

# INDUSTRY PERSPECTIVES VETERINARY DRUG SUPPLY INTERRUPTIONS

September 26, 2019

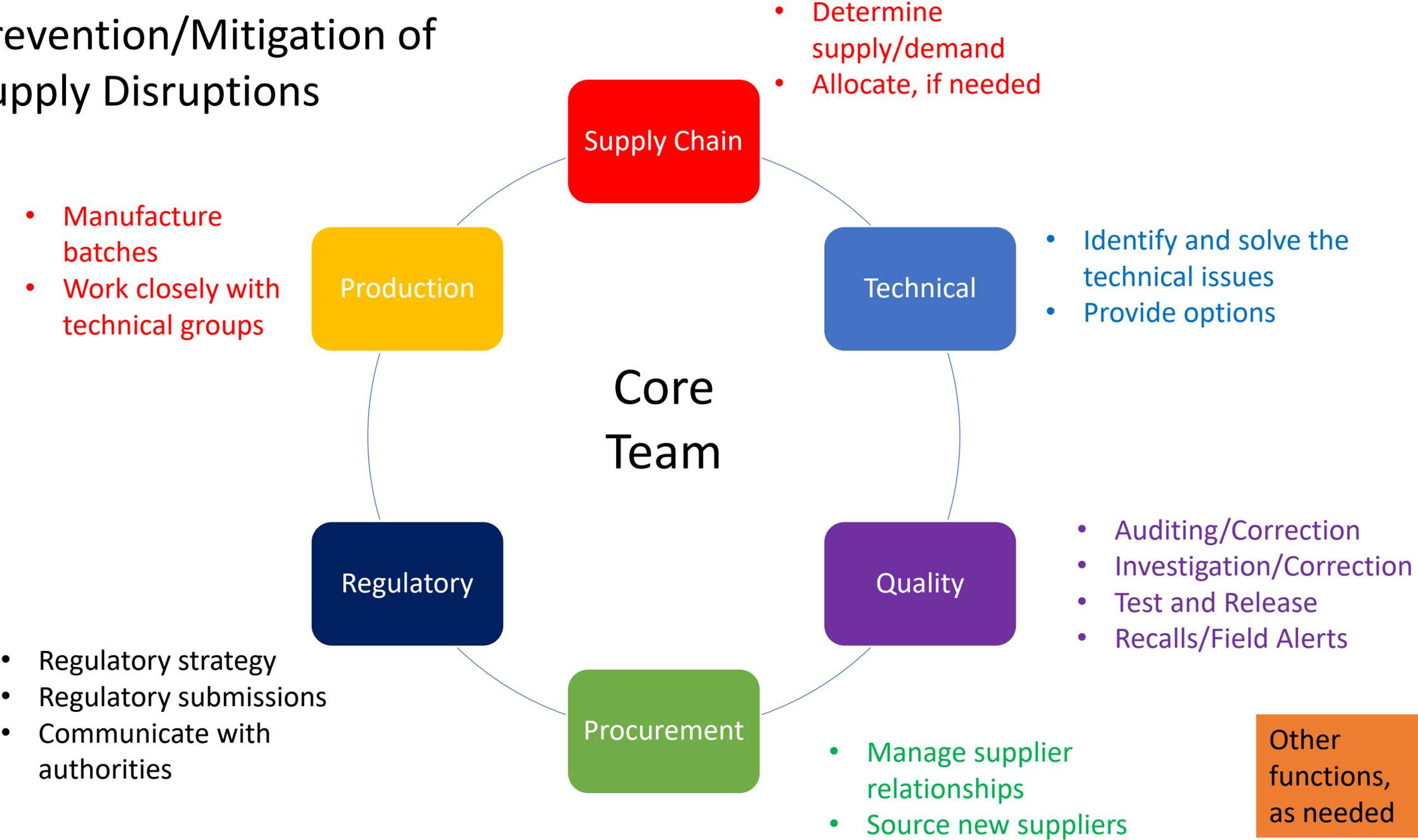
Jeanne Greenwald

Director Regulatory Affairs

 **MERCK**  
Animal Health  
The Science of Healthier Animals®

 Confidential

# Prevention/Mitigation of Supply Disruptions



Example 1	
Issue	API Production Interruption
Root Cause	Industrial Hygiene Issue
Impact	Disruption of Product Supply for Several Weeks Anticipated Once API Stock is Consumed
Mitigation	Work with Supplier to Minimize Disruption
Prevention	<p>Qualify Alternate API Supplier            -technically challenging            -will take over a year, which will not mitigate this disruption, but could prevent in future</p> <p>Anticipate Industrial Hygiene Issues at Suppliers?</p> <p>Larger Safety Stock of API?</p>
Involved Functions	Technical, EHS, Supply Chain, Procurement, Production, Quality, Regulatory



Example 2	
Issue	API Intermediate Supplier Stops Manufacture
Root Cause	Raw Material Used to Manufacture Intermediate Changed and Supplier Cannot Meet Required Quality for Intermediate
Impact	Potential for Disruption of Drug Product Supply
Mitigation	<p>Work with Intermediate Supplier to Bridge the Gap</p> <p>Use Existing Alternate API Supplier (Can they supply enough? Registered in all markets?)</p>
Prevention	Qualify a new supplier of the intermediate
Involved Functions	Technical, Supply Chain, Procurement, Production, Quality, Regulatory



Example 3	
Issue	Contract Manufacturing Organization (CMO) Stops Manufacture of Drug Product
Root Cause	FDA Inspection Deficiencies Caused CMO to decide its not worth remediation
Impact	Disruption of Drug Product Supply in the US once Stocks are Consumed Medically Necessary Veterinary Product?
Mitigation	Temporary import of EU product? Compounding? Regulatory Supplement to Introduce EU Manufacturing Site (expedited CVM review?)
Prevention	Alternate Drug Product Manufacturing Site Better Anticipate CMO Quality Deficiencies Generics? New Products?
Involved Functions	Technical, Supply Chain, Procurement, Production, Quality, Regulatory



Example 4	
Issue	Drug Product Supply Interruption, Product Fails to Meet a Specification on Stability
Root Cause	Site Transfer of Product Critical Manufacturing Process Step Not Well Enough Defined
Impact	Long Term Disruption of Product Supply in the US while the issue was investigated and solved No disruption in other markets
Mitigation	Switch US Customers to Alternatives Allocate Compliant Product to US Customers that Cannot Easily Switch
Prevention	Establish Critical Process Parameters New Products, Generics
Involved Functions	Technical, Supply Chain, Procurement, Production, Quality, Regulatory, R&D





## My Conclusions:

- There is a constant threat of supply disruptions for veterinary drugs
- The types of threats vary
- We must be proactive to head off the threats
- When a disruption cannot be avoided, then we must mitigate, where possible, to minimize the interruption
- All core functions need to be engaged in order to be successful

THANK YOU!

