

# Getting the Basics Right

What are the pre-requisites for a Blood Service before considering a plasma for fractionation program?

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Australian Red Cross Blood Service













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# How many days since the Montague Street Bridge has been hit?

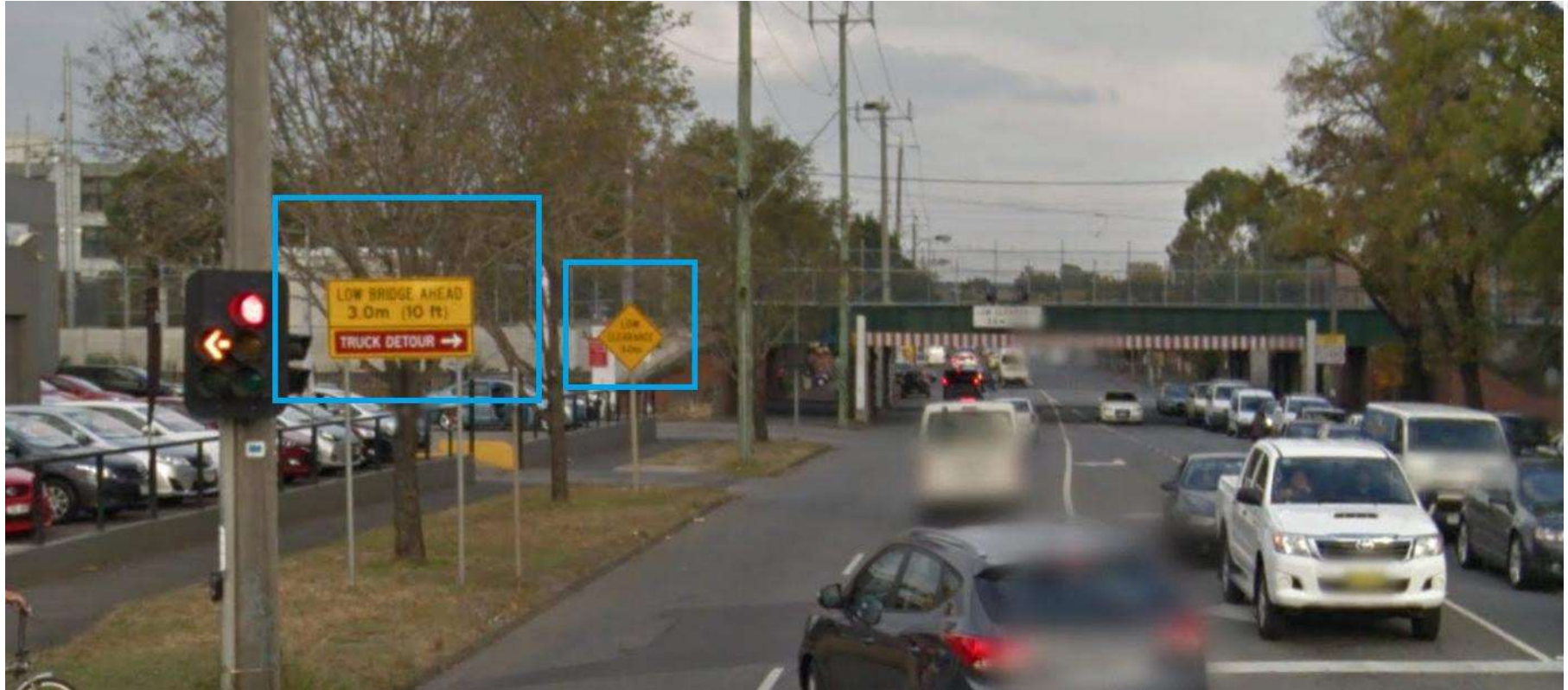


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Last Championship Bout: Monday 16th January 2017  
Losers: [Truck](#) (& [Gantry](#))









**a** alamy stock photo

FA0MAK  
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# Why the Bridge?

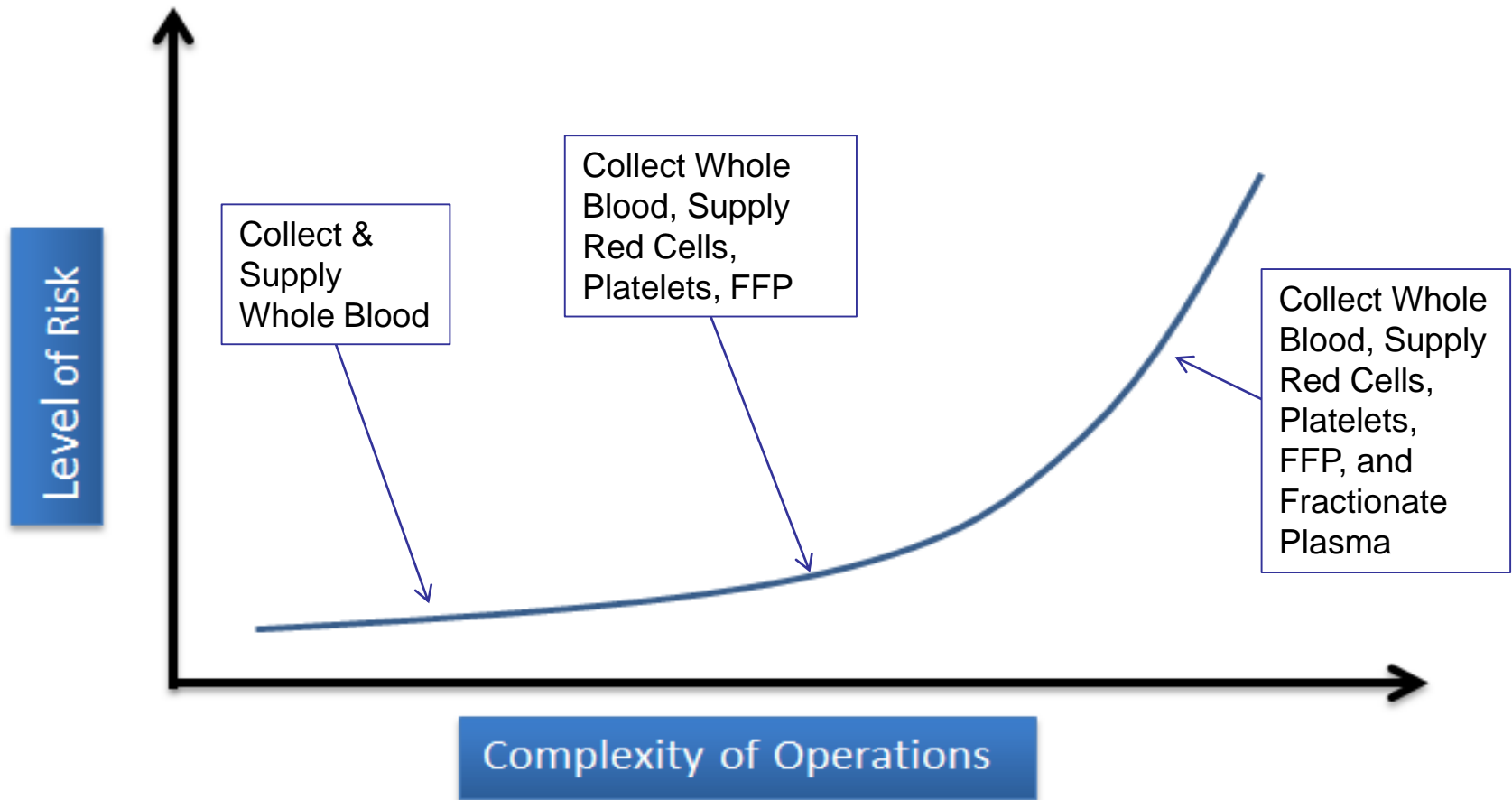
- Was purpose built for a different context
- Does not adequately serve the purpose for today's context
- Attempts to modify some practices are only partially effective
- Without fundamental redesign, accidents will continue to occur



# Blood Establishments and Bridges

- Moving from supplying blood and blood components to fractionating plasma is a fundamental shift in process
- Moving towards biological pharmaceutical manufacturing
- Significant increase in complexity

# Complexity vs. Risk



# Basic Principles



Effective Quality Management System



Appropriate Governance and Risk Management Practices



Adequate Regulatory/Legislative Framework



# Adequate Regulatory/Legislative Framework

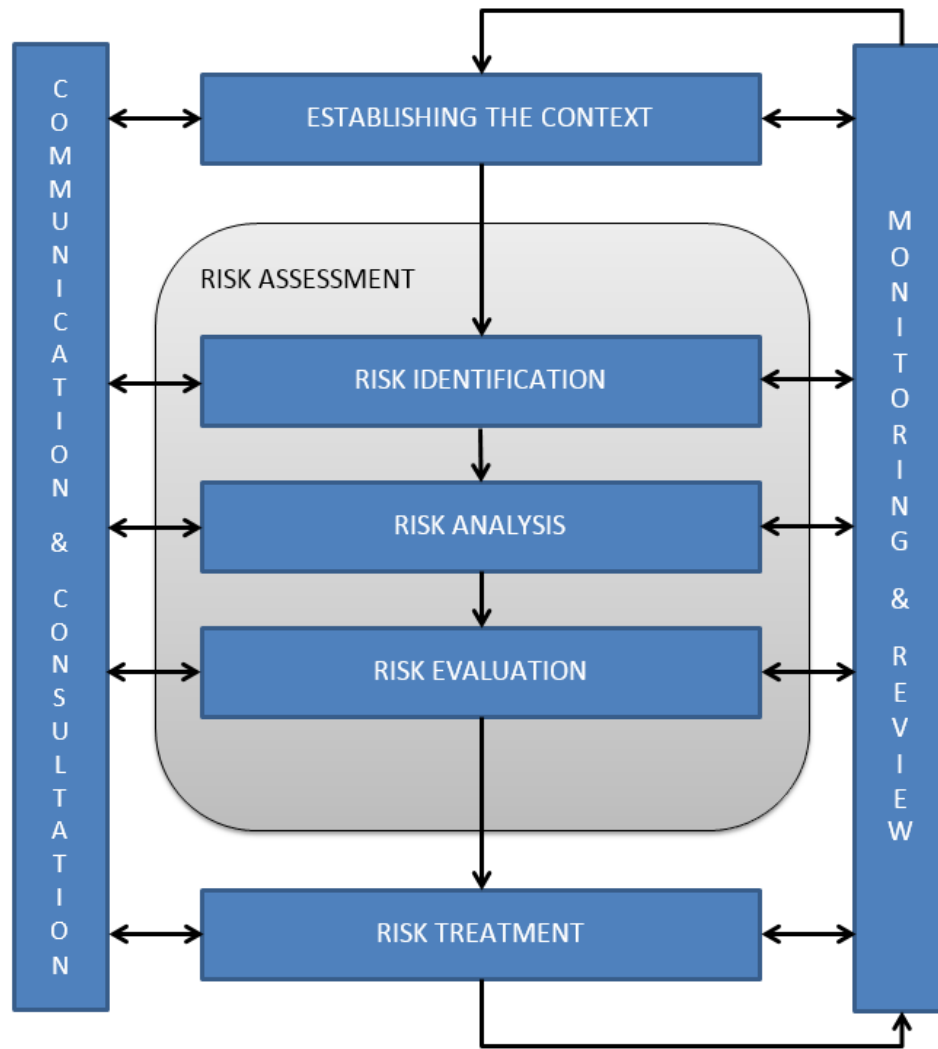
- Independent body that can regulate, and monitor compliance
- Should consider the following:
  - Minimum standards of operations – Good Manufacturing Practice (GMP)
  - Ethical use of blood and blood products
  - Ensuring that providers of blood and blood products are authorised
  - Consider international best practice
  - Consider local customs and situations

# Appropriate Corporate Governance

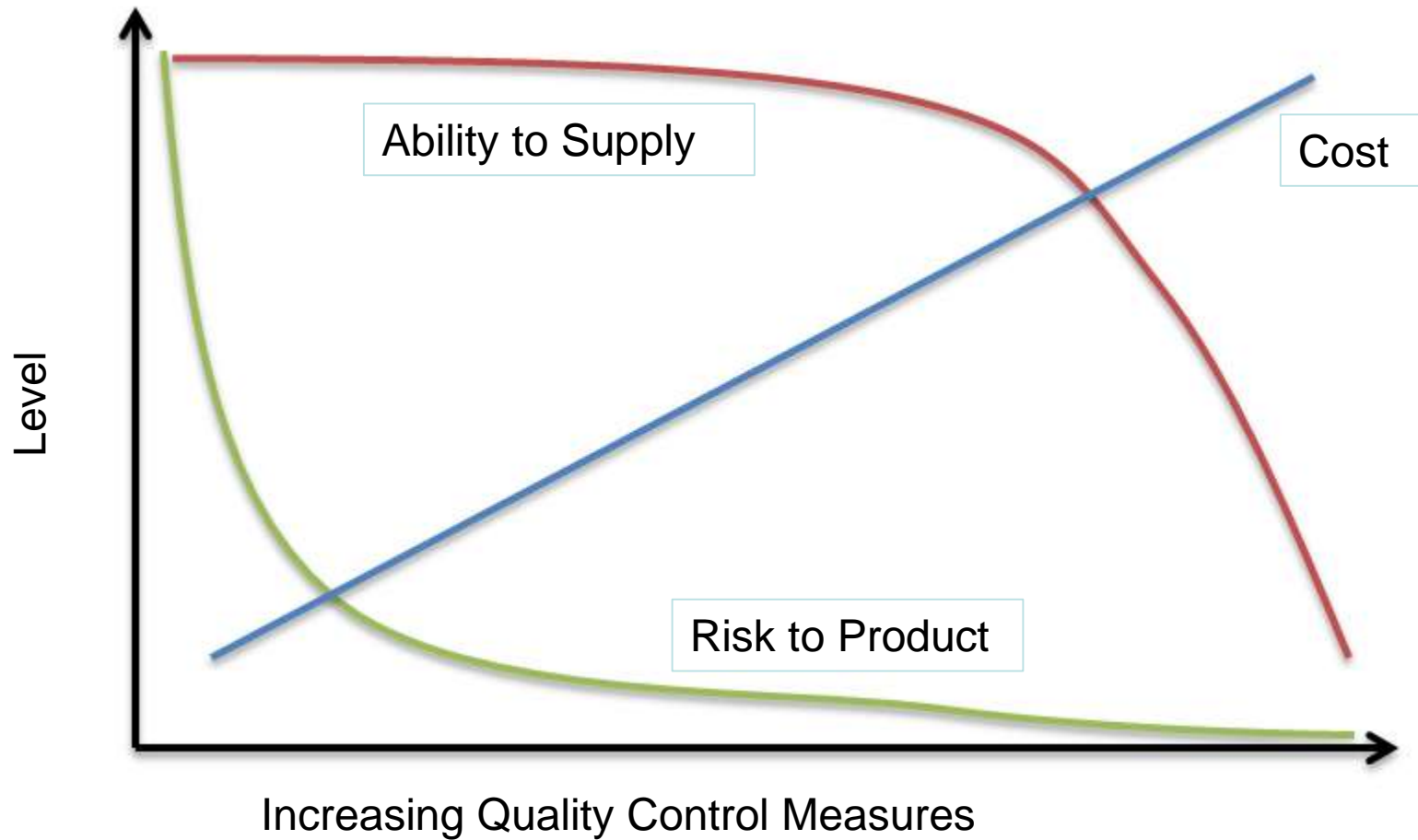
Effective governance:

- System by which an organisation makes and implements decisions in pursuit of its objectives
- Encompasses both managing stakeholder expectations, and also internal risk management practices
- This will differ depending on the country's approach to managing blood and blood products, e.g. Red Cross, vs. Government run blood establishments
- All relevant activities need to be included, e.g.:
  - Medical
  - Technical/Scientific
  - Finance
  - Human Resources
  - Quality

# Risk Management



# Balancing Act





# Effective Quality Management System

“A quality management system (QMS) is a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives.

A QMS helps coordinate and direct an organization’s activities to meet customer and regulatory requirements and improve its effectiveness and efficiency on a continuous basis.”

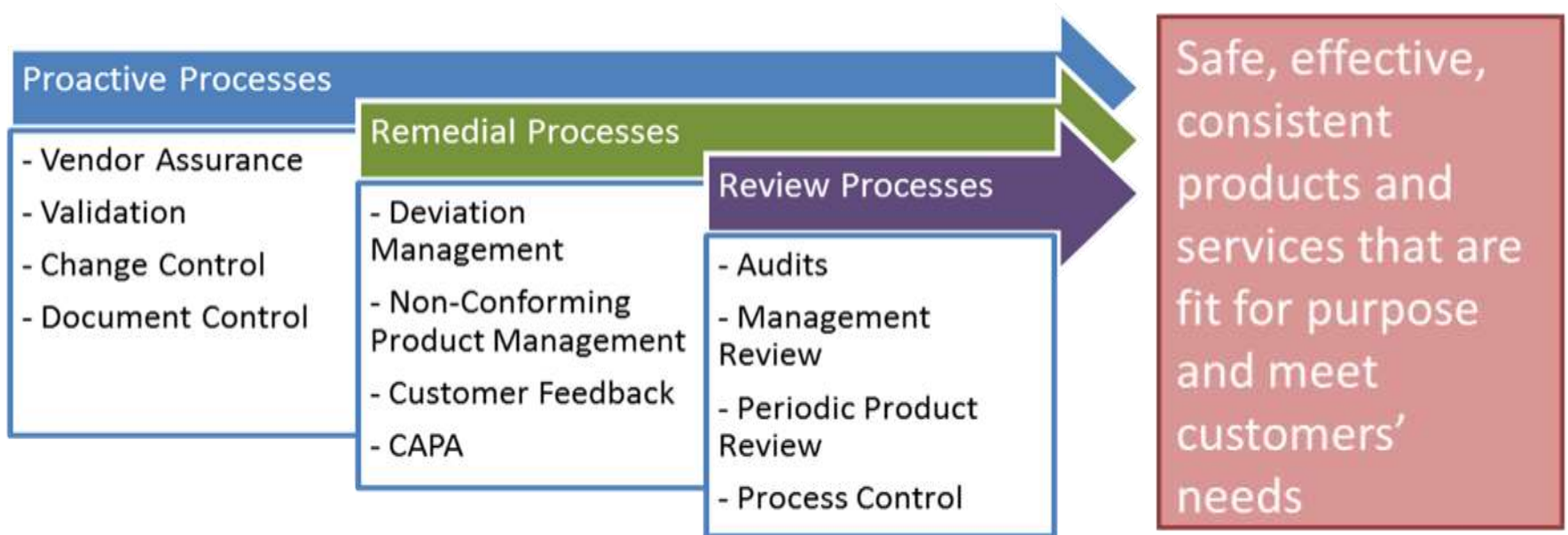
# ISO 9001:2015 – Quality Management Principles

- Customer Focus
- Leadership
- Engagement of People
- Process Approach
- Improvement
- Evidence Based Decision Making
- Relationship Management

# Good Manufacturing Practice

- Integral part of a Quality Management System
- Set of principles and practices for assuring safe, reliable and effective products
- Numerous examples of standards:
  - PIC/S Guide
  - ICH Q series
  - Various national codes of GMP

# Elements of a GMP-Based Quality Assurance System





# Product and Process Knowledge

- With these basic fundamentals in place, it is important to understand your products and processes intimately
  - Critical Quality Attributes (CQA's)
  - Critical Process Parameters (CPP's)
  - Critical Control Points (CCP's)
  - Validated state
- Understanding product and process attributes is required to truly be able to understand and manage risk

# In Summary

- Moving from a Blood Establishment to a plasma fractionator is not a simple step, and changes the context of your organisation
- A robust regulatory/legal framework should be in place in your country
- Good corporate governance and risk management principles should be in place
- Your Quality Management System should be effective, and broad enough to factor in the requirements for blood collection and processing, as well as plasma fractionation