



Risk Management outside Your Four Walls: Implementing Risk Strategies for the Supply-Chain

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Agenda

- Looking at the challenges surrounding the Supply-Chain
- Understand the risks associated with Supply-Chain Compliance
- What is the Supplier Network and how does it impact operations?
- Identify the Gaps and Fillers the Supplier Network can control
- Understanding the Risk Management dynamic in the Supply Chain
- Tools for assessing risk in the Supply-Chain

Increasing Rate of Change



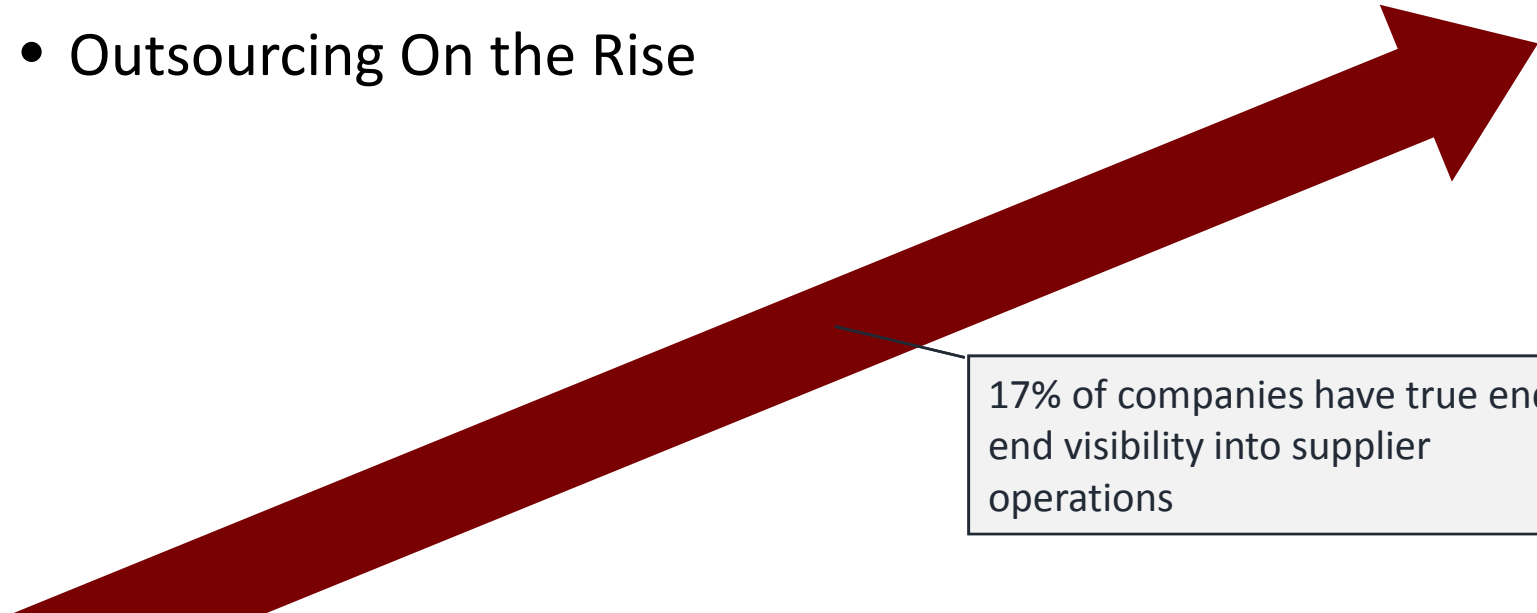
There is an Increasing Rate of Change

- We are more complex
 - Global Scale of Production, Design, Sourcing
 - More Mergers, Acquisitions
 - Growing Supply-Chain
- There is more competition
 - Competition leads to shorter product lifecycles
 - Increases in product complexity
 - More variety of goods in more areas
- Companies need to maintain compliance AND keep up with the pace of business!



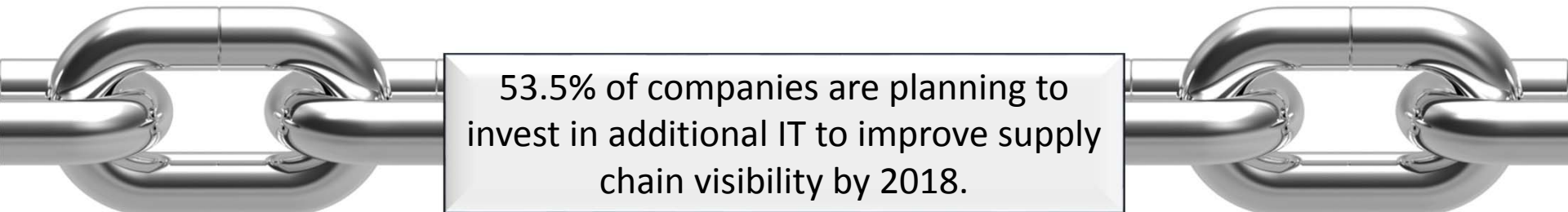
Challenges in the Supply Chain

- Outsourcing On the Rise



17% of companies have true end-to-end visibility into supplier operations

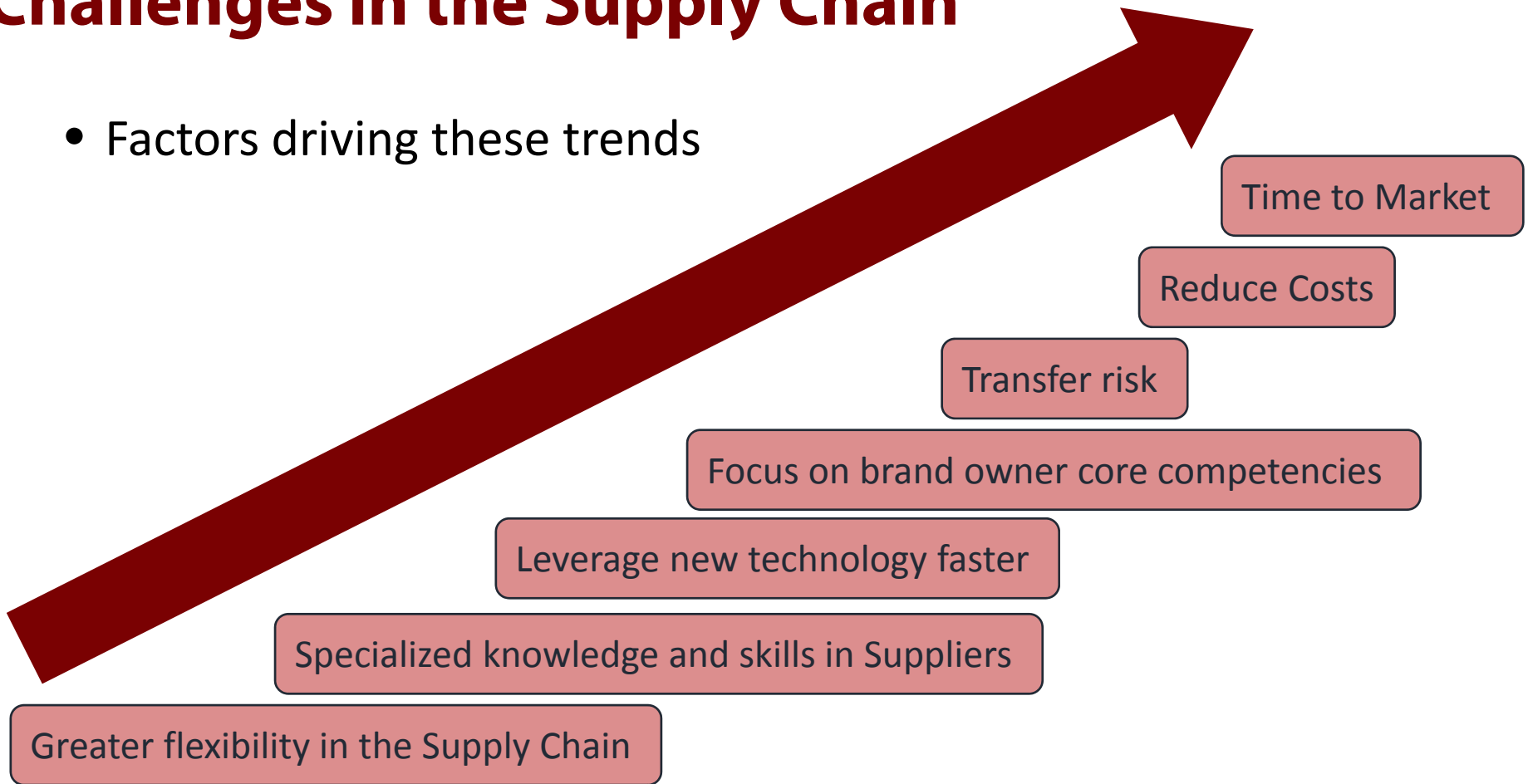
Just 25% of a typical company's end-to-end supply chain is being assessed in any way for risk.



53.5% of companies are planning to invest in additional IT to improve supply chain visibility by 2018.

Challenges in the Supply Chain

- Factors driving these trends



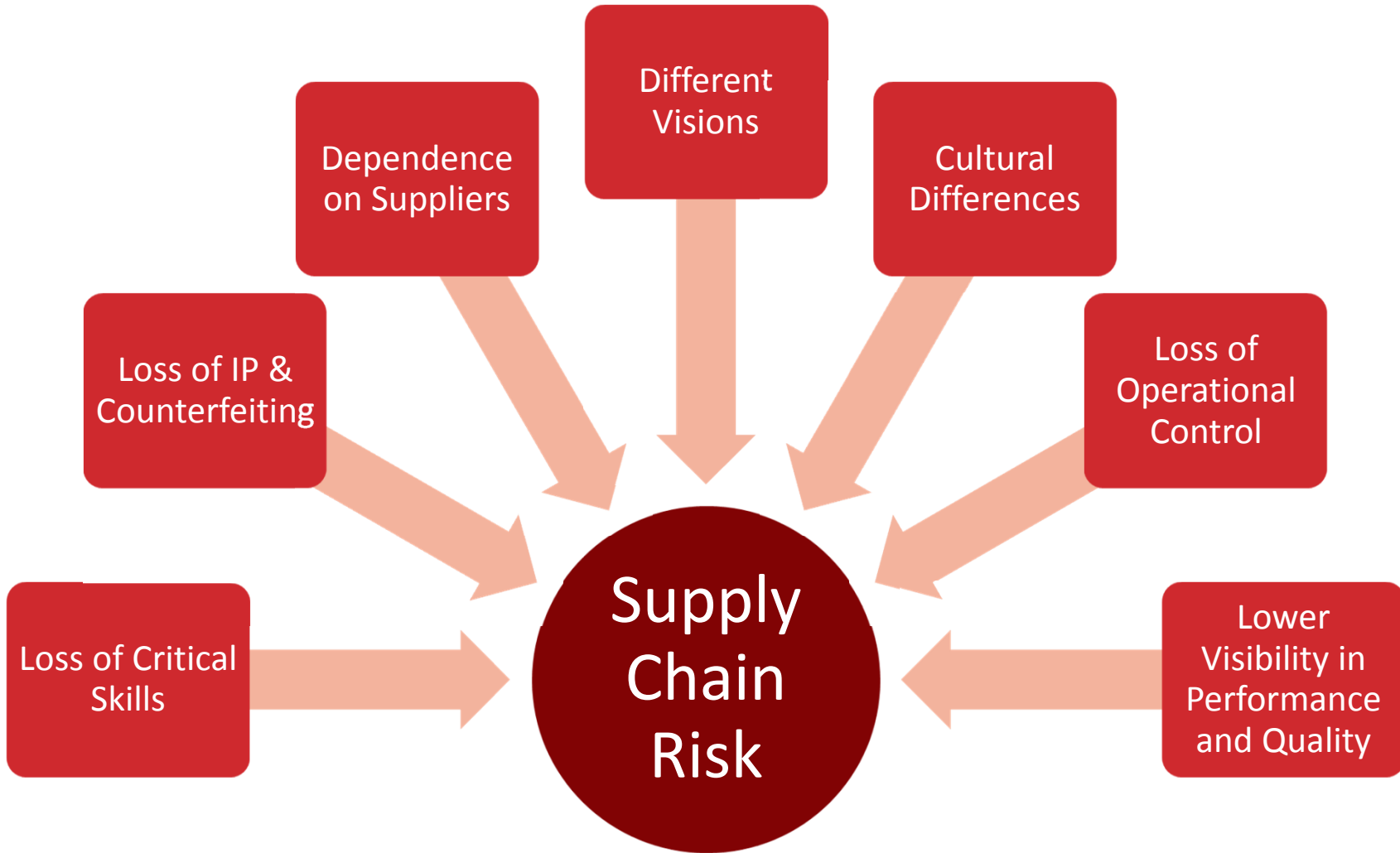
- Challenge: increased outsourcing creates new risks!

Challenges in the Supply Chain: Trends

- **The Internet of Things (IoT)**
- **Digitization of Data**
- **Shift to Big (but Usable) Data**
- **SCM Organizations Will Begin to Adopt Application Convergence Strategy**
- **Risk Management Comes to the Forefront**
- **Operations Planning and Inventory Optimization Go Under the Microscope**

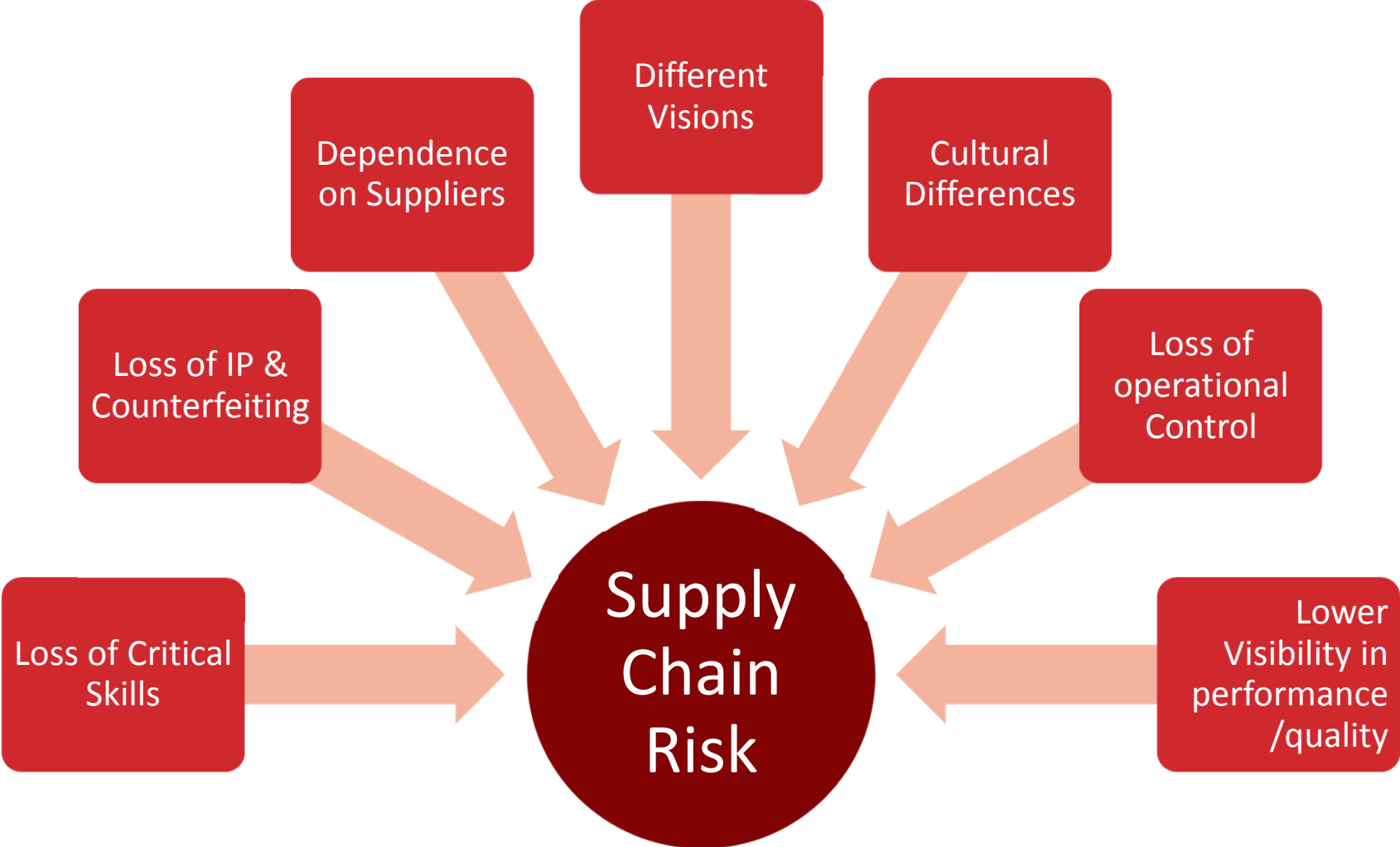
Challenges in the Supply Chain

- Risks Associated with the Supply Chain



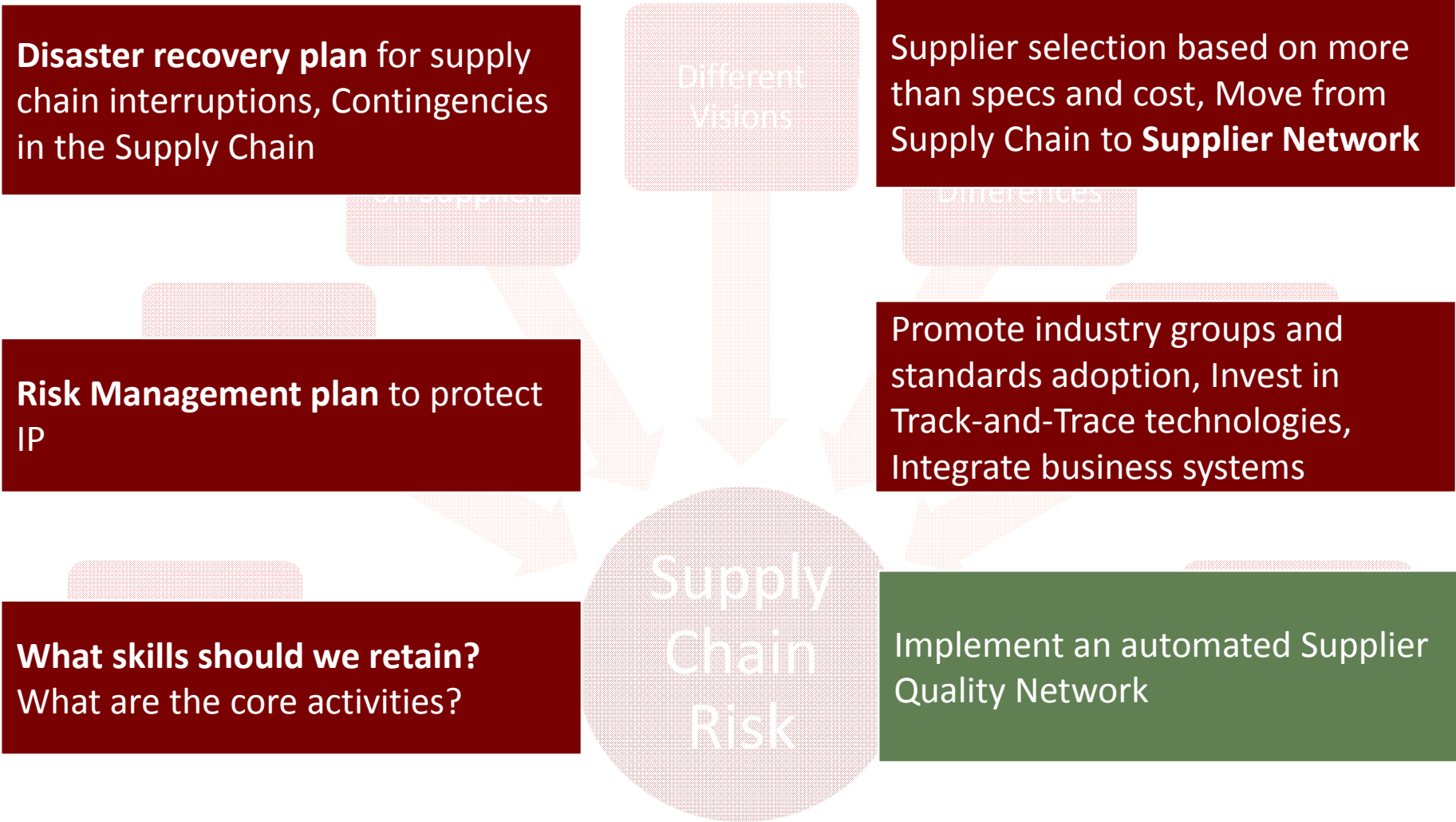
Challenges in the Supply Chain

- How can we mitigate Risk?



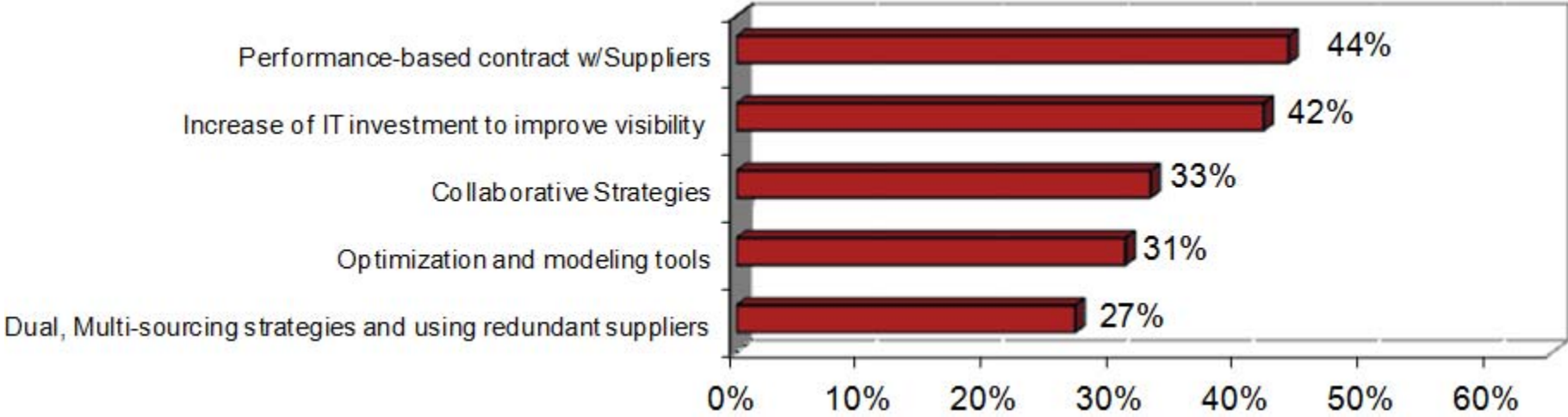
Challenges in the Supply Chain

How can we mitigate Risk?



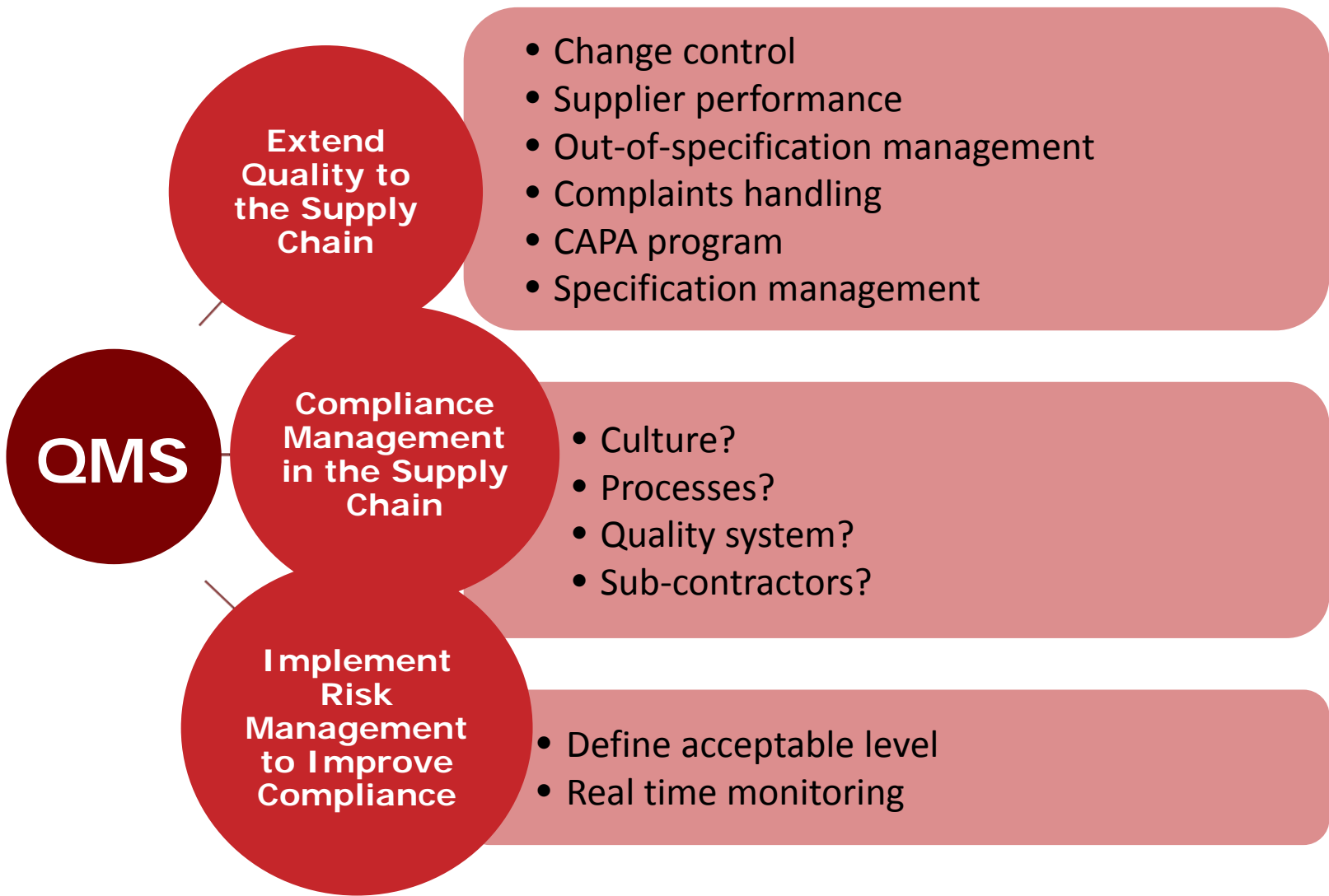
Challenges in the Supply Chain

- Top risk mitigating strategies



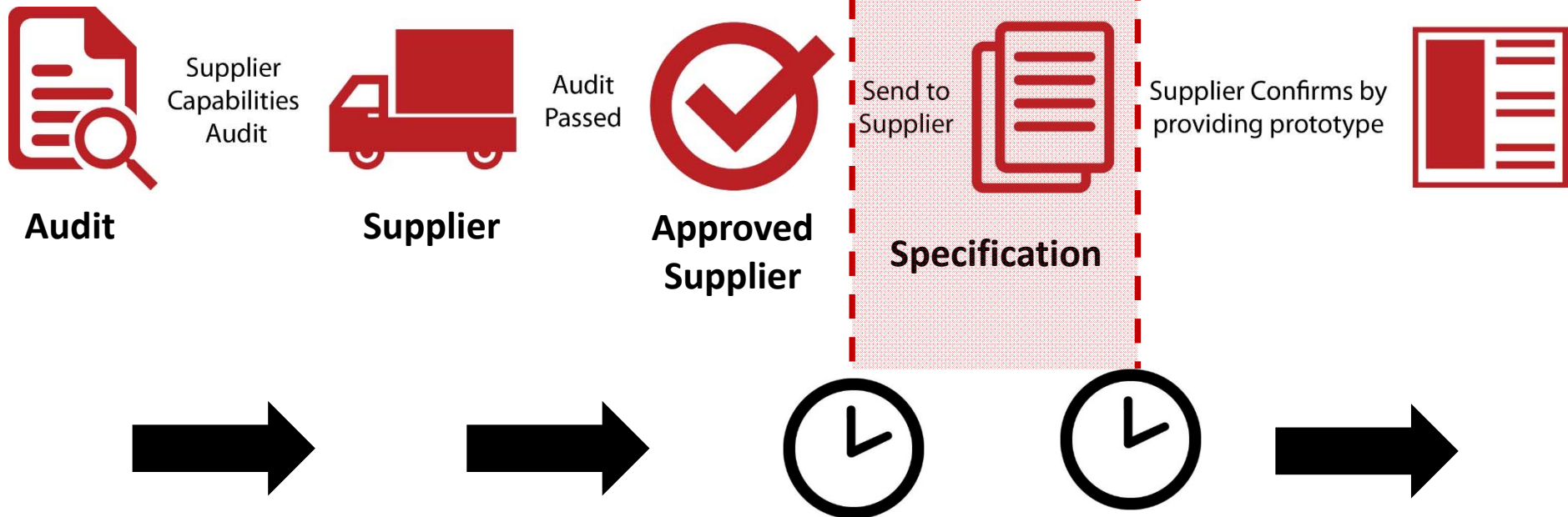
Source: Aberdeen Group

How your QMS Supports the Supply Chain



Current Gaps: Supplier Onboarding

--- Manual or Offline process



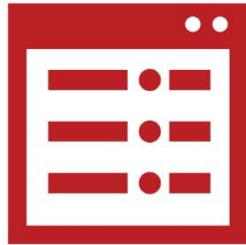
Filling the Gap: Automating Supplier Approval

1.



URL
Supplier Clicks
on Link

2.



Register
(Enter Registration
Information, Address
Contacts, etc.)

3.



Submit
Registration
Form &
Sends a
Notification to
Internal Person

4.



Supplier &
Contact Info. Reviewed

Supplier & User
Profiles Created

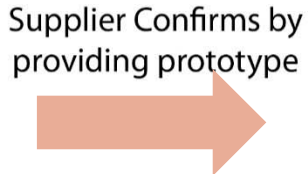
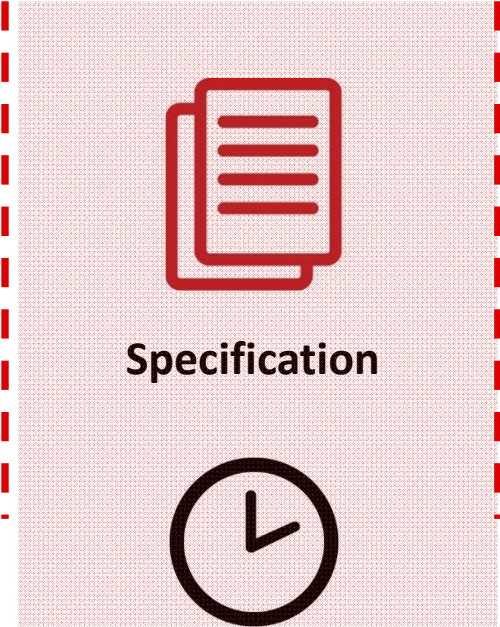
- Access provided to relevant modules
- Dashboard assigned to the Supplier
- Allow the supplier administrator to build their profile
- Filters applied to the User's profile to show only the relevant data

Current Gaps: Existing Supplier Collaboration

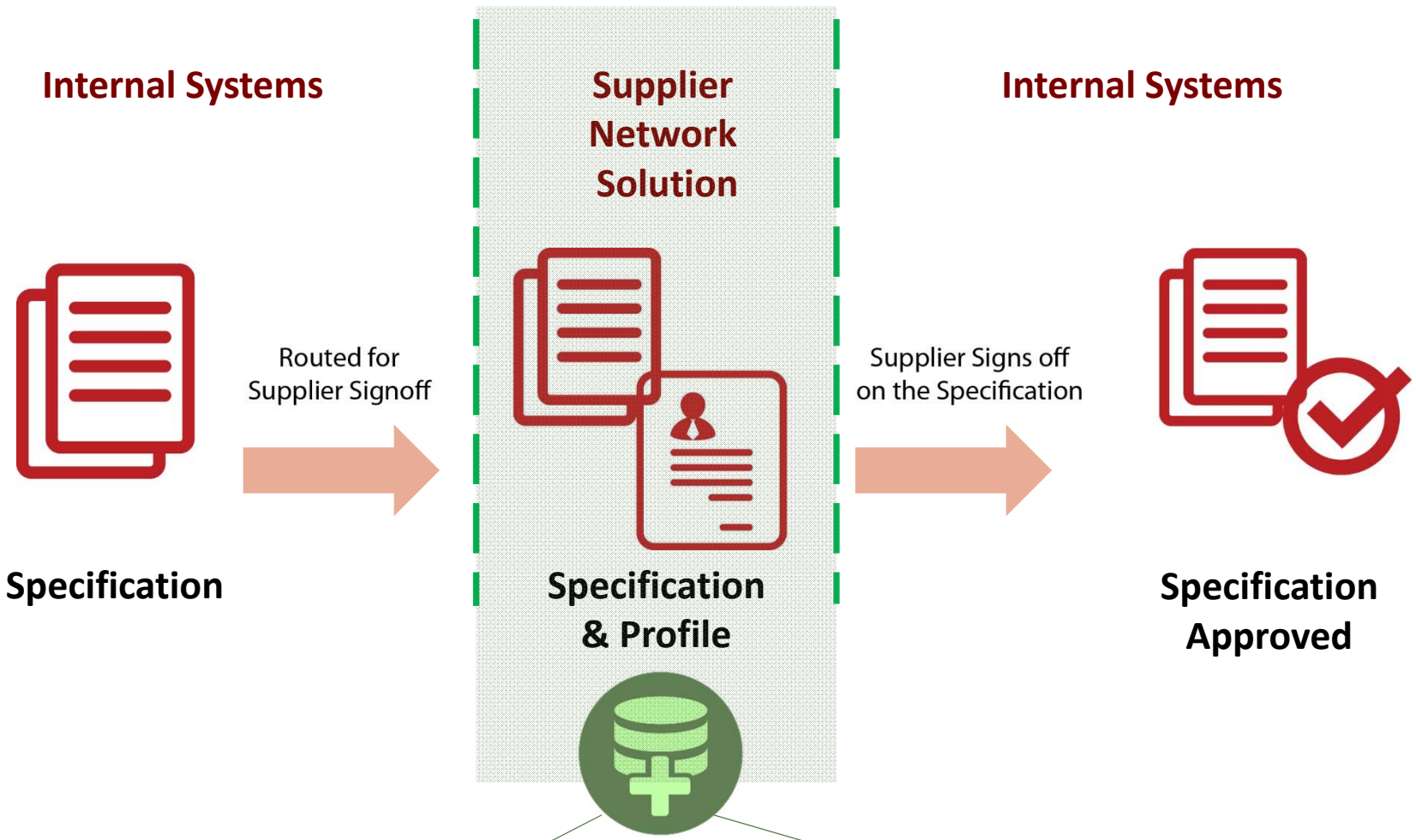
--- Manual or Offline process



Approved Supplier



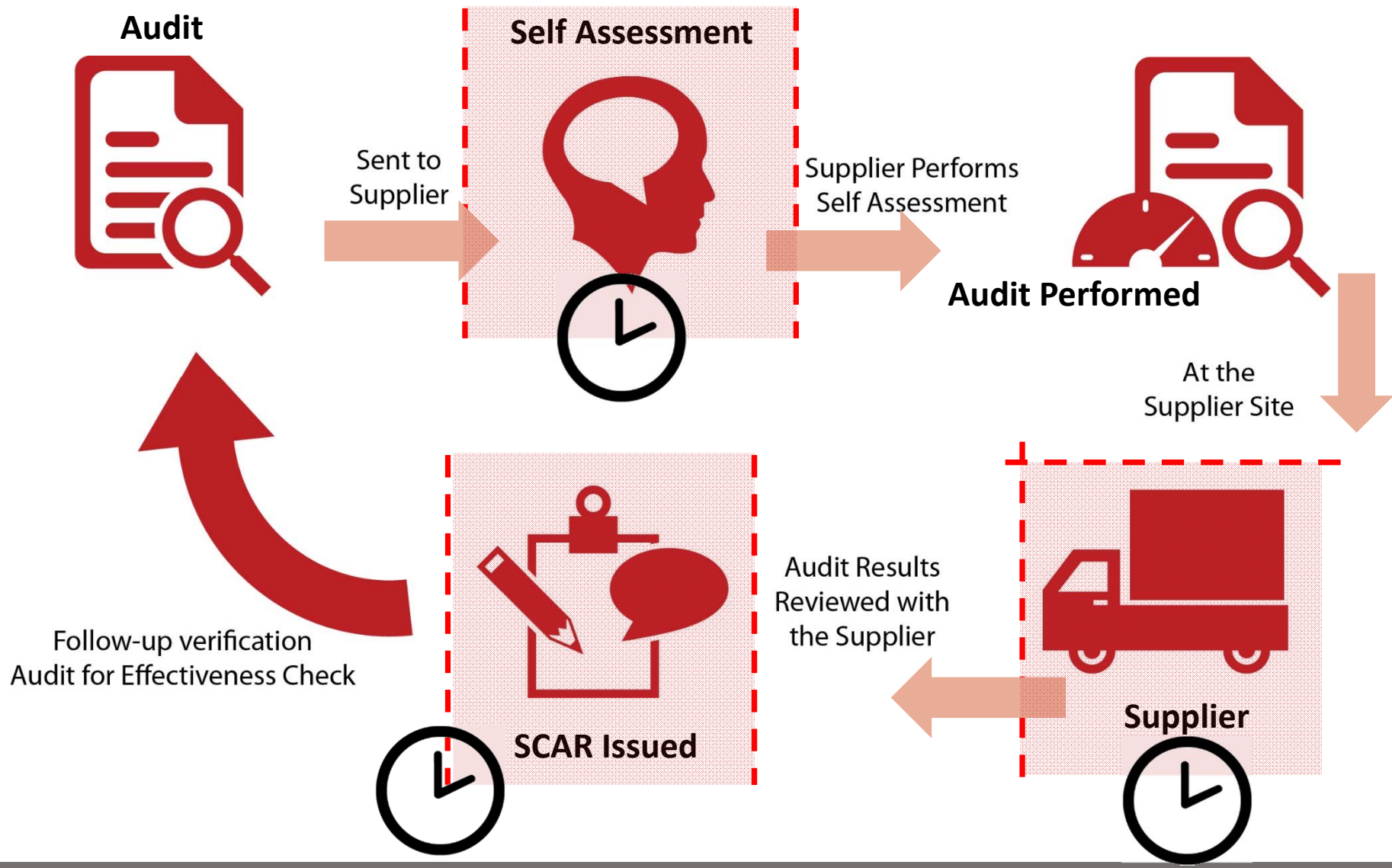
Filling the Gap: Automate Specification Approval



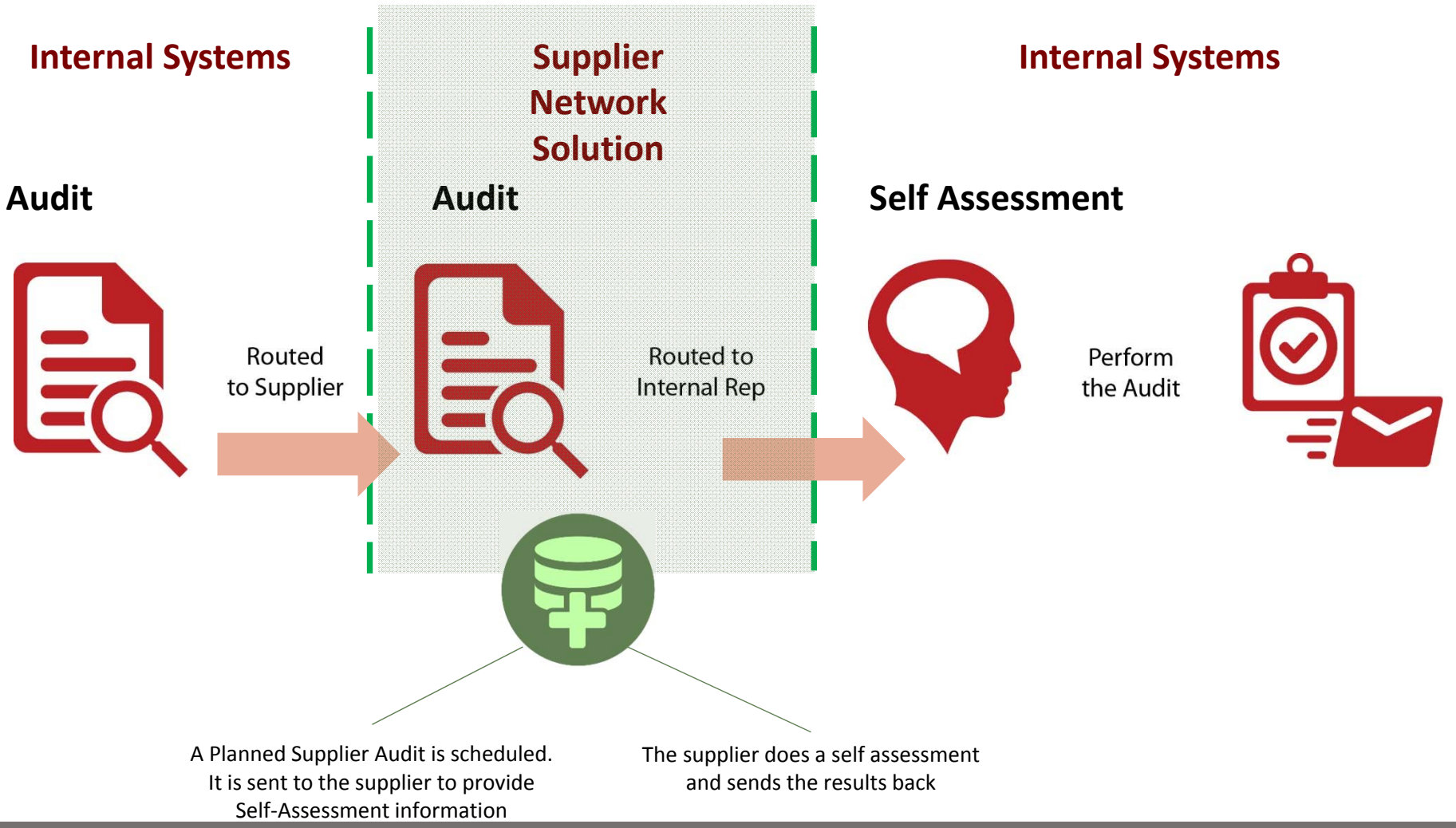
A copy of specification is created along with the information needed for the supplier to approve the spec

The Supplier signs off on the Specification. If the Supplier cannot deliver to the specification, it is sent back and forth till a version is agreed upon

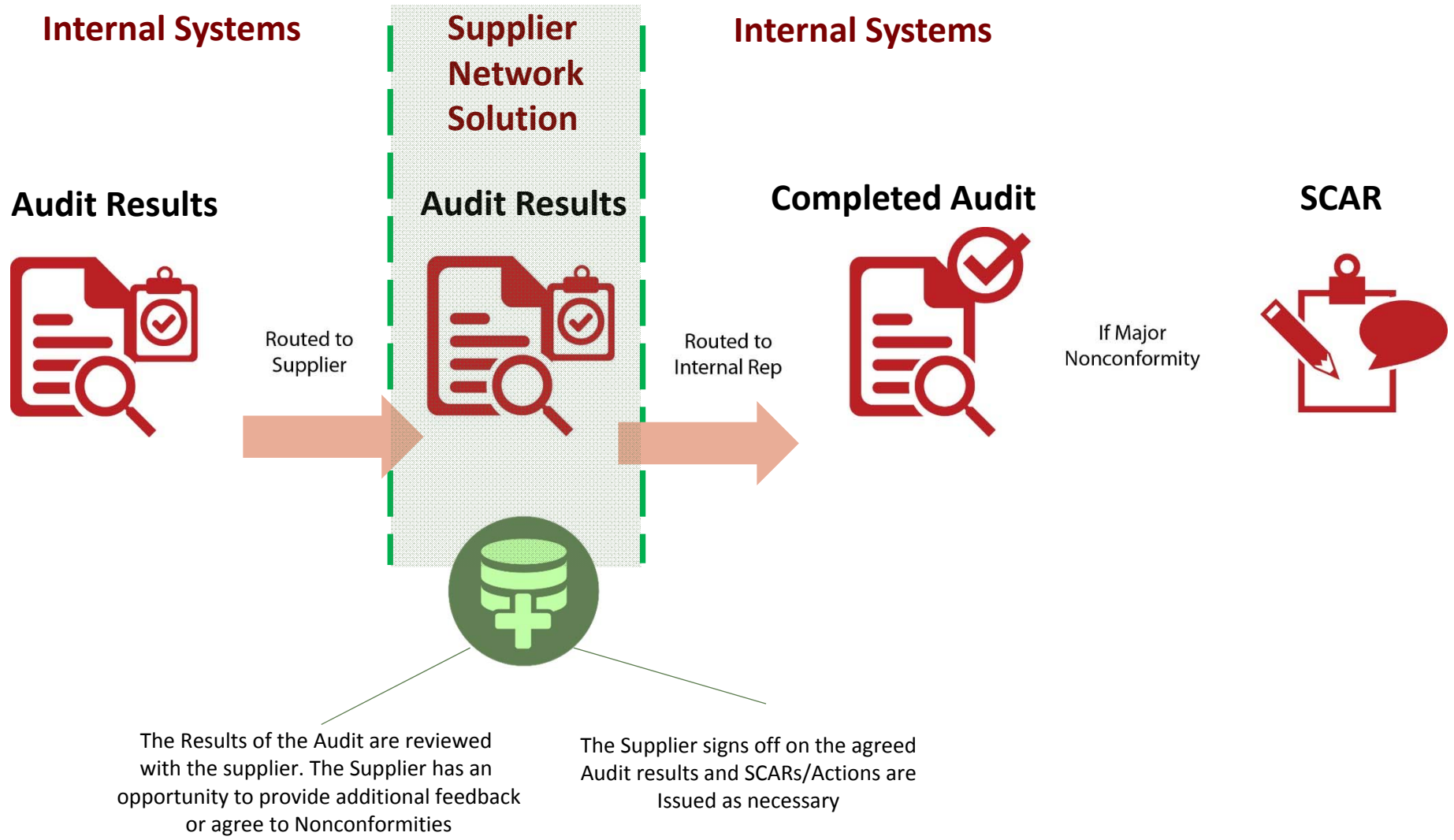
Current Gaps: Annual Supplier Audits - - - Manual or Offline process



Filling the Gap: Automate the Supplier Audit

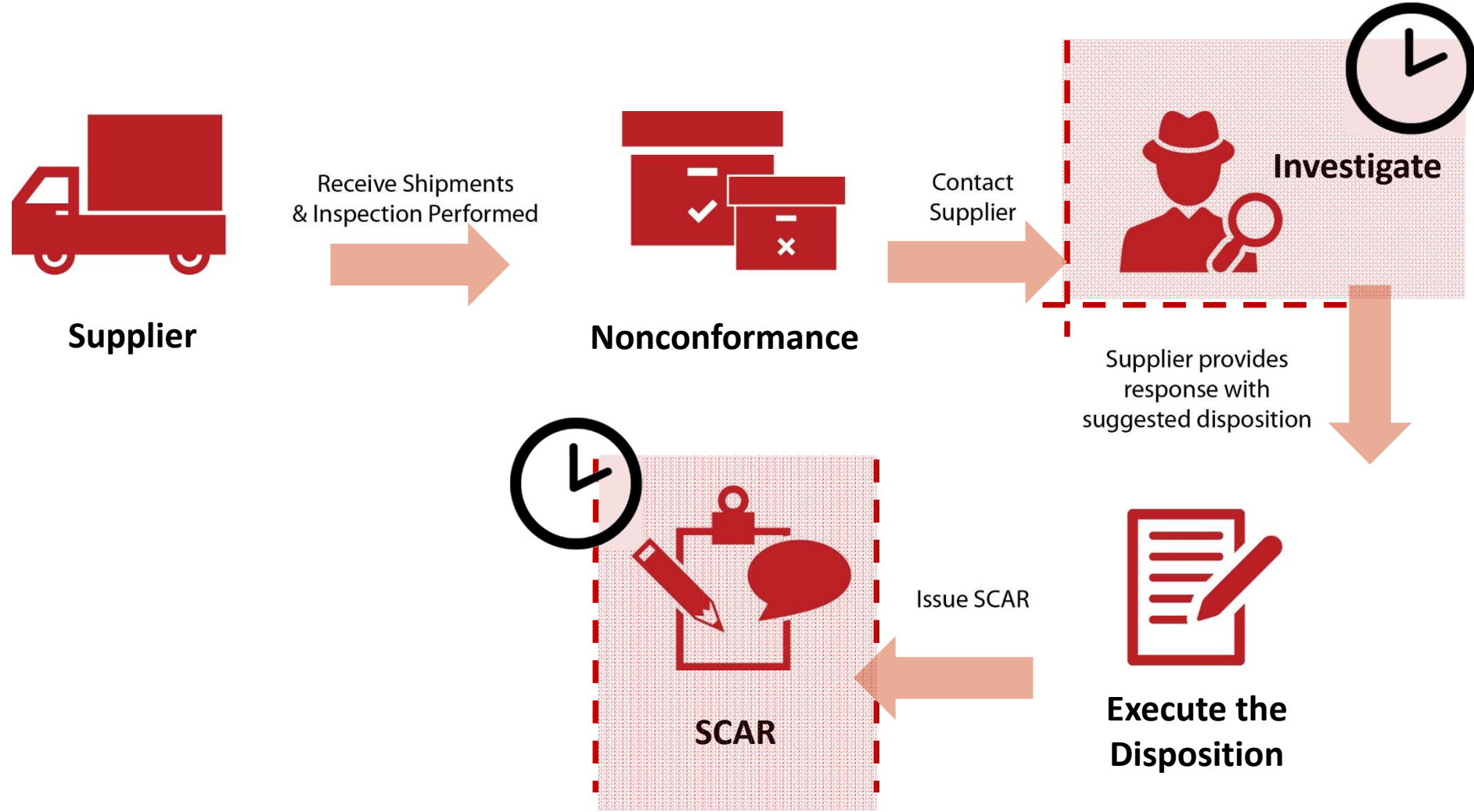


Supplier Audit (cont.)



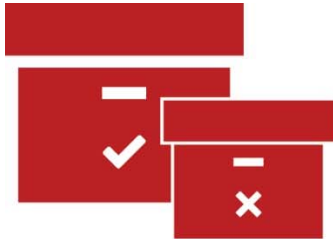
Current Gaps: Receiving Shipments

--- Manual or Offline process



Filling the Gaps: Resolving Material Nonconformance

Internal Systems



Nonconformance

Routed to Supplier for Investigation



Internal Systems

Supplier Recommends Disposition

A nonconformance with batch/lot information is sent to Supplier along with the nonconformance information

The Supplier investigates the issue and recommends a disposition. This Information is then sent to the Internal Rep for Review



SCAR

If Supplier Fault



Execute the Disposition

Current Gaps: Supplier Corrective Actions

Manual or Offline process



SCAR

Sent to Supplier



Supplier

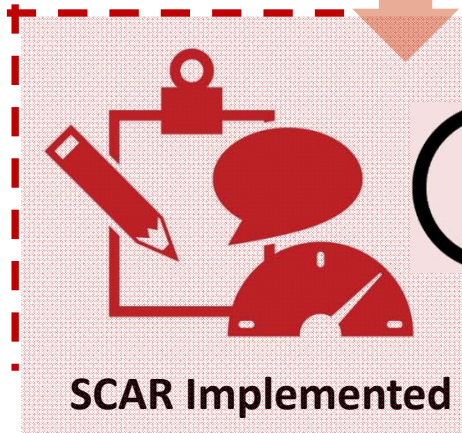


Supplier Responds with Suggested Corrective Actions



Review of SCAR UNDER REVIEW

Mutually Agreed Upon Actions



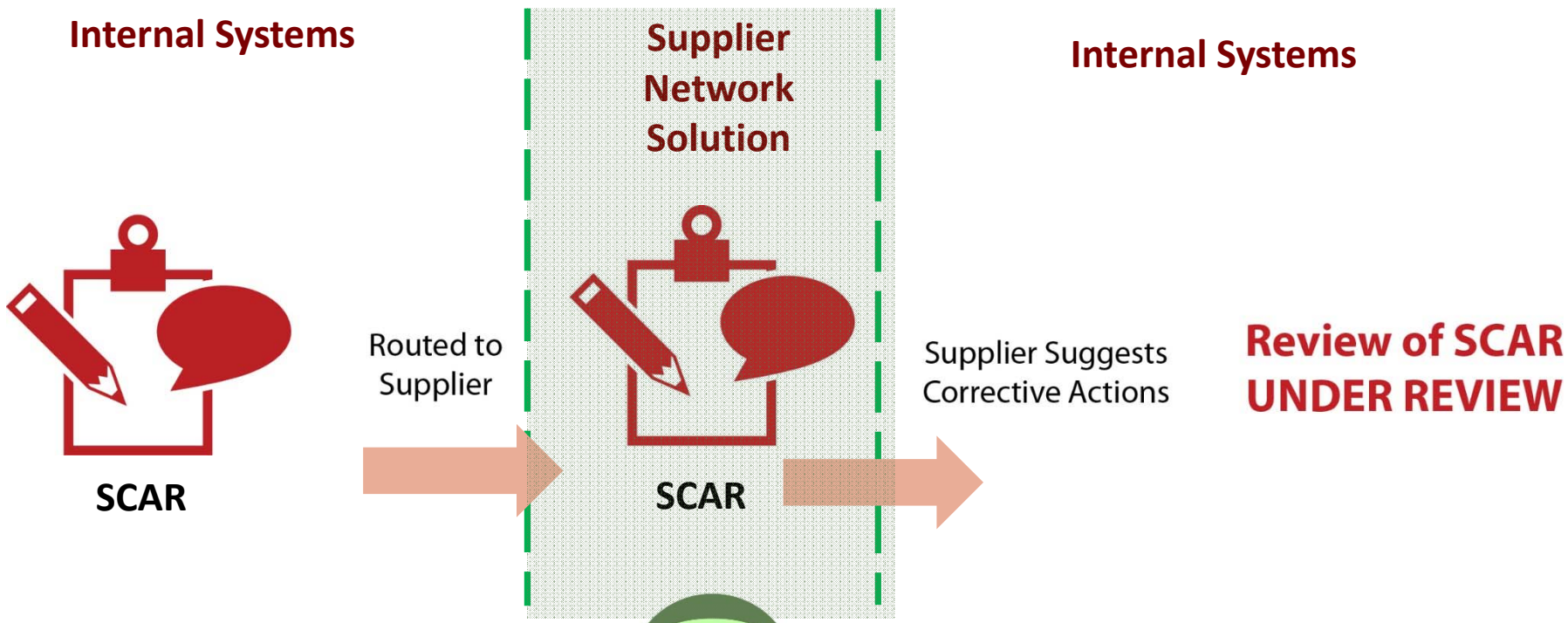
SCAR Implemented

Supplier provides evidence of completion



SCAR Verified & Completed

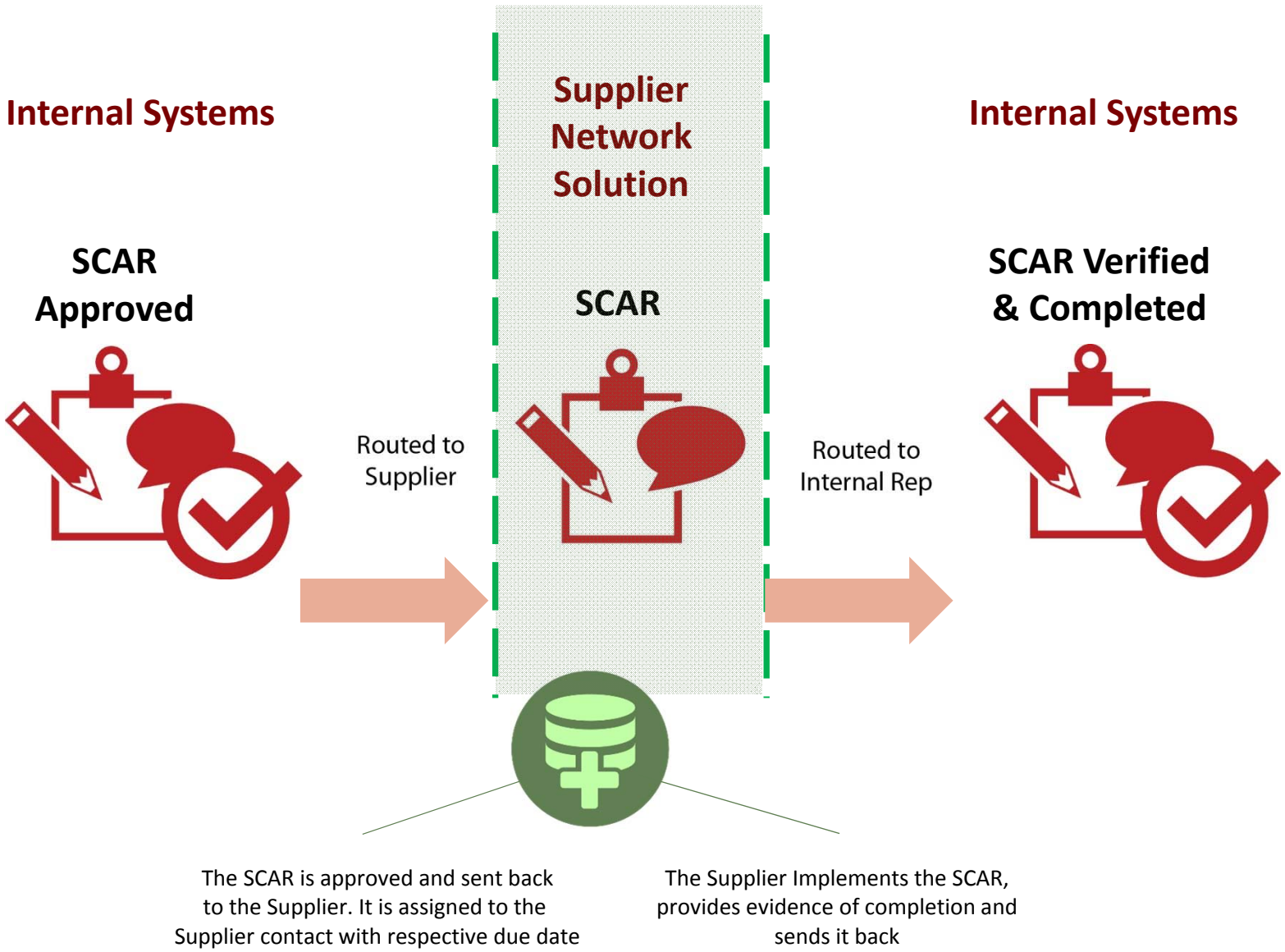
Filling the Gap: SCAR



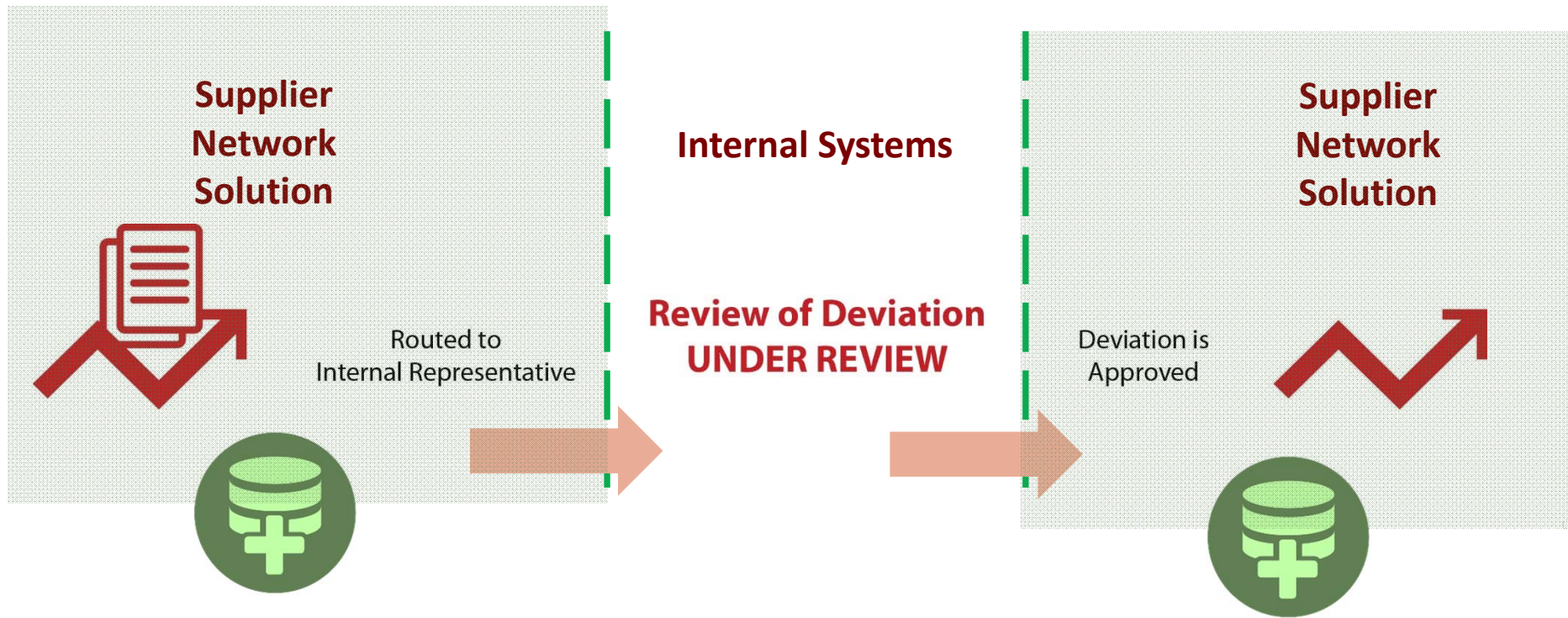
A SCAR is sent to the Supplier. This record is assigned to a Supplier contact, and is assigned a due date

The Supplier performs Root Cause analysis, determines corrective action, and due dates and sends it back

SCAR (cont.)



Filling the Gap: Supplier Deviations/Waivers

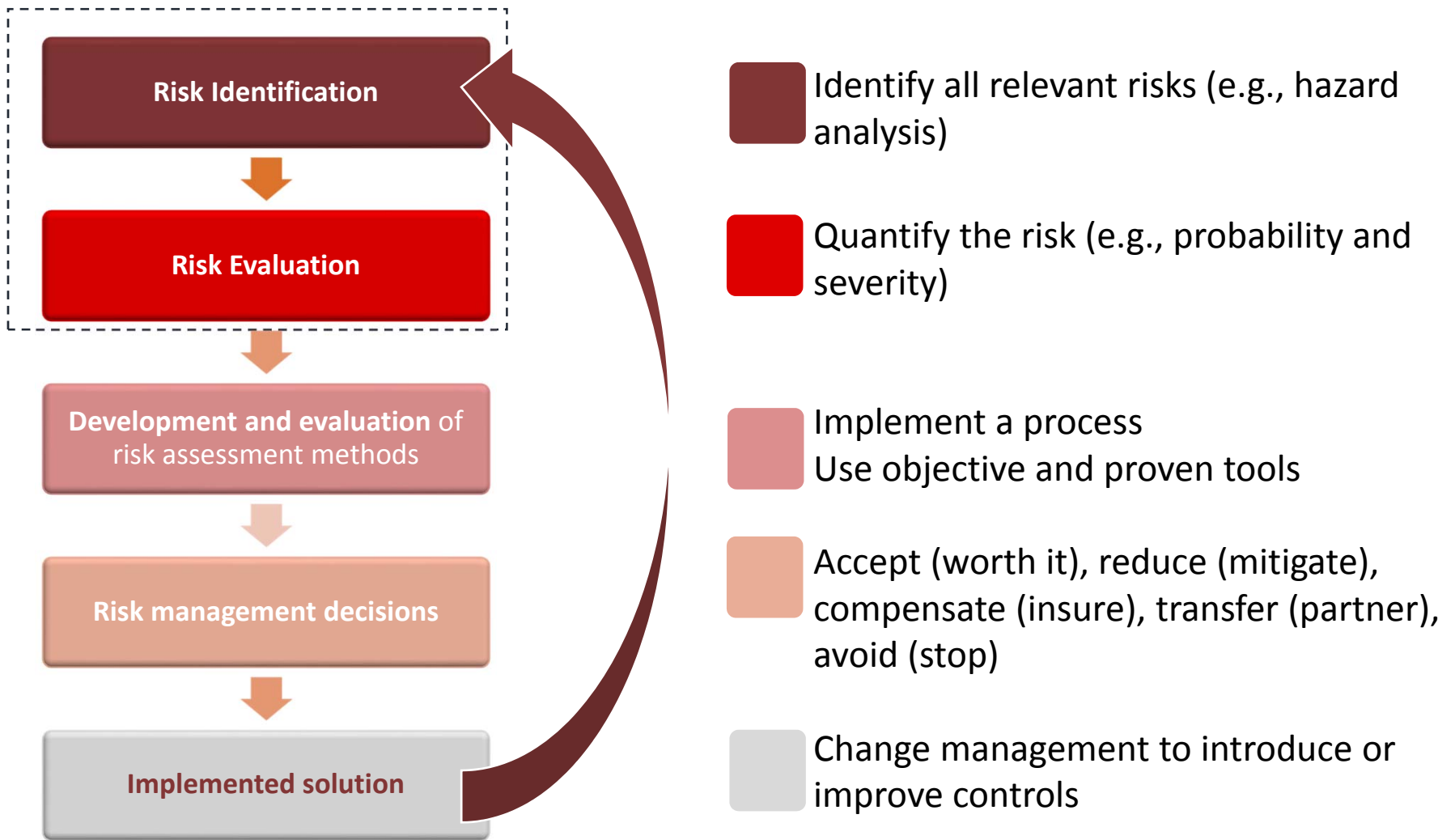


The Supplier sends a Waiver request to deviate from the Approved specification.

The Deviation is reviewed and approved Internally and upon receiving internal Approvals, is sent back

Risk Management Process

- Risk Management is a broad standard (ISO 31000)



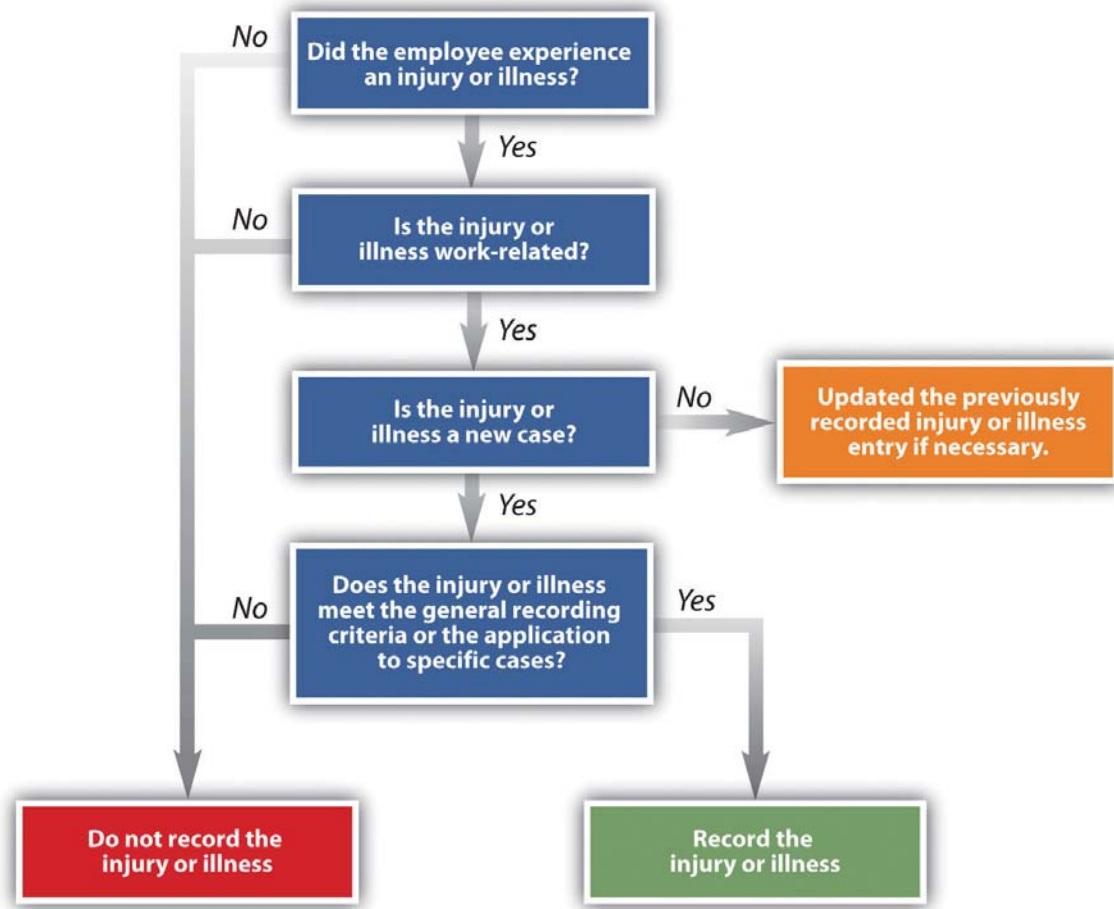
Common Tools for Risk Management Treatment

(a sample)



Decision Tree Analysis

Easy to integrate with everyday processes



Risk Matrix

Quick, easy, colorful

Quantifies the risk level using tested assumptions

SEVERITY

| | Minor (1) | Negligible (2) | Marginal (3) | Critical (4) | Catastrophic (5) |
|--------------------|----------------|----------------|--------------|--------------|------------------|
| PROBABILITY | Frequent (5) | Yellow | Red | Red | Red |
| | Probable (4) | Yellow | Yellow | Red | Red |
| | Occasional (3) | Yellow | Yellow | Yellow | Yellow |
| | Remote (2) | Green | Yellow | Yellow | Yellow |
| | Improbable (1) | Green | Green | Green | Green |



Failure Modes and Effect Analysis

For design of products and processes

| | | | | |
|---|-----------------------------|-----------------------|------------------------|----------|
| <input type="checkbox"/> System | Customer | Customer Part No. | Org. Date | Page |
| <input type="checkbox"/> Subsystem | Chrysler Motors Corporation | DC-77323-XYZ | 2/11/98 | 1 of 2 |
| <input checked="" type="checkbox"/> Component | Supplier | Code | Dwg. Rev. | Key Date |
| | Any Company, Inc. | ACI-001 | 8 | 2/11/98 |
| Part Name | | Design Responsibility | Application/Model Year | |
| Filter | | Brad Anderson | Sedan / 1998 | |
| Core Team | | | Prepared By | Date |
| Brad Anderson, Jerry Benware, Lisa Brown, Ken Caracci, Bill Cox, Fred Jordan, Ken Kratz | | | Brad A. Anderson | 2/11/98 |

| Item / Function | Potential Failure Mode | Potential Effect(s) of Failure | S | C | Potential Cause(s) / Mechanisms of Failure | O | Current Design Controls | D | R. | Recommended Action(s) | Responsibility & Target Completion Date | Action Results | | | | | |
|--|--|--|---|---|--|----|---|--|---|--|---|---|------|------|----------|---------------|-----|
| | | | | | | | | | | | | ev | lass | ccur | et P. N. | Actions Taken | sev |
| Filter for assembly with B44 to firewall | Insufficient wax coverage over specified surface | Deteriorated life of door leading to: Unsatisfactory appearance due to rust through paint over time, Impaired function of interior door hardware | 4 | ◇ | Insufficient wax thickness specified | 4 | Supplier certification | 1 | 16 | None | N/A 2/11/98 | | | | | | |
| | | | | | Inappropriate wax specified | 5 | set up set up | 4 | 80 | | | | | | | | |
| | | | | | Five piece setup, in-process, end of run study | 2 | 40 | None | N/A 2/11/98 | | | | | | | | |
| | Corroded interior lower door panels | Improper oxide coating | 6 | ⊂ | Entrapped air prevents wax from entering corner/edge access | 6 | Test spray pattern at startup and after idle periods, and ... | 5 | 180 | Add team evaluation using production spray equipment and specified wax | Engineering and Assembly Operations 2/18/98 | Based on test results (Test #0089) spray head modified to ... | 6 | 2 | 5 | 60 | |
| | | | | | Spray heads clogged: Viscosity too high, Temperature too low, Pressure too low | 4 | Incomming audit per 200-16 certification, SPC Lot/Qtr Laboratory test using "worst case" wax and application hole size | 2 | 48 | | | | | | | | |
| | | | | | 3 | 72 | Add laboratory accelerated corrosion testing Conduct DOE on wax thickness | ABC Labs 2/27/98 Engineering Associates 2/18/98 | Test results show specified ... DOE shows 25% variation in specified thickness is acceptable | 6 | 3 | 3 | 54 | 6 | 2 | 2 | 24 |
| | | | | | 3 | | | | | | | | | | | | |



FMEA Process

Planning Stage

Develop and Execute FMEA Strategic Plan

Develop and Execute FMEA Resource Plan

Analysis Statge

Develop Program Specific FMEAs

Test and Field Failures

Review Stage

Management Review

FMEA Quality Audit

Supplier FMEAs

Implementation Stage

Execute Actions to Reduce or Eliminate Risk

Linkage to Other Processes

Sample FMEA Form

Design FMEA

Revision 6.0 2/11/98

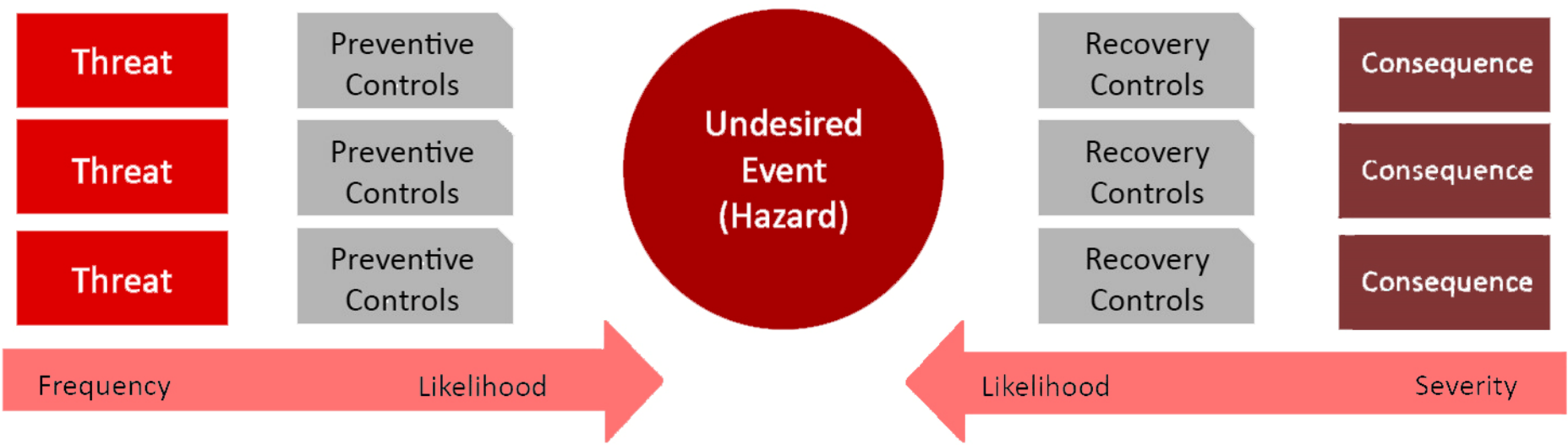
| | | | | |
|--|---|-----------------------------------|--|-----------------------|
| <input type="checkbox"/> System | Customer Chrysler Motors Corporation | Customer Part No. DC-77323-XYZ | Org. Date 2/11/98 | Page 1 of 2 |
| <input type="checkbox"/> Subsystem | Supplier Any Company, Inc. | Code ACI-001 | Supplier Part No. A-9514 | Dwg. Rev. 8 |
| <input checked="" type="checkbox"/> Component | | | Key Date 2/11/98 | FMEA No. DFMEA-001 |
| Part Name Filter | Design Responsibility Brad Anderson | | Application/Model Year Sedan / 1998 | |
| Core Team Brad Anderson, Jerry Benware, Lisa Brown, Ken Caracci, Bill Cox, Fred Jordan, Ken Kratz | | | Prepared By Brad A. Anderson | Date 2/11/98 |

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|--|--|--|---|---|--|--|---|---|-----|--|--|---|---------------|---|----|----|
| | | | | | | | | | | | | A | Actions Taken | S | O | D |
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| | | | | | | Conduct DOE on wax thickness | | | | Engineering Associates 2/18/98 | DOE shows 25% variation in specified thickness is acceptable | 8 | 2 | 2 | 24 | |
| | Feeder not properly or | | | | 3 | | | | | | | | | | | |



Bowtie Model

For low-occurrence events that are catastrophic



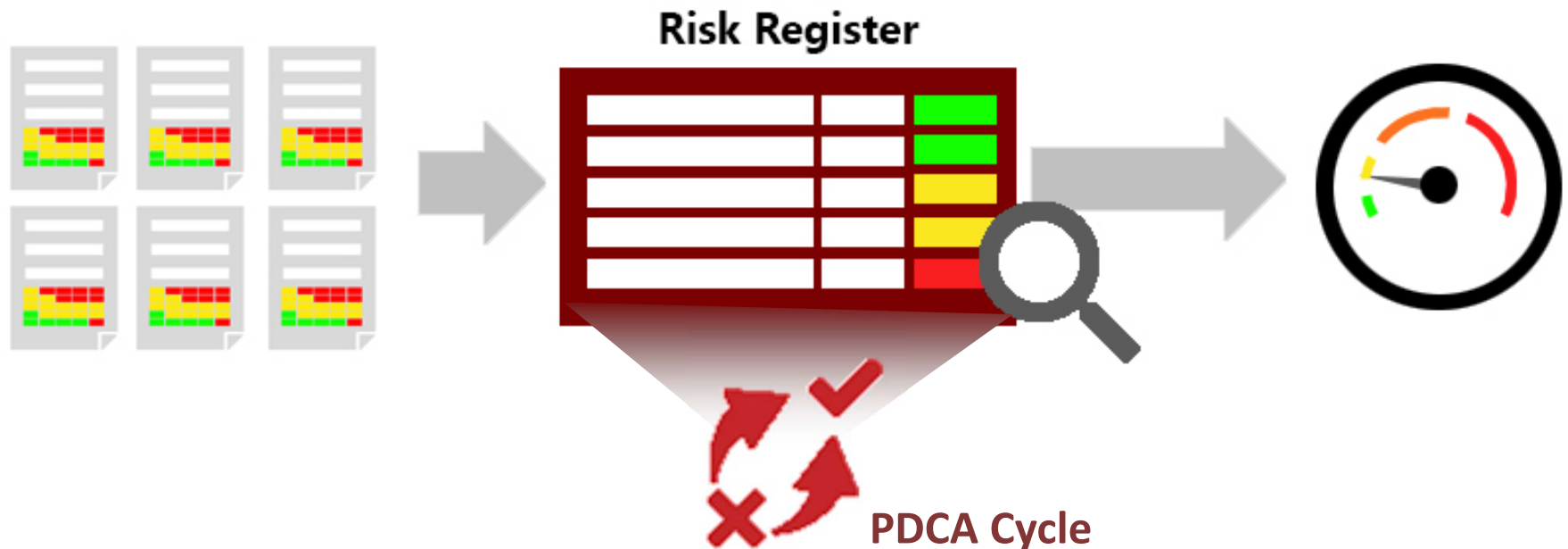
Bowtie Example

For low-occurrence events that are catastrophic



Risk Register

- Monitors risk levels over time
 - Library of hazards (typically known for each industry)
 - Collects risk assessment data from many processes
 - Provides visibility into critical events and data for trend reporting



Summary

- Supply Chain is Becoming More Complex
 - Many risks associated with growing supply chain
 - Mitigating risks is primarily a strategic initiative
- Supplier Quality Network Cornerstone of Compliance
 - Comprehensive, standardized
- QMS extends to Supply Chain through the This network
 - Key quality processes encompass supplier operations
 - Risk management is critical to maintaining compliance
- Apply Risk Management to the supply-chain
 - Use a objective and repeatable risk management tools
 - Integrate risk assessment into the compliance processes
- Risk Management is also a Strategic Initiative

Thank you! Questions?



Designed for small workgroups in Quality, EHS and Compliance looking to track events, issue action items and launch corrective actions.

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