



# Supplier Quality Management Challenges

Pharmaceutical Industry Association of  
Puerto Rico 21st Regulatory Conference  
18-Aug-2023

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# SUPPLIER QUALITY MANAGEMENT CHALLENGES

- Pharmaceutical Industry Challenges
- Current External Environment
- What can you do...

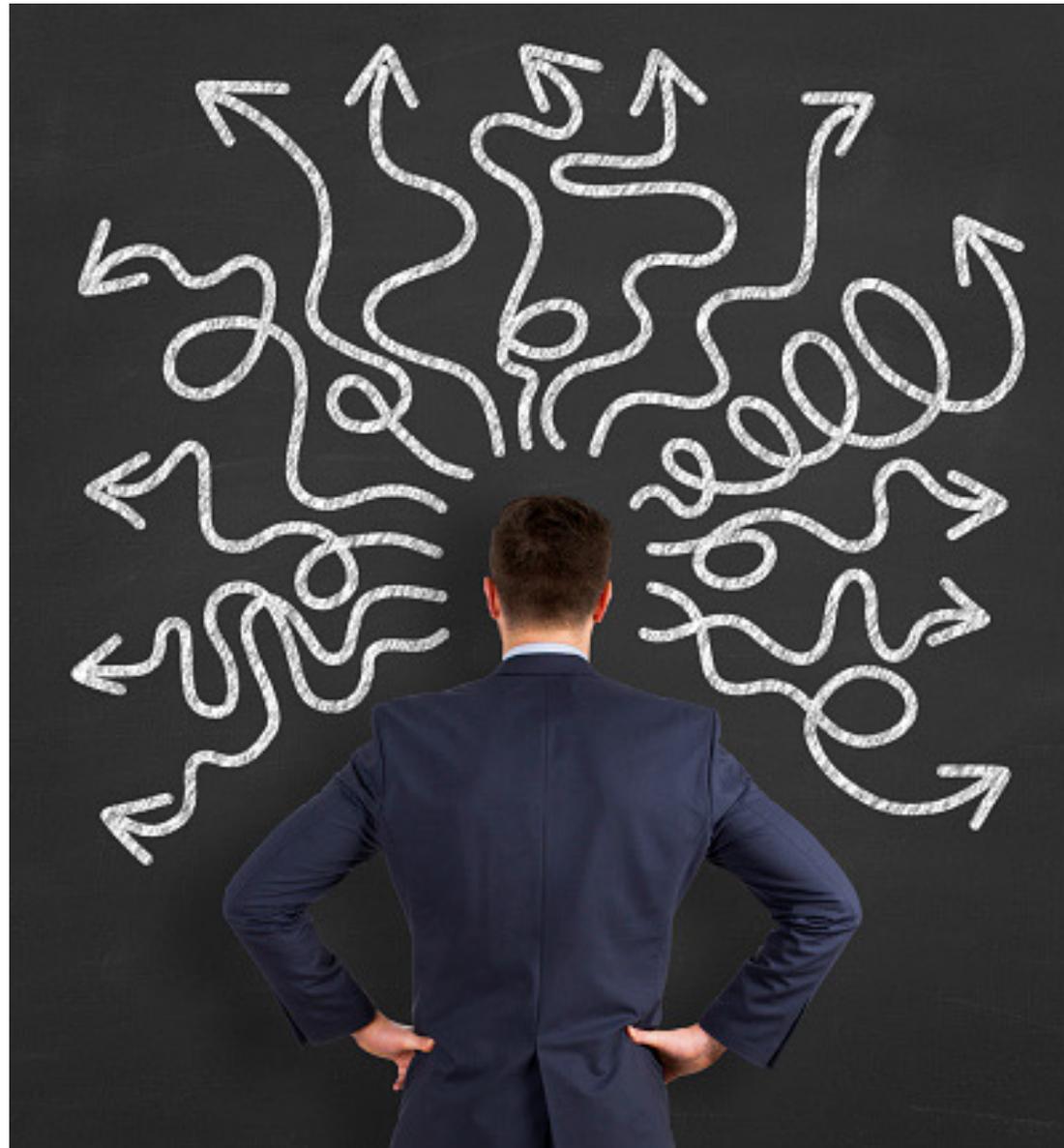
# Eli Lilly and Company

- Our Mission: Lilly unites caring with discovery to create medicines that make life better for people around the world.
- Our Vision: We will make a significant contribution to humanity by improving global health in the 21st century.
- Our Values: Integrity, excellence, respect for people

*Lilly*

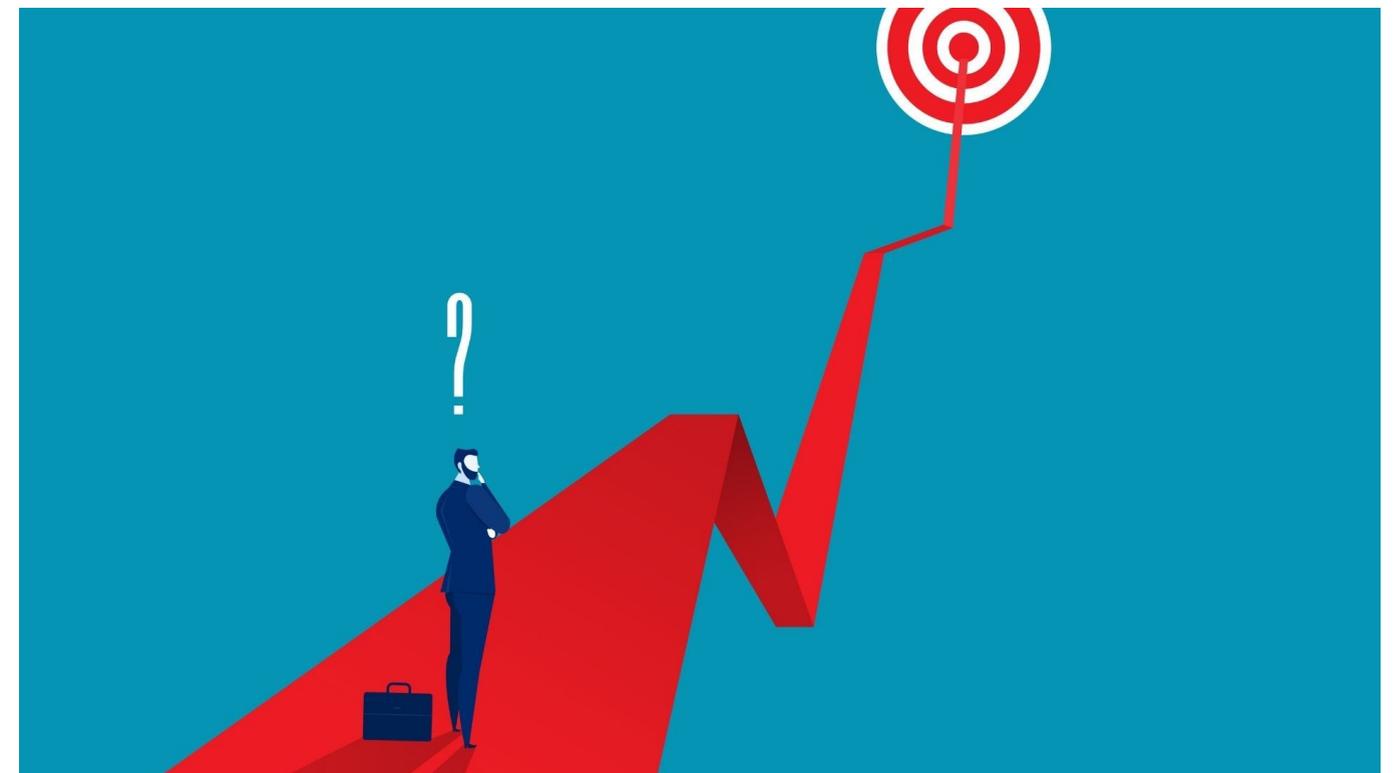


# Wait...Supplier Management is Not Easy?



# Industry Challenges

- Purchasing low volumes from suppliers
- Non-pharmaceutical grade material specified when supplier offers a pharmaceutical grade material
- Having a single source for material
- Inconsistent handling of third-party contractors/partners of our suppliers/service providers
- Using areas requesting audits when not required/supplier not ready
- Cross-referencing supplier part/item number to internal part/item number for traceability

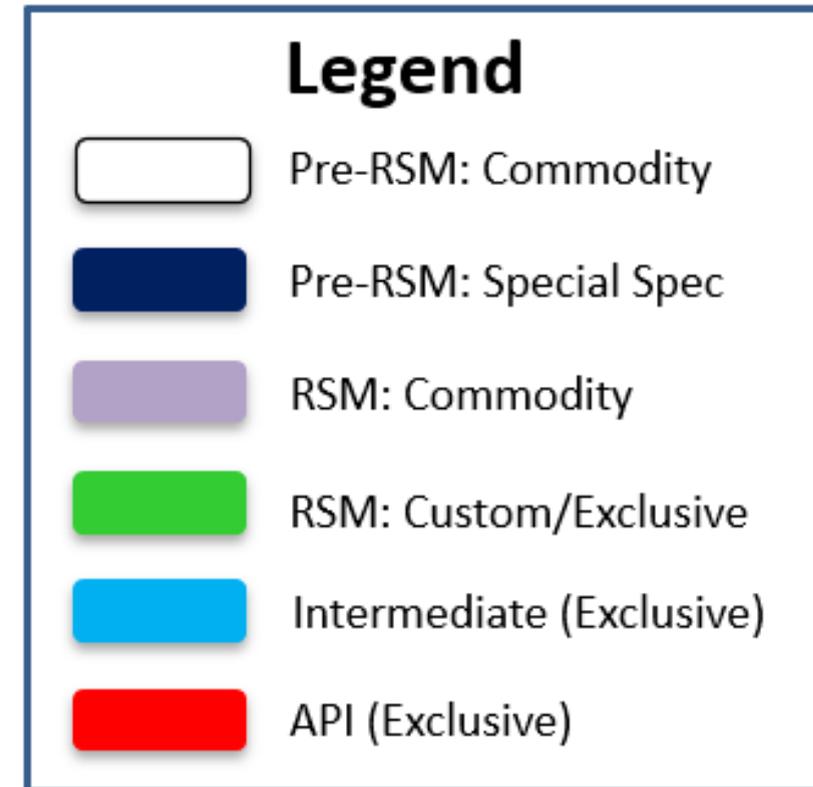
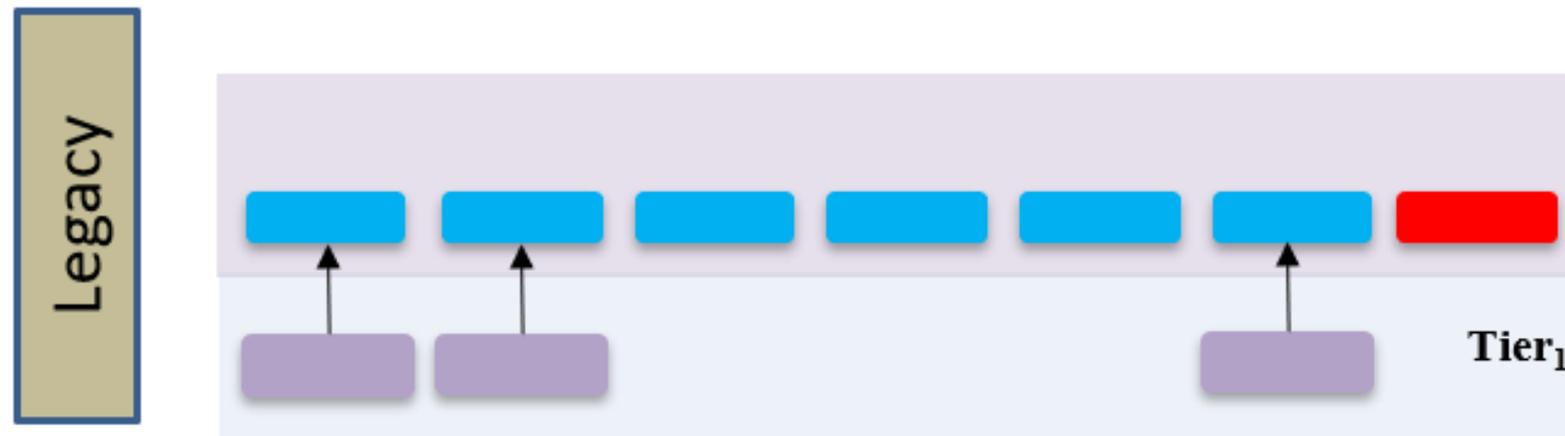


# Industry Challenges (cont.)

- Local vs. Global supplier management
- Differing risks applied for similar service/materials from same supplier
- Multiple groups performing audits of the same supplier/service provider
- Same service is named differently internally for different service providers
- Supply chains becoming more complex



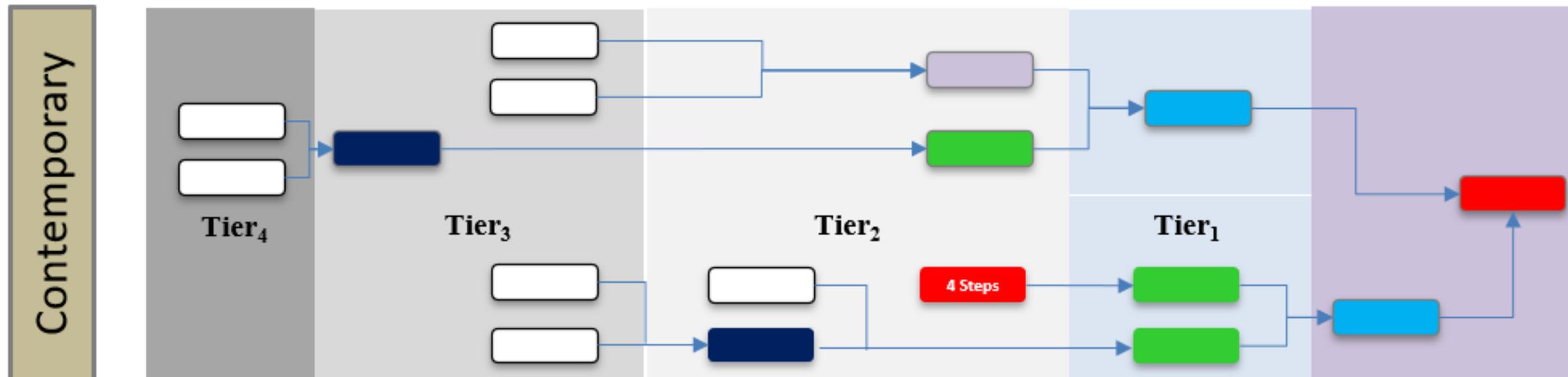
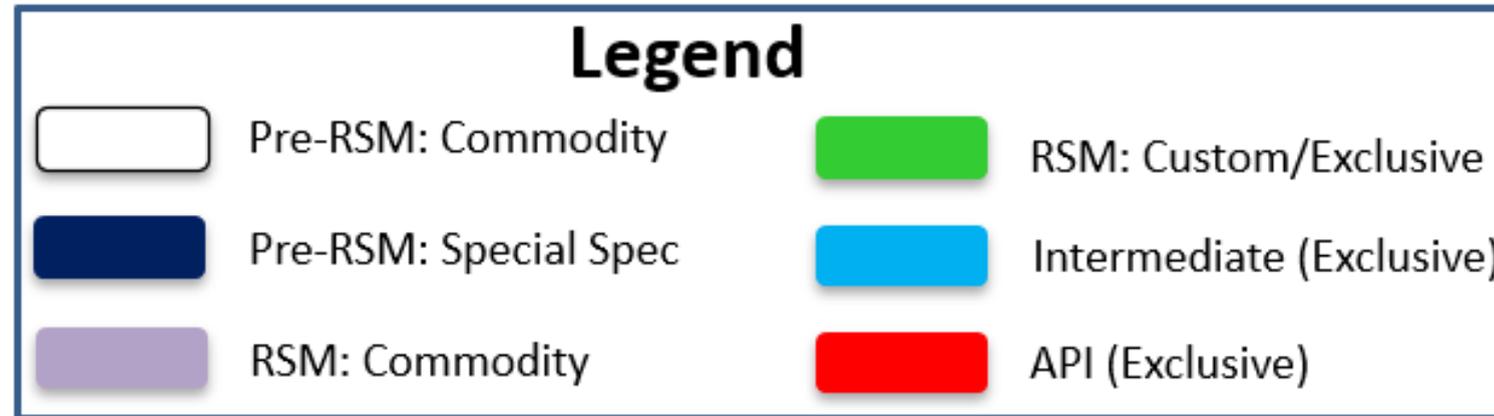
# Supply Chains – “Legacy”



\*RSM – Registered Starting Material

\*API – Active Pharmaceutical Ingredient

# Supply Chain - “Contemporary”



# What Can You Do?



- Harmonize/Centralize/Integrate



- Communicate



- Multi-source

# Current External Environment



# Current External Environment - Audits

- Audit refusal
- Forced remote audits
- "Group" audits
- Limited access when on site
- Response / CAPA refusal



# Current External Environment - Performance

- “Poor” performance
- Regulatory issues
- Recall notifications
- “Bad” sites
- “Impurities”



# Current External Environment - General



- Issues with reduced testing
- Quality agreement refusal
- Non-pharma primary business
- Distributor “owning” SQM processes
- “MMMM” Changes

# Current External Environment - Ethical

- “Special” Issues...



# What Can You Do?

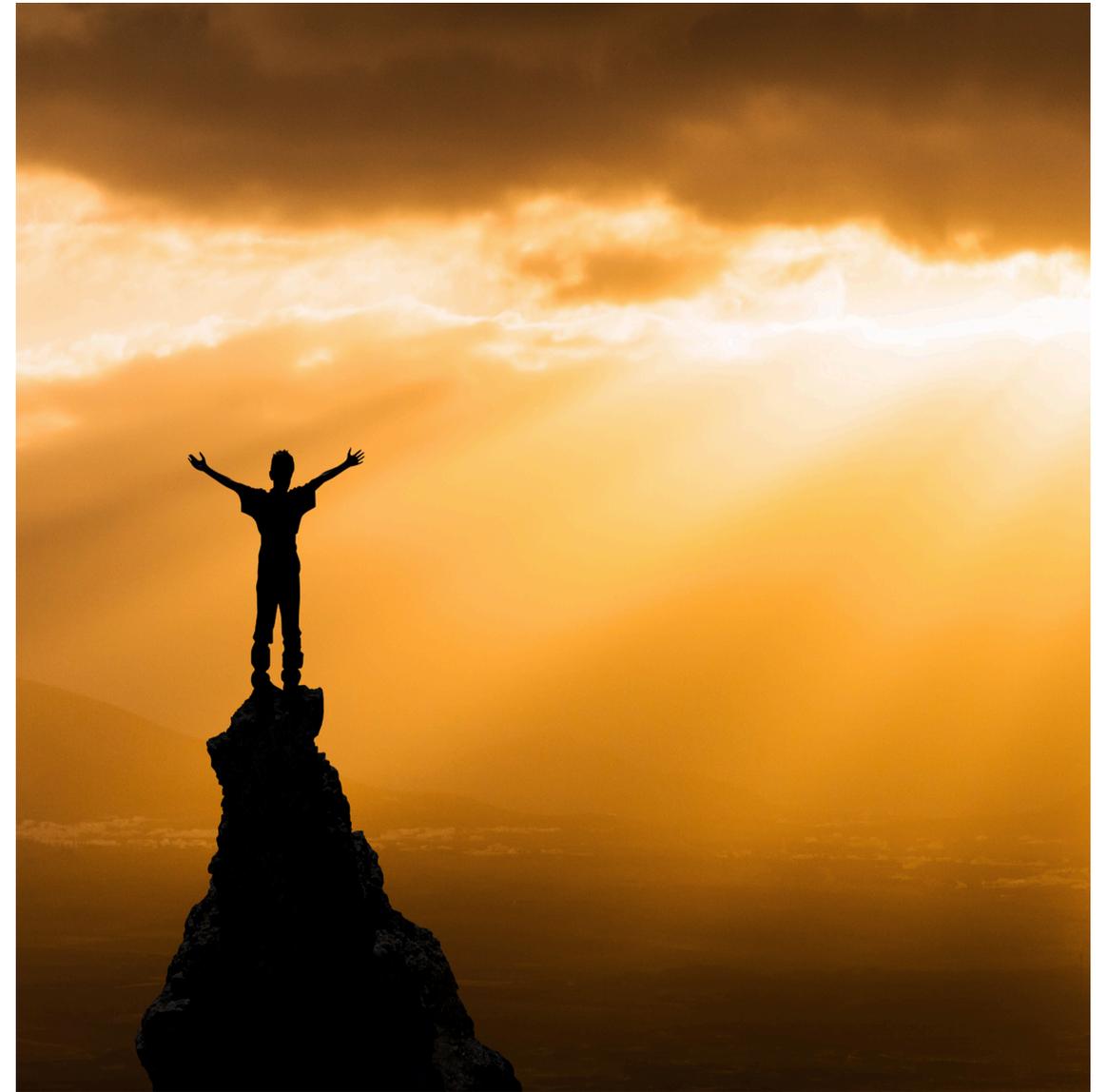
- Find a new supplier (easy?)
- Get help (e.g., Procurement)
- Utilize 3rd-Party Firm
- Increase testing
- Enhanced oversight



# What Is Lilly Doing?

Transitioning from a site-based to a global-based approach:

- Integrated IT solution for global visibility of all supplier management aspects
- Single point of accountability to coordinate the Quality oversight for all materials supplied by a supplier to multiple Lilly locations
  - Allows for risk classification to take into account the entire range of products /components being purchased from a supplier
  - Coordination of audits, questionnaires, change notifications, and complaints



*Lilly*

**QUESTIONS?**