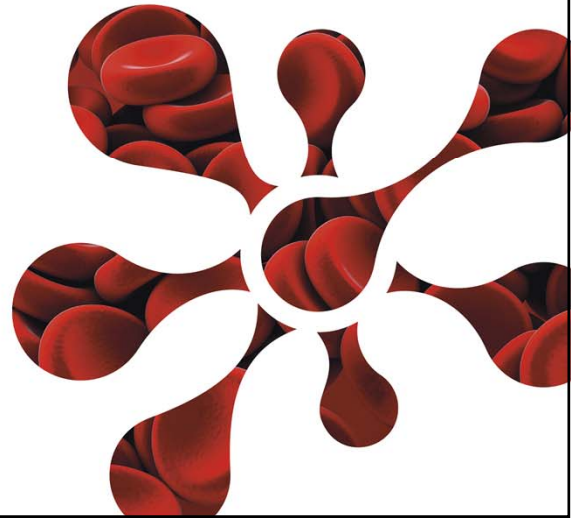


Business continuity to ensure blood supply, viewpoint from a supplier

Nigel Talboys, President of BTA

EDQM meeting
27-29 October 2020



About BTA

- BTA is a non-profit trade association for blood bag set manufacturers.
- With an international scope, BTA's mission is to promote the correct use and safe supply of blood for transfusion.
- BTA supports policies that allow for blood bag set manufacturers to meet public health needs.

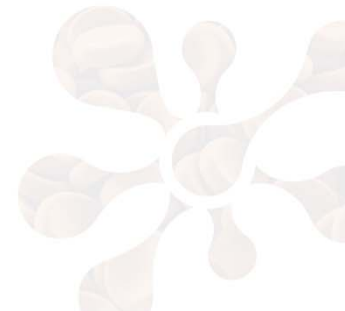


Current members

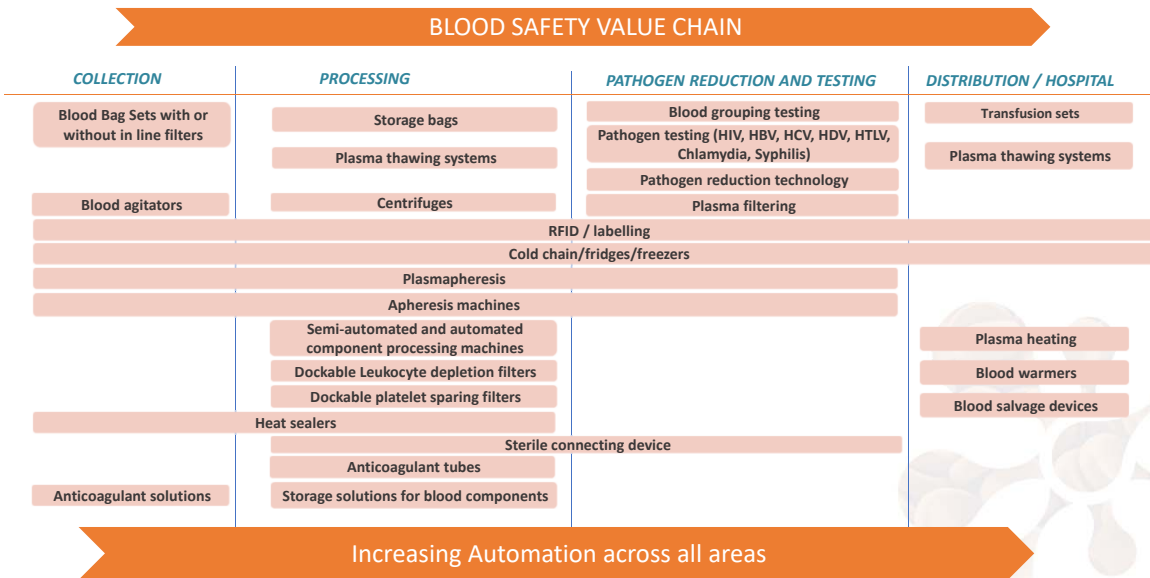


Agenda

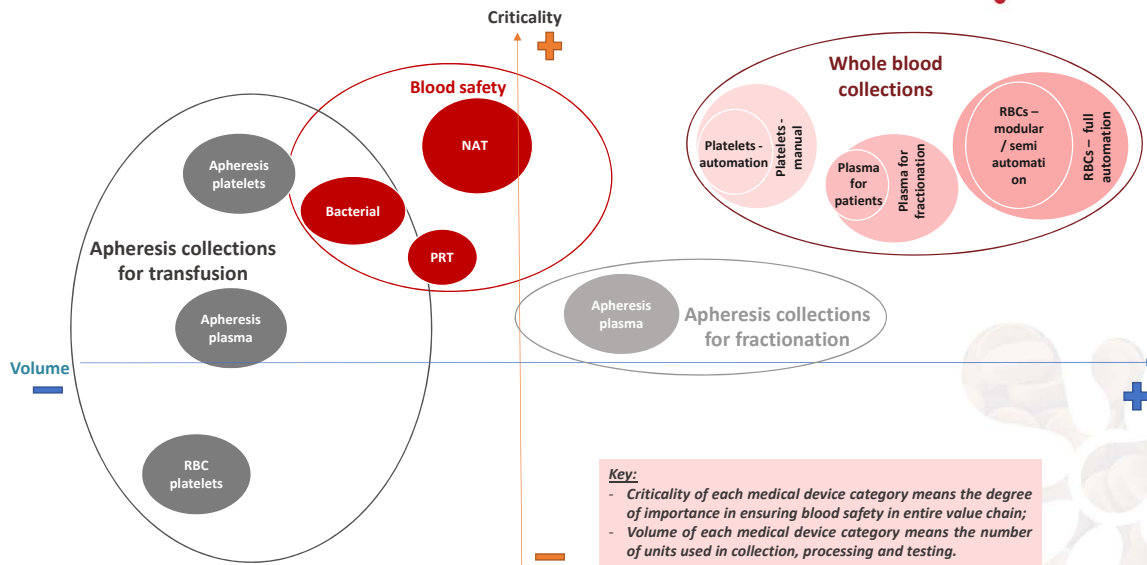
- 1 Why is Business continuity so important. Criticality of medical devices in the Blood Safety Value Chain
- 2 Overview of Business Continuity and why is it so key to industry
- 3 Principles and methodologies of Business Continuity
- 4 Lean Business Continuity – Customer focus
- 5 Conclusion



Critical medical devices that could impact the continuity of the blood supply



What are the most critical products?



What Business Continuity is about?

Dictionary definition:

Business Continuity is *the strategic and tactical capability of the organization to **plan for** and **respond to** incidents and business disruptions to continue business operations at an acceptable predefined level.*

Our customers need **confidence and trust** that we will be able to supply the right product at the right time.

Our priority is **on preventing or mitigating** any interruptions of product supply to customers by taking a comprehensive, global approach to business continuity.



Why is Business Continuity so key?



- Changing and Globalizing environment:
 - Political & Social instability
 - Natural disasters (Tsunami in Japan, Volcano in Iceland, Earthquake in Italy, **pandemics...**)
 - Cybersecurity
 - Changing regulations (MDR, Blood Directive, Brexit)
 - Increasing concern regarding supply security



- Cost Pressure at our customers:
 - Working Capital scrutiny → strict inventory control
 - Increasing concern regarding supply reliability and velocity

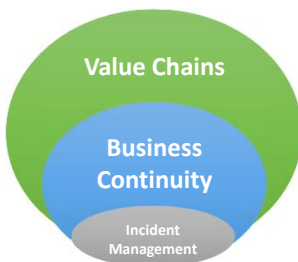


- Dedicated consumables
 - Uniqueness of technologies
 - Increasing concern regarding supply dependency

7

Business continuity is often linked to disasters

Disaster planning is a subset of incident management – only a piece of business continuity



- Business Continuity is a Component of Each Value Chain
 - Product Chain – Product Development
 - Supply Chain – Movement of Materials
 - Material Conversion Chain – Production
 - Order Fulfillment Chain – Delivery
 - Service Chain – Post-Sales Warranty & Repair

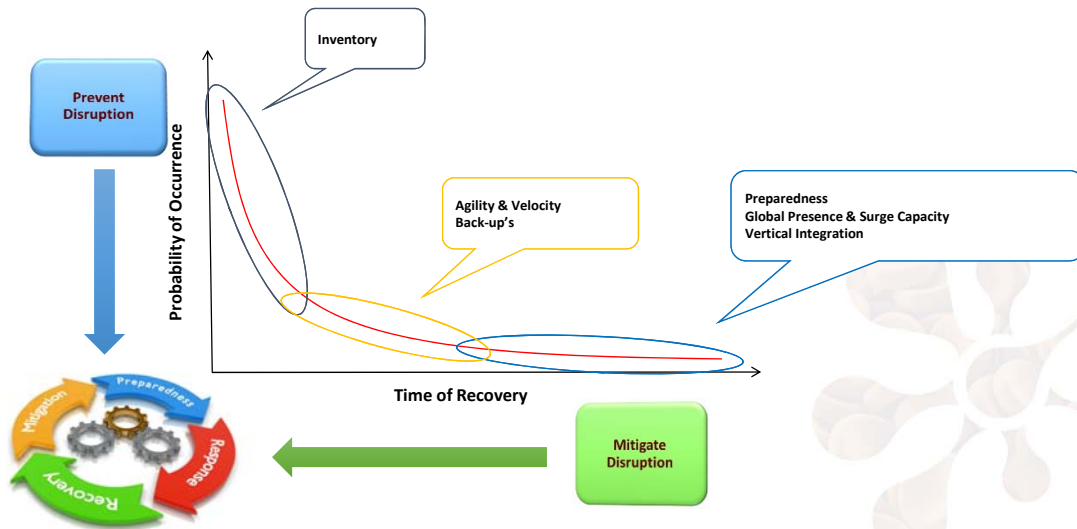
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Key Principles of Business Continuity



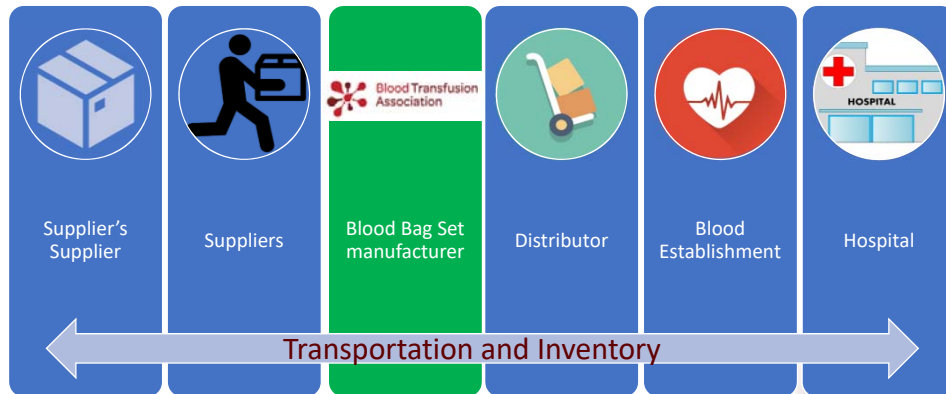
Business Continuity Focus

Aligned Business Continuity answer to risk profiles



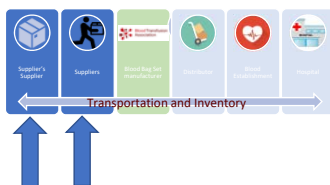
Lean Business Continuity

Focus on value from a customer's perspective



Lean Business Continuity

Reduce variation within our control by seeking to "single source" and avoiding "sole source"



- Robust continuity planning with critical suppliers
- Supply Chain
 - Shorten supplier lead times
 - Decrease transit time
- Increase production agility
 - Increase product uniformity
 - Increase vertical integration
- Surge capacity

Lean Business Continuity

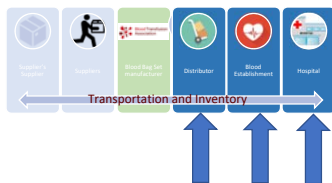


Focus on value from a customer's perspective



- Backup systems and robust predictive maintenance
- Internal and external risk assessments (external standards)
- Lean manufacturing
- Improve Quality at each step of the supply chain
- Increase production agility
 - Global presence
 - Increase vertical integration

Lean Business Continuity



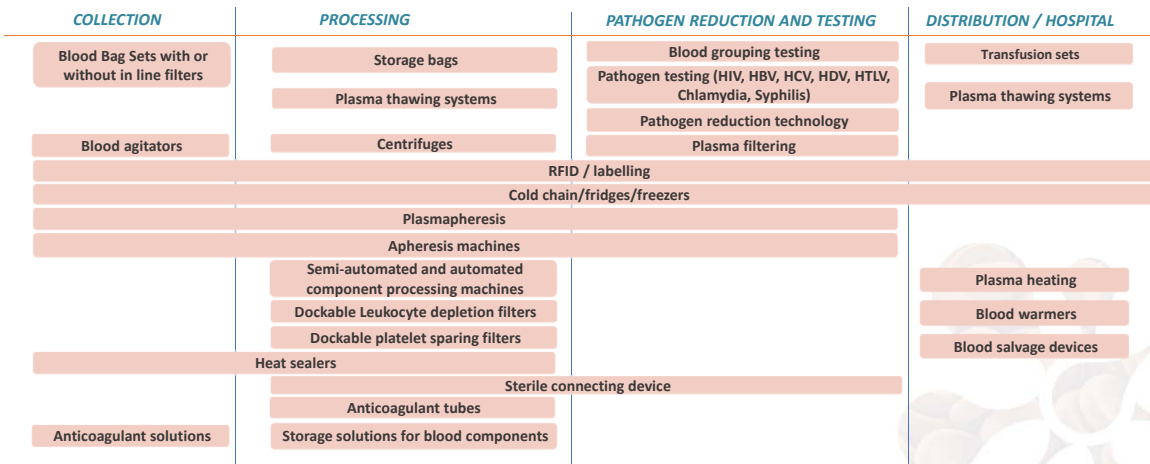
Focus on value from a customer's perspective



- Increase Market forecast accuracy
- Supply Chain
 - Shorten supplier lead times
 - Decrease transit time
- Inventory
 - Multiple locations
 - In relation to market demand
- Robust Continuity planning with critical suppliers
 - Warehouse
 - Logistic providers

Conclusion

BLOOD SAFETY VALUE CHAIN



Increasing Automation across all areas

Conclusion

The Blood Bag Set Industry operates in critical processes across the **Blood Safety Value Chain**

- We have a responsibility to ensure that there are robust processes in place
- We will use our best commercial efforts to help our customers deliver an uninterrupted supply of blood components to patients
- We put considerable efforts in quality systems including BCP
- We are in uncertain times
 - Pandemics
 - Environmental disasters
 - Regulatory changes
 - Political changes (Brexit)



Thank you for your time and attention

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