Quality Reflections:

Transportation & Logistics

PUERTO RICO LIFE SCIENCES AIR CARGO COMMUNITY

LOGISTICS · QUALITY · CONNECTIVITY

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November 1st, 2023
University Ana G. Mendes Carolina
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Key aspects of Quality in our Supply Chain

Patient Impact

Product Availability

Brand Protection

Cost of Quality

Patient Impact

Products are used in a wide variety of healthcare treatment and intervention for humans. Patients, Doctors and Nurses trust that the Quality of our products is warranted from our suppliers, transit journey, and our manufacturing controls.

Product Availability

Our supply chain is as strong as our weakest link.

- Could cause surgeries or treatments to be delayed or not occur as scheduled causing patient impact
- Trust from our customers and investors resulting in business impact – subsequently impact to our service providers.

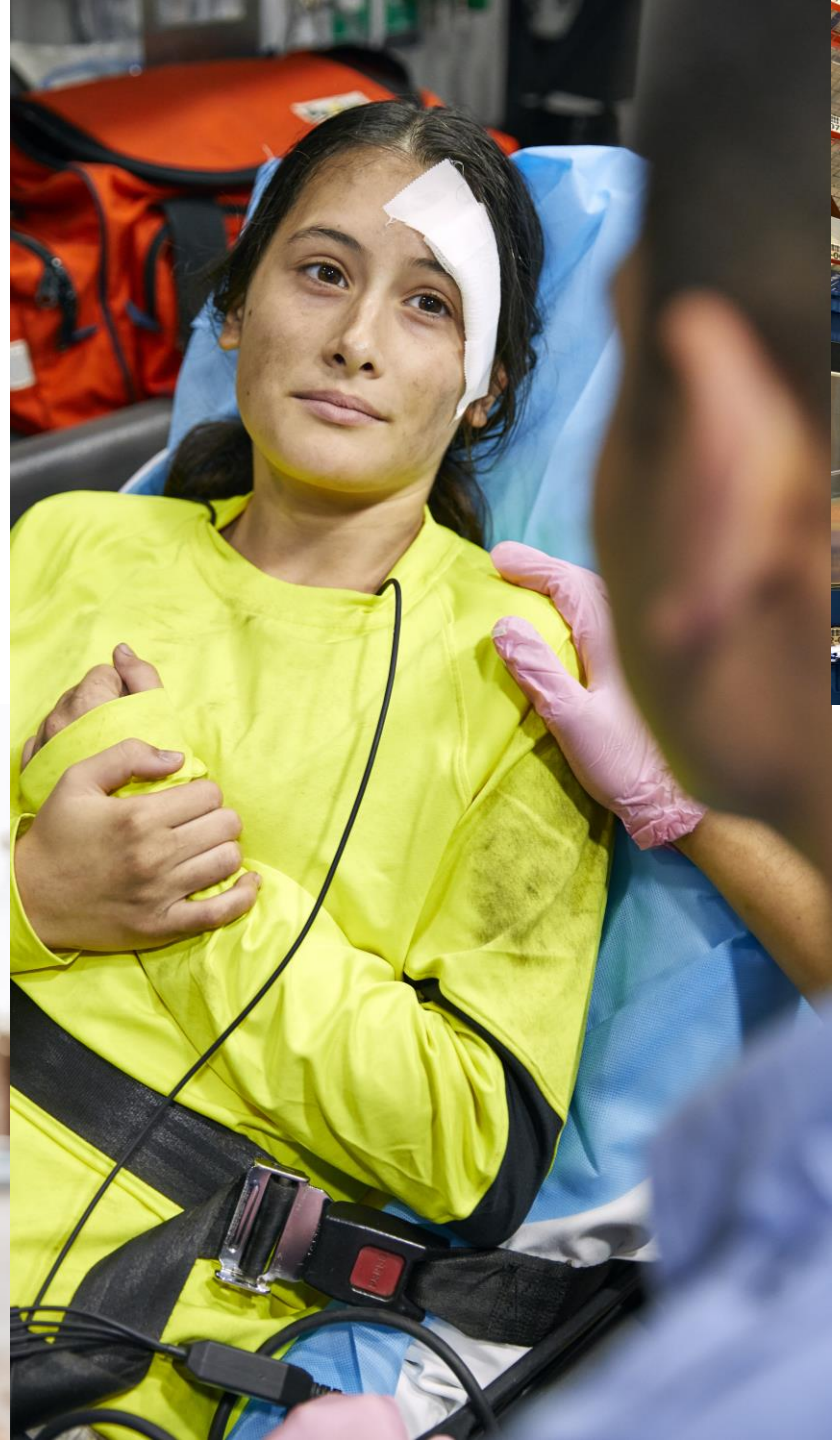
Brand Protection

Protecting our brand from counterfeit and theft.

Factors

- Inadequate treatment or application of the medicine or device from unauthorized personnel
- Losing trust from our customers
- Cause for long term adverse effect on patients or even death

Cost of (poor) Quality

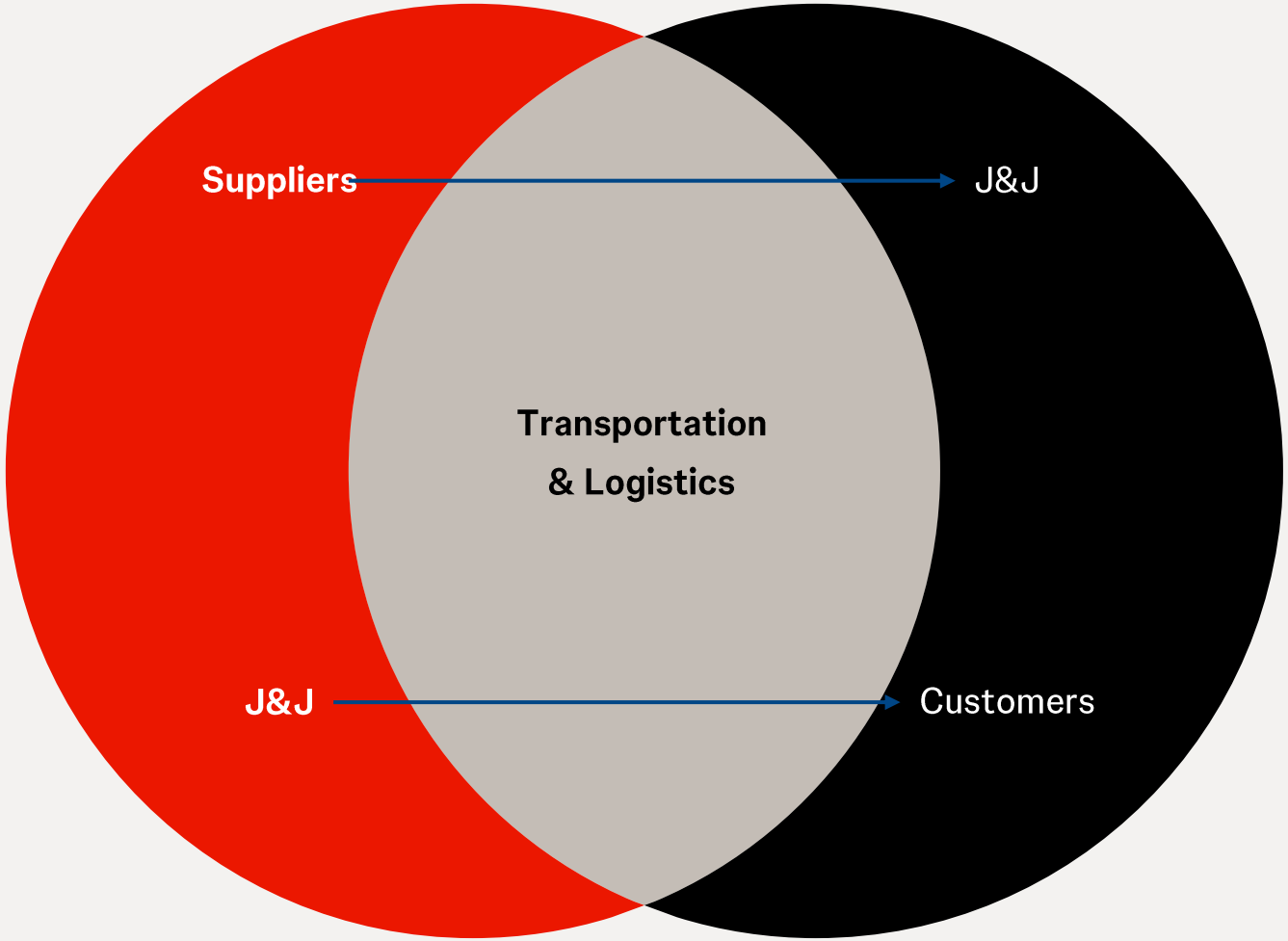


1 non-conformance = $$$$$

- Direct / indirect labor
- Material rework or scrap costs
- 3PL return/credits
- Investigation costs

A critical link in our Supply Chain

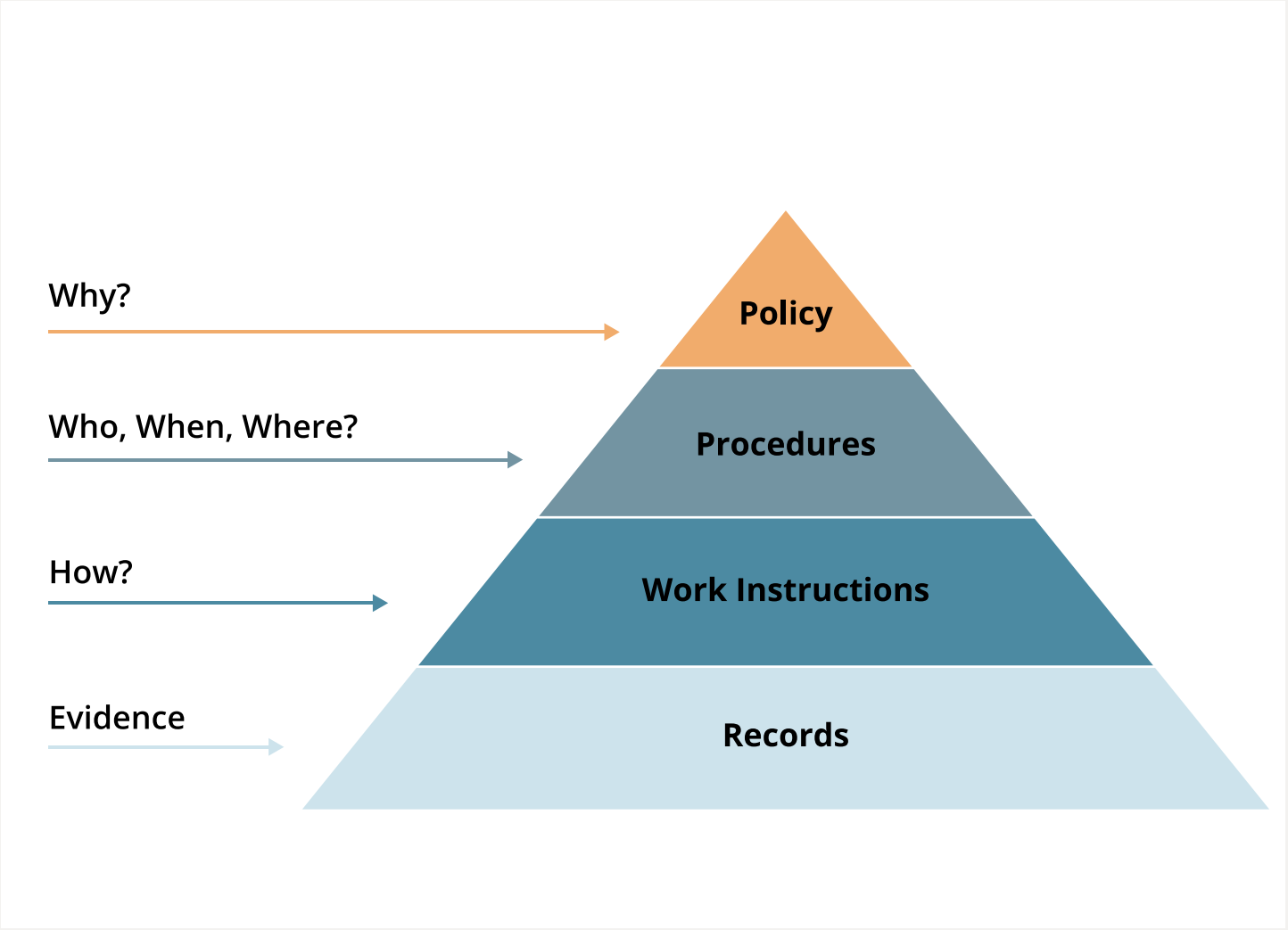
T&L enables/links key elements of our Supply Chain.



Basic Quality Management System

QMS

- Key for a sustainable QMS
- Build with change control and adaptability
- Everyone must understand this is in place and follow it as part of their role

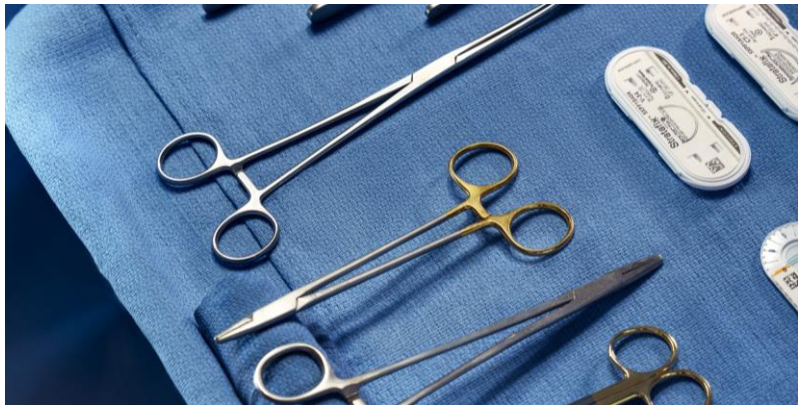


Our Expectations

Do it right the first time.

General Quality Considerations

Key Takeaways



Quality Requirements

- Are you aware of what's "inside the box"?
- Are there any environmental monitoring requirements? Temperature Control?
- No use of pesticides limitations?
- Is there special pallet or packaging configuration?
- Is product content sterile?
- Is this a regulated or control medicine or medical device?

Controls and Reaction Plans

- Do I have the capability and equipment to monitor specified requirements?
- How do I react to "out of the ordinary" signals?
- Who is my point of contact?
- How do I formally document traceable and legible documentation of events – such as temperature excursions, broken pallets, damage boxes?
- How can I prevent out of specification conditions

Investigation, Corrective/Preventive Action

- Upon noticing or been notified of an out of specification event (non-conformance), one shall initiate a documented investigation, to determine what caused the event
- Establish immediate containment actions
- Define actions to correct the situation
- How can you further prevent this from happening again
- Monitor and confirm effectiveness of implemented actions

Thank you

If you have more questions, please contact:
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