



XAVIER
HEALTH

Stakeholder Awareness



What is your stakeholder's critical need, and what is the value to them?	Internal Stakeholder	What is the value they bring to the situation
	Quality	
	Regulatory	
	R&D	
	Procurement	
	Marketing	
	Legal	
	Finance	
	(add others)	



Stakeholder Awareness

How does this situation impact them???	External Stakeholder	What type of information are they expecting to have communicated to them
	Key Opinion Leaders	
	3 rd Party Manufacturers	
	Suppliers	
	Customers	
	Distributors	
	(add others)	

What is your stakeholder's critical need, and what is the value to them?	Internal Stakeholder	What is the value they bring to the situation
Compliant, nonconforming products and processes	Quality	Investigation of the issue; Risk assessment to support your decisions; ability to drive the improvement
Information to communicate the issue with regulatory authorities	Regulatory	Expertise on product clearance considerations and regulatory communications
Will this require a design change? All relating information to help determine root cause.	R&D	Ability to re-design the product or process to fix the problem.
How will this impact the supply chain?	Procurement	Ability to source additional suppliers if needed
Meeting customer needs	Marketing	Understanding of user needs and alternative device options
Defend the company from liability	Legal	Understanding of product liability considerations
How long will it be removed from the market? What resources are required to remediate?	Finance	Assessment of financial impact

How does this situation impact them???	External Stakeholder	What type of information are they expecting to have communicated to them
Financially	Investors	amount of time off the market; ability to get market share back after resolution
Impact on treatment/ treatment efficacy	Patients/Users	Recall logistics, resolution timeframe
Potential change in device/ part design, order numbers, etc.	Suppliers	Changes in specifications and orders
Financial	Payors	affected product details and resolution timeframe
Financial	Board of Directors	affected product details and resolution timeframe
Perception of product	Key Opinion Leaders	High level information regarding situation and resolution



Scenario I

- One of your Class II, 510(k) exempt devices has been released to market and is your Company's main source of sales.
- You have received three complaints for three separate devices out of 150 sold thus far.
- After investigation, you find that all 150 devices have been manufactured out of specification.
- While there is no apparent, immediate, severe harm present, the defect may result in delay of patient procedures.
- You have decided that the devices need to be recalled.

Goal: Convince the major stakeholders as to why the Company must proceed with this decision.



Scenario II

- Say that a similar situation occurs with a different device, where, similarly:
 - You have received three complaints for three separate devices out of 150 sold thus far.
 - After investigation, you find that all 150 devices have been manufactured out of specification.
 - While there is no apparent immediate, severe harm present, the defect may result in delay of patient procedures
- However, in this case, this device is the only option available for this patient population. Lack of access, although not life threatening, could impact patient quality of life.
- You have decided that the devices should not be recalled.

Goal: Convince the major stakeholders as to why the Company must proceed with this decision.