic, and effective medicines to the consumer?



courtesy of Brian Johnson





courtesy of Brian Johnson

Conclusion

- ICH Q10 provides valuable information and guidance regarding Quality Systems that can be applied to many areas including Supplier Qualification, Management and Monitoring.
- The concepts in Q10 can be applied to assist in management of the supply chain with a focus on Quality and Quality Systems

Acknowledgements

- Londa Ritchey – Pfizer
- Brian Johnson - Pfizer