

**SHARE YOUR HEALTH
AND VITALITY WITH
SOMEONE IN NEED**



Safety and quality of tissue product in Canada

**Tissue Expert Committee
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Canadian Blood Services
it's in you to give

Solutions Discussed by Tissue Expert Committee

Case for Change Problem	Potential Solution
<p>The safety and quality of tissue product in Canada cannot be assured:</p> <ul style="list-style-type: none">• Inconsistent quality and safety• Incomplete traceability• No effective surveillance system• Incidents with imported tissue products• No systematic follow-up of medical outcomes	<ul style="list-style-type: none">• Nationally standardized quality program with some regional/local customization<ul style="list-style-type: none">➤ Standardized packaging and labelling (ISBT 128)➤ Standardized information for tissue recipients (informed consent)➤ Risk management approach to allow different levels of effort for different tissues• Real time integrated information system covering donor, recipient and product information and linked bank-to-bank, to ensure 100% traceability from donor to recipient for all products including imported products• Audit and accountability are critical for both domestic and imported tissue

Discussion is premised on a common language

⇒ **Quality (vs safety)**

⇒ **Quality Management System**

↳ **Quality Assurance**

↳ **Quality control**

Common language

Quality

- Degree to which a product meets clinicians' needs.

Common language

Safety vs Quality

Quality processes that make up a quality management system, i.e., a “quality program”

- ✓ Product specifications development
- ✓ Product realization
- ✓ Document management (review, approval, control, etc.)
- ✓ Validation (product, equipment, process, computer systems)
- ✓ Qualification and Training
- ✓ Records management
- ✓ Information management
- ✓ Suppliers management
- ✓ Materials management
- ✓ Equipment management
- ✓ Facility management
- ✓ Change management
- ✓ Problem management (non-conformances, deviations, errors & accidents (E/As), customer complaints, etc.)
- ✓ Process management
- ✓ Surveillance
- ✓ Reporting (E/As, adverse reactions, etc.)
- ✓ Corrective actions/Preventive actions (CAPA)
- ✓ Audit
- ✓ Management review
- ✓ **Continuous improvement**
- ✓ **Customer satisfaction**

Safety

- Blood regs
- CTO regs
- ISO 13485



GMP environment

Quality

- ISO 9001
- NQI
- Baldrige

Common language

- ➔ **Quality Management System (QMS):** System (organizational structure, responsibilities, processes, procedures, instructions, processes, and resources) to establish policy and objectives and to **direct and control (i.e. manage) an organization with regard to quality.**
- ↳ **Quality assurance (QA):** Coordinated activities of a QMS that focuses on **providing confidence that quality requirements are being fulfilled**
- ↳ **Quality control (QC) :** Component of a QA program that **control the quality of a given product or service**, most often by verifying outputs against defined customer requirements (internal or external). This verification is achieved through inspection and testing.

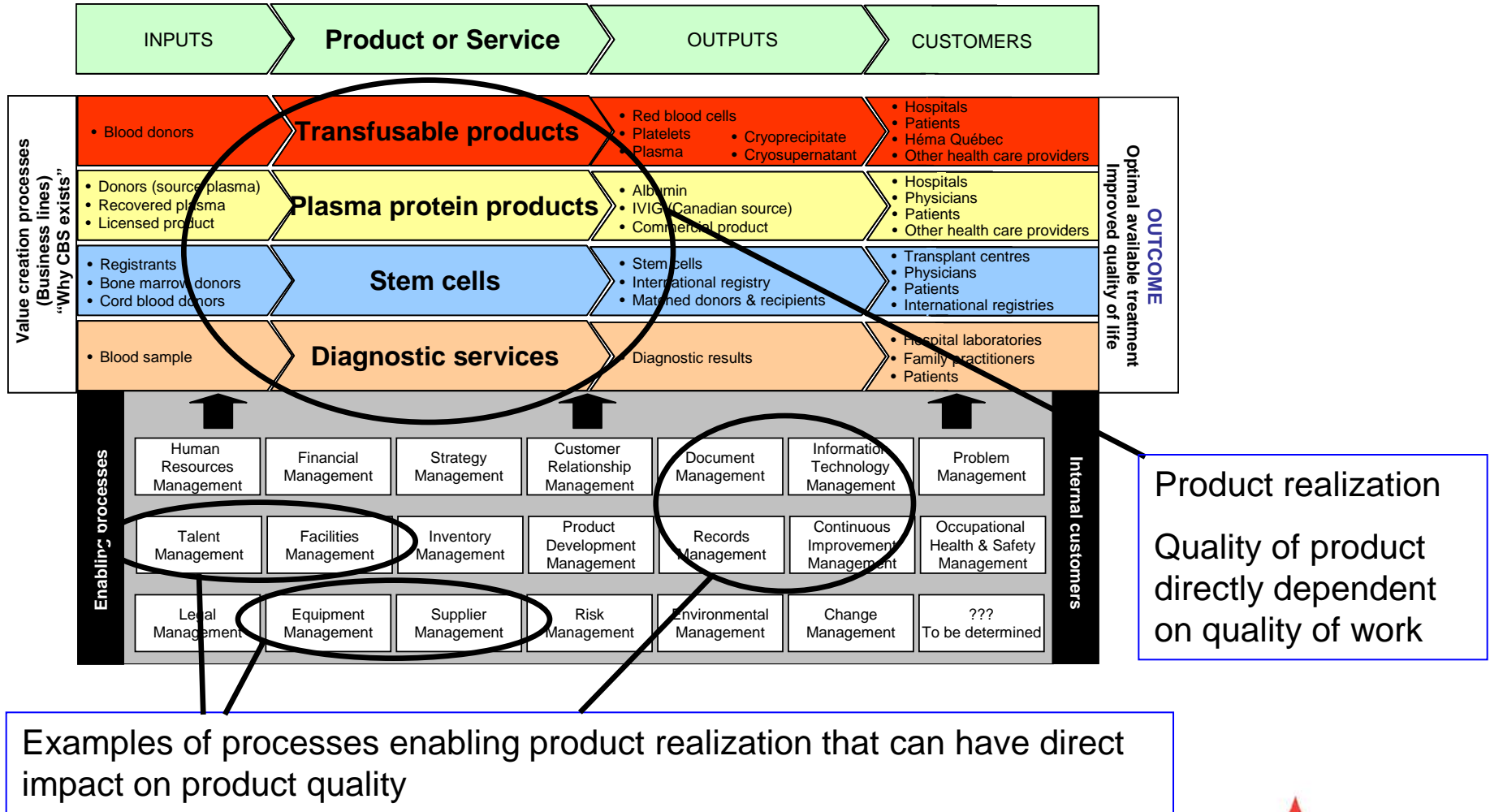
Nationally standardized quality program with some regional/local customization

- How much standardization vs local customization ?
- Where, i.e. which processes?

Quality processes that make up a quality management system, i.e., a “quality program”

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Standardization vs local customization



BLOOD.CA WWW.BLOOD.CA WWW

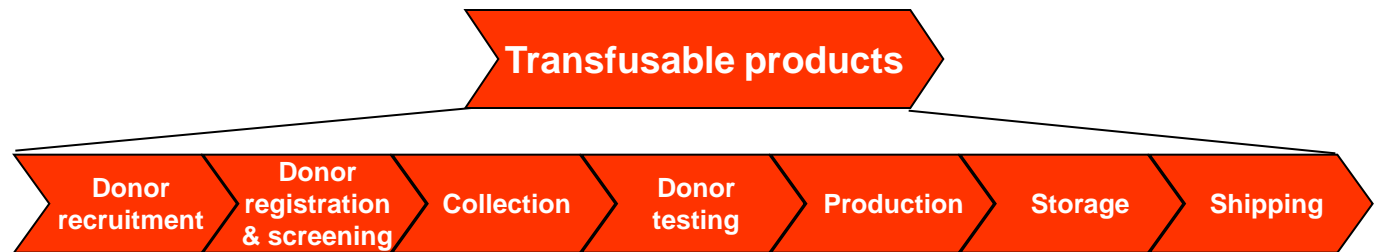
Standardization vs local customization

Product realization



Striving for complete standardization:

- Product specifications
- Core manufacturing processes (work instructions, forms, etc.)



- Product labelling (labels, package insert)

A unit of blood from Vancouver meets clinicians' needs to the same extent as a unit of blood from Halifax

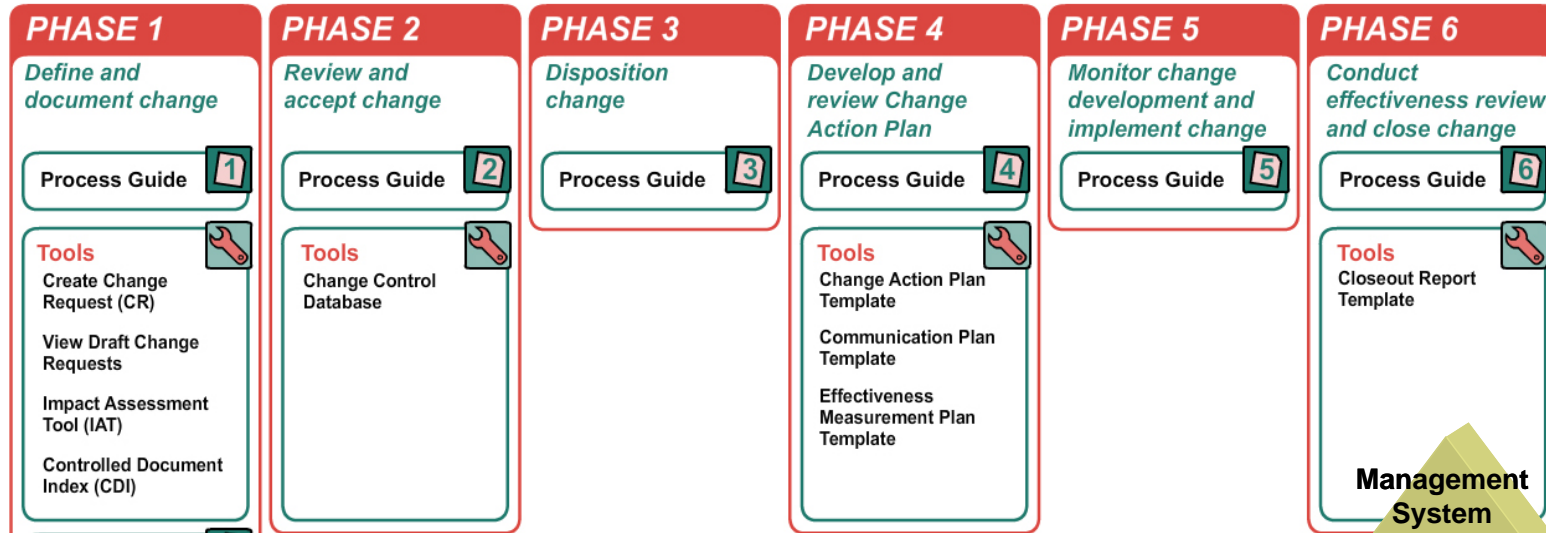
Standardization vs local customization

Enabling processes

Change Control Policy

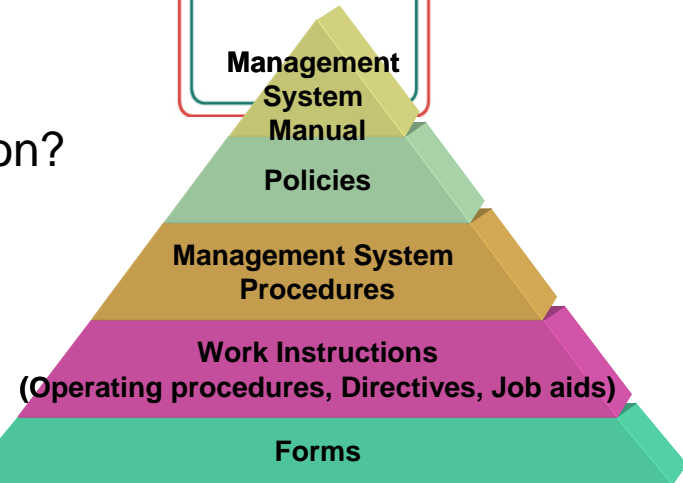
SOP 08 500

Process Guide



What is the right level of standardization/customization?

- General directions/expectations ⇨ Policy level
- What needs to be done ⇨ Management system procedure
- How it needs to be done ⇨ Work instructions
- How it is documented ⇨ Forms



Operationalizing a quality program

Quality processes

- Product specifications development
- Document management
- Validation
- Qualification and Training
- Records management
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- Suppliers management
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To develop, implement, maintain and improve requires investment of time and resources.

Head Office resources for the following processes:

- Document management
- Deviation management
- Quality training
- Validation
- Change control
- CAPA
- Reporting
- Submissions

Operationalizing quality assurance activities

- ✓ Review and approval
 - ◆ Product specifications
 - ◆ Standard Operating Procedures (SOP)
 - ◆ Validation plans and results
 - ◆ Suppliers
 - ◆ Training plans
 - ◆ Corrective action plans
 - ◆ etc.
- ✓ Product disposition (quarantine, release, recall)
- ✓ Tracking and trending
 - ◆ Errors/Accidents
 - ◆ Adverse reactions
 - ◆ Non-conformances
 - ◆ Audit observations
 - ◆ Complaints
 - ◆ Quality control results
 - ◆ Etc.
- ✓ Quality control
- ✓ Quality reports
- ✓ Effectiveness checks (CAPA)
- ✓ Audit
- ✓ Root-cause analysis and problem solving

- ➔ Resources in manufacturing sites across Canada (30% for QC testing)
- ➔ Resources at Head Office
- ➔ Audit is one of numerous activities to provide adequate assurance to organization

Economy of scale

QC requirement for Plateletpheresis (April 2008)

CBS site	# units collected/ month	# units tested/ month ¹	% of production
Toronto	700	10	1.4 %
NEON	500	10	2.0 %
BC/Yukon	400	10	2.5 %
Hamilton	200	10	5.0 %
Calgary	200	10	5.0 %
Edmonton	200	10	5.0 %
Saskatchewan	180	10	5.5 %
Winnipeg	150	10	6.6 %
New Brunswick	150	10	6.6 %
Halifax	125	10	8.0 %
London	100	10	10.0 %
Newfoundland	100	10	10.0 %

¹ QC requirement according to CSA standard is 1% of production or a minimum of 10 per month.

Verification of compliance

Quality processes

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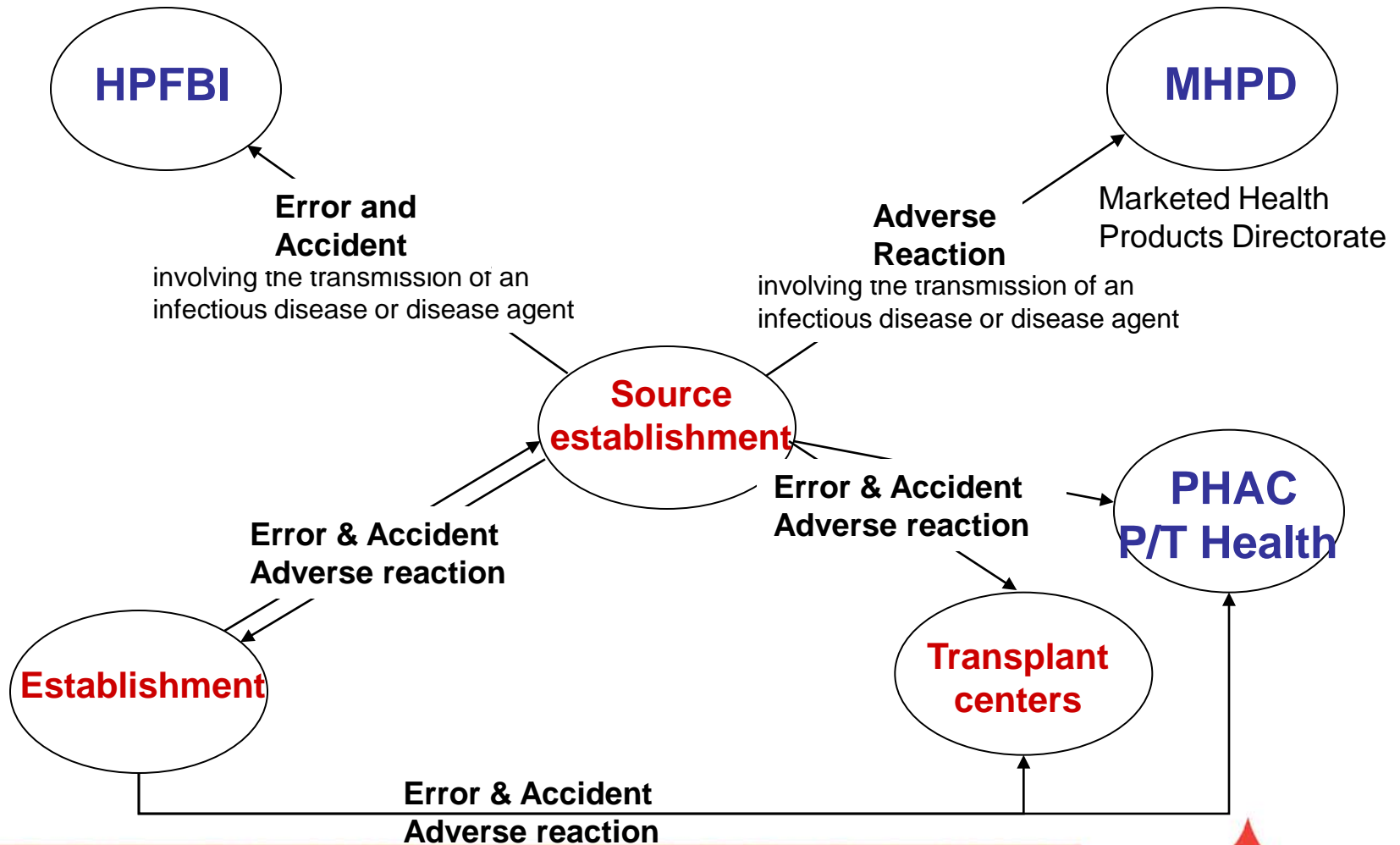
Health
Canada

Santé
Canada

- ⇒ Inspections by Health Canada focus on compliance to GMP
- ⇒ In 2009-10, 25 inspections of different CBS sites by Health Canada
- ⇒ Inspections can be anywhere from 1 to 10 days based on scope (collection, production, testing, apheresis, etc) and size of activities
- ⇒ Observations must be responded to within 21 days
- ⇒ Corrective actions verified during next inspection
- ⇒ **Resources at Head Office to coordinate and manage Health Canada inspections**

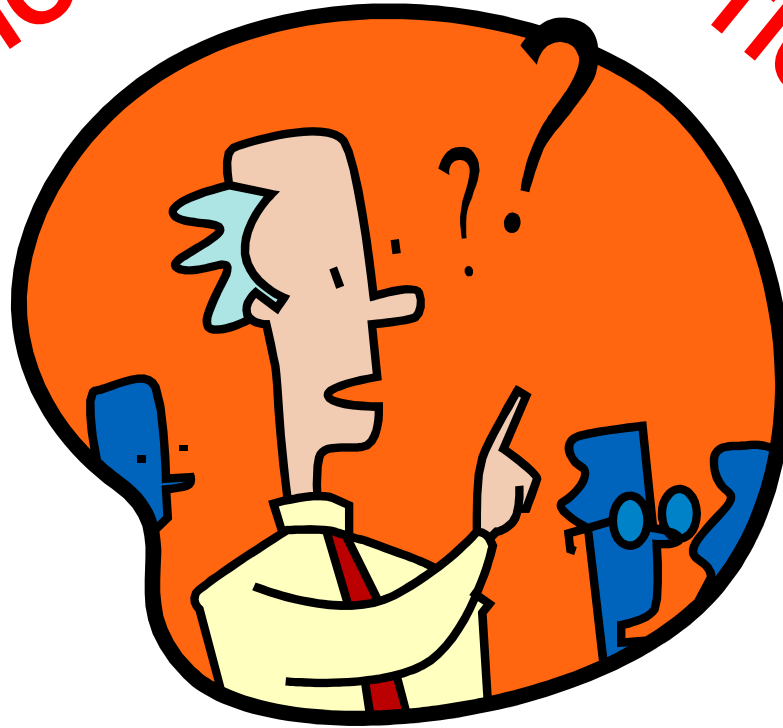


Reporting Who does what??



QUESTIONS??

QUESTIONS??



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