



# Managing Significant Regulatory Events

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- ❑ Significant Regulatory Events – Some Examples
- ❑ Bad Press – When it Goes Wrong
- ❑ Global Pharmaceutical Supply Chains at a Glance
  - *The Landscape & Challenges*
- ❑ Effective Management of Significant Regulatory Events – GSK's Value Proposition
- ❑ Summary & Key Takeaways
- ❑ Q&As

# What is a Significant Regulatory Event?



## Some Examples

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Product Incident

Significant  
Regulatory  
Inspection  
Observations

Regulatory  
Non-Conformance

Product Recall

Supply Constraints –  
Medically Critical /  
Medically  
Necessary Drugs

Suspected product theft  
or counterfeit

Critical  
Deviation

# Bad Press!



## Some Real Examples of When it Goes Wrong

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Pharma Manufacturing Consent  
Decrees: 16 Black Holes

Enforcement  
Activities by FDA

FDA Continues  
Crackdown on  
Noncompliant  
Pharmaceutical  
Manufacturers

After the Consent Decree  
– An Uphill Battle

U.S. Files Consent Decree  
for Permanent Injunction  
Against Pharmaceutical  
Giant

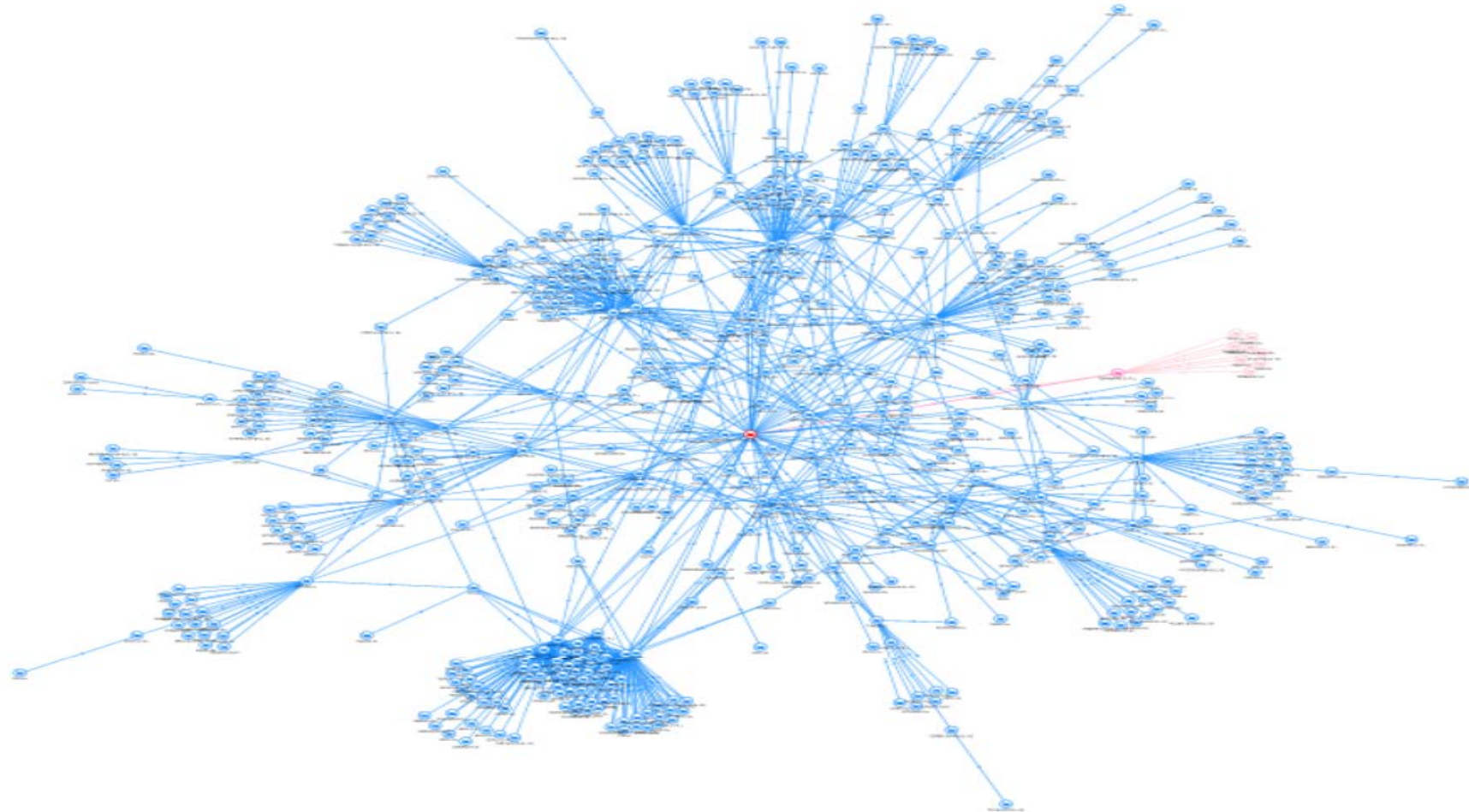
API Plant smacked By FDA  
Warning Letter, Adding to  
Drugmaker's Burdens

API Manufacturer  
Barred from Exports to  
US After FDA Import  
Alert

Pharmaceutical Manufacturer  
Shares Fall 20% after  
USFDA Import Alert

# Global Pharmaceutical Supply Chains

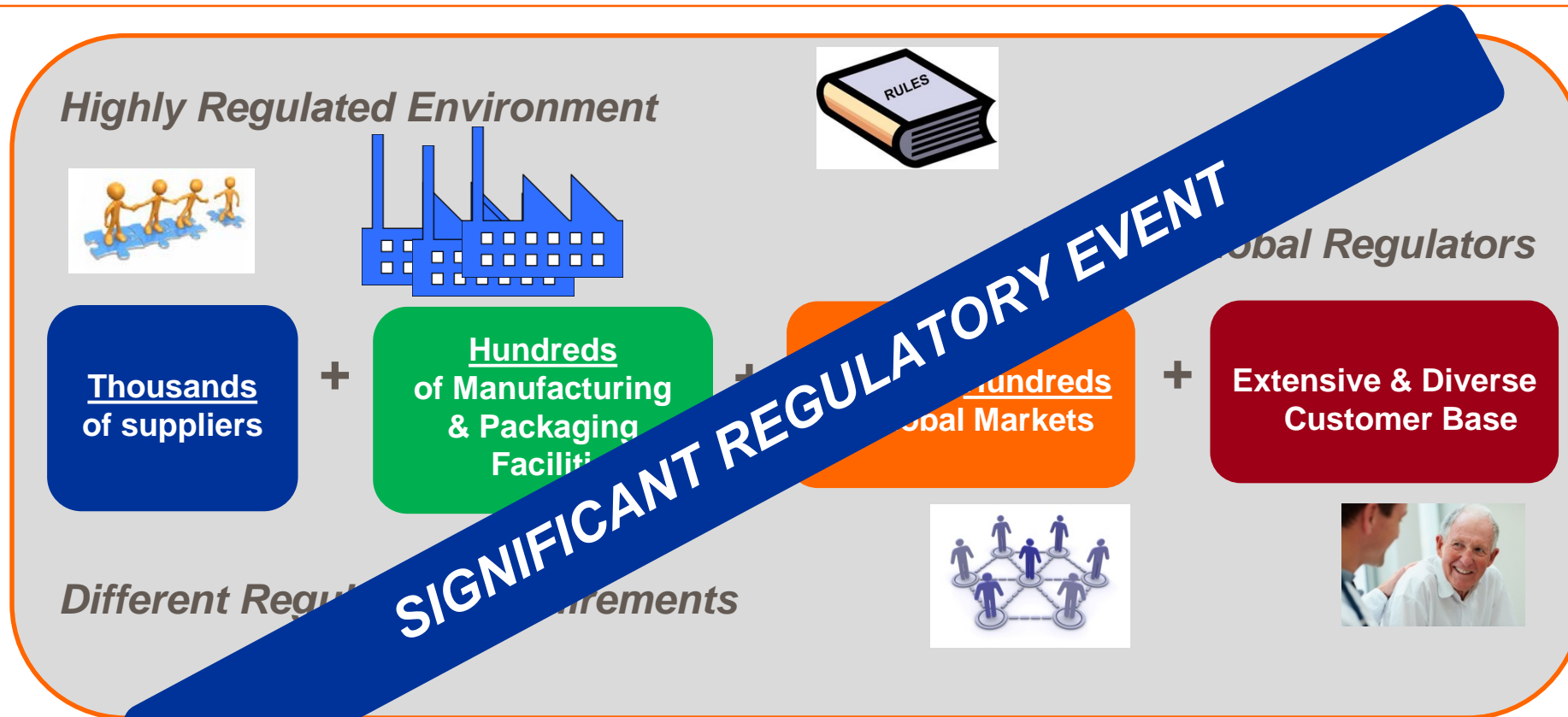
## At a Glance





# Global Pharmaceutical Supply Chains

## The Landscape & Challenges



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Complexity, complexity, complexity

# GSK – Our Value Proposition

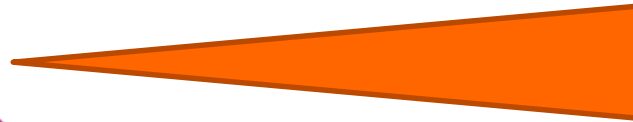


## Effective Management of Significant Regulatory Events

Maturity & Experience	Organizational Structure	Robust Processes For Incident Management	Dedicated Incident Management
<ul style="list-style-type: none"> <li>Large <b>established global Pharmaceutical</b> company</li> <li>Experience managing <b>complex global supply chains</b></li> <li>Experience working with <b>3<sup>rd</sup> Parties</b></li> </ul>	<ul style="list-style-type: none"> <li><b>End-to-end</b> functional supply chain model</li> <li><b>Quality &amp; Regulatory</b> presence</li> </ul>	<ul style="list-style-type: none"> <li><b>Standardized</b> definitions</li> </ul>	<ul style="list-style-type: none"> <li><b>Communication strategy &amp; plan</b> developed, facilitating delivery of <b>effective, transparent &amp; consistent information</b> to all impacted stakeholders (internal &amp; external)</li> </ul>
<ul style="list-style-type: none"> <li><b>Supplier</b> aligned products</li> </ul>	<ul style="list-style-type: none"> <li><b>Collaboratively</b> working with our business partners to create a <b>win-win</b> relationship</li> </ul>	<ul style="list-style-type: none"> <li>Incidents managed via a <b>multi-disciplinary team of leaders &amp; experts</b> (Quality, Regulatory, Medical, Legal, Communications, Supply)</li> <li><b>Action plan</b> developed within the scope of Regulatory Guidance</li> <li><b>Proposal</b> discussed &amp; agreed with regulators</li> </ul>	<h3>Collaboration with Global Regulators</h3> <ul style="list-style-type: none"> <li><b>GSK presence</b> in each global market</li> <li><b>Quality &amp; Regulatory expertise</b> of individual regulatory requirements</li> <li><b>Established relationships</b></li> </ul>

**UNDERPINNED BY OUR VALUES:**  
 Patient Focused  
 Act with Integrity  
 Demonstrate Respect for People  
 Operate with Transparency

# GSK – Bringing it All Together



Targeted Communication



What we know

What the customer needs



# Summary & Key Takeaways



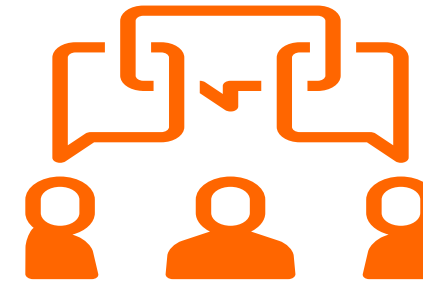
## Effective Management of Significant Regulatory Events

### ❑ The Importance of Experience & Leadership

- *In the face of sudden overwhelming circumstances, many organizations risk to equivocate*
- *Customers, Patients & Governments are **looking for answers***
- ***Strong leadership** is required for **clarity & decision making***

### ❑ It's Vital to Know the Landscape

- *Regulatory environment*
- *Supply Chain*
- *Customers & other stakeholders*



### ❑ Organization & Capabilities

- ***Robust Processes** for Incident Management & Regulatory Engagement*
- ***Expertise** is required from **multiple disciplines***
- ***Clearly defined & approved strategies** for **Transparent & Consistent Communications** to all stakeholders (internal & external), e.g. Patients, Regulators, Customers, HCPs*

### ❑ The need to be an Agile & Learning Organization

- ***Learning** from experience*
- *Continuously **improving***
- ***Building** on successes*



# THANK YOU – Q&A

