Quality in Tissue Banking

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Quality Leader, Regional Tissue Bank

Regional Tissue Bank

Capital Health

Healthy People, Healthy Communities

What is **“Quality”**

In manufacturing, a measure of excellence or a state of being free from defect, deficiencies and significant variations, brought about by strict and consistent adherence to measureable and verifiable standards to achieve uniformity of output that satisfies specific customer or user requirements

Quality Culture

- A continuous improvement culture helps organizations to deploy best practice, develop committed employees, manufacture value added products and services and to have the expectations of the customers exceeded
- The way employees actually behave and think while no one is watching is “quality culture”
- Continuous improvement encompasses all forms of improvement in the form of elimination of defects, incremental improvements adding value, innovation which are then measured, monitored, managed and maximized

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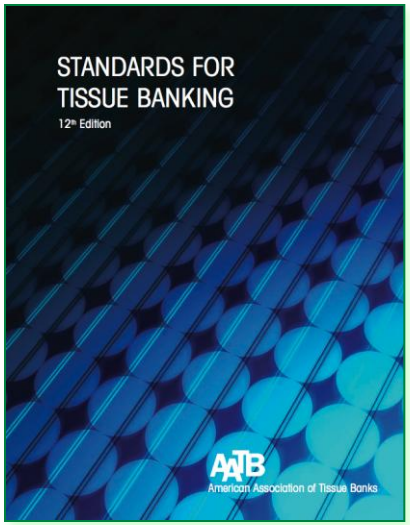
Regulators, accreditors – In Canada

•**CTO's** - Health Canada Regulations – **"Safety Human of Cells, Tissue sand Organs for Transplantation Regulations"**

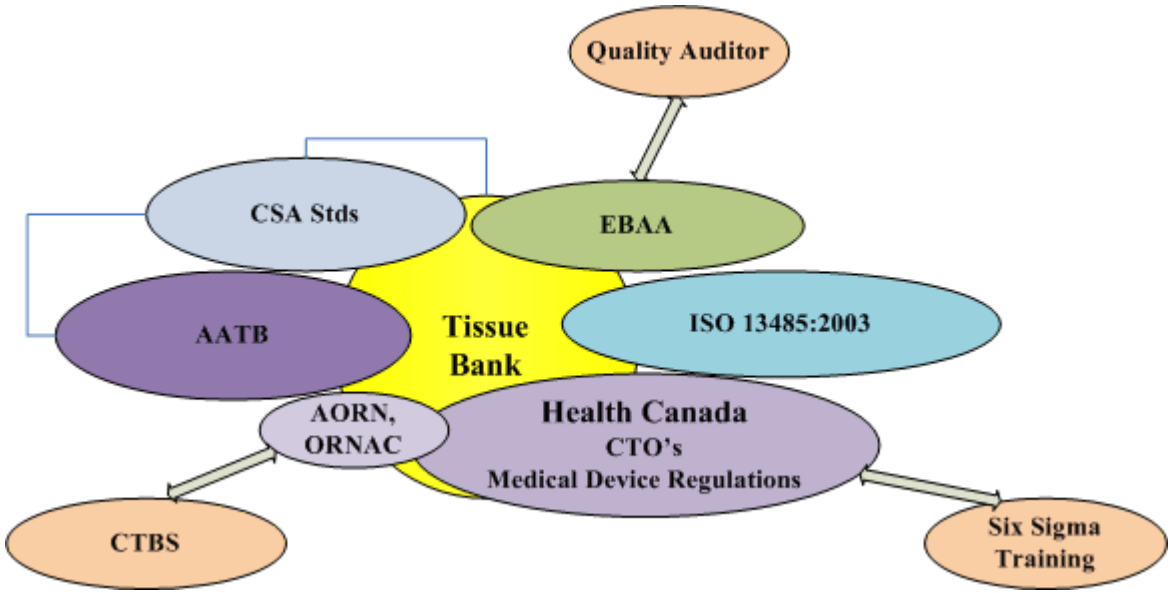
•**Medical Device Regulations (MDR)** – Device License Class IV, required to distribute Heart Valves in Canada

•ISO 13485 – Quality Management Stds for Regulators
•AATB Standards
•CSA Standards (Z900 series)
•EBAA Standards

Health Canada Santé Canada



Integration of Standards



Quality Management System

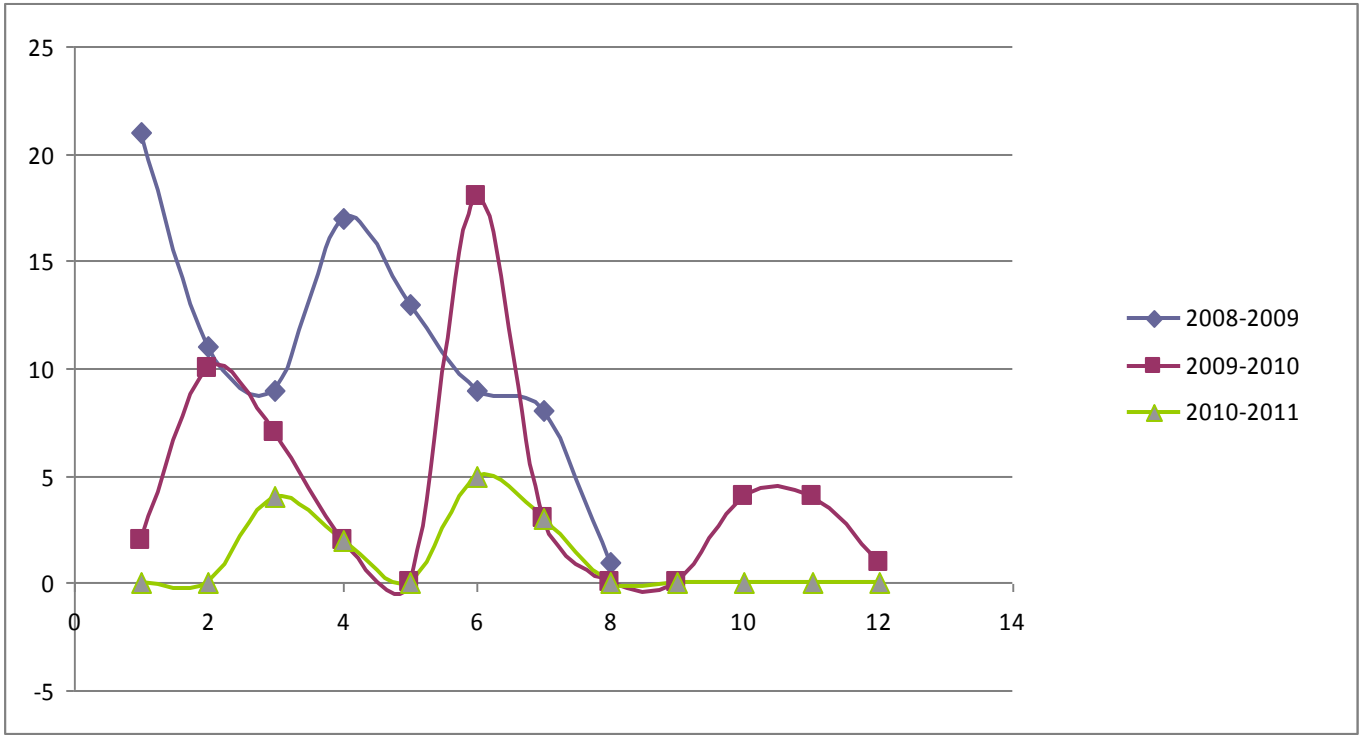
- Quality System
  - Quality manual, Quality Plan
- Management Responsibility
  - Roles and responsibilities
- Resource Management
- Product Realization
- Measurement, analysis and improvement
- Customer requirements and satisfaction

Quality Tools

- FMEA
- Cause and Effect Diagram
- Check sheet
- Control Charts
- Histogram
- Pareto Charts
- Scatter Diagram
- Stratification (Flowchart, Run chart)
- Plan, Do, Check Act
- Six Sigma

Continuous Quality Improvement

of incidents



# of Months

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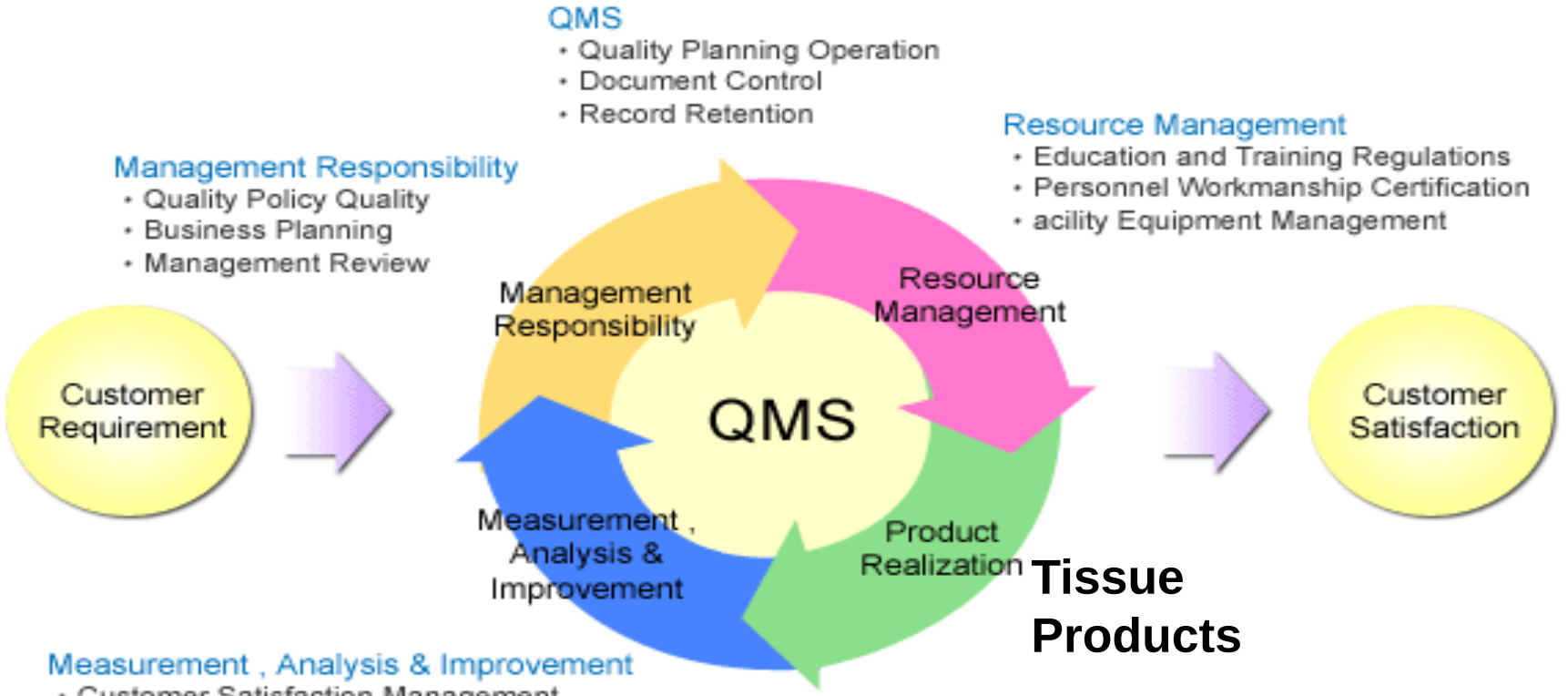
General Overview of a QMS (ISO)



QMS
- Quality Planning Operation
- Document Control
- Record Retention

Management Responsibility
- Quality Policy Quality
- Business Planning
- Management Review

Resource Management
- Education and Training Regulations
- Personnel Workmanship Certification
- acility Equipment Management

Tissue Products

Measurement , Analysis & Improvement
- Customer Satisfaction Management
- Internal Audit
- Process/ Product Monitor
- Quality Improvement Team

Product Realization
- Customer Requirement Management
- Advanced Product Quality Planning
- Validation of processes for production and service provision
- Control Plan
- Travel Card
- Process Control
  * SPC/OCAP
- Operation Procedure & Work Instruction
- Engineering Change Notification
- Identification & Traceability

QMS

Quality Manual – provides an overview as to what you do, what standards you adhere to

Document Control

Control of Records – How long to store, where?

Change Management – Track changes made to policy, objectives, SOP's, Suppliers, Validations

Management Responsibility

- **Commitment**
- **Customer Focus**
- **Quality planning, policy**
- **Planning – i.e. Initiatives, Objectives**
- **Responsibility, Authority and communication**
- **Management Review**

Quality Policy – **i.e**. Provide the highest quality tissue for transplantation by meeting or exceeding industry standards.

Resource Management

•Provision of resources

People, infrastructure, work environment, information, suppliers and partners, financial resources

•Human Resources

Personnel performing work affecting product quality and device safety and effectiveness must be competent ….

Qualifications include:

- Education
- Experience
- Skills
- EFFECTIVE Training (initial and refresher)
- Formal certification (e.g. welding, soldering)

•Infrastructure

•Work Environment

Product Realization

(**Screening , Procurement, Processing, Storage**)

- Planning of product realization
- Customer Related processes
- Design and development (Medical device)
- Purchasing – **Supplier Qualification**
- Production and service provision – **Validation of products, processes**
- Control of Monitoring and Measuring Devices

Product Realization
Supplier Qualification - Example

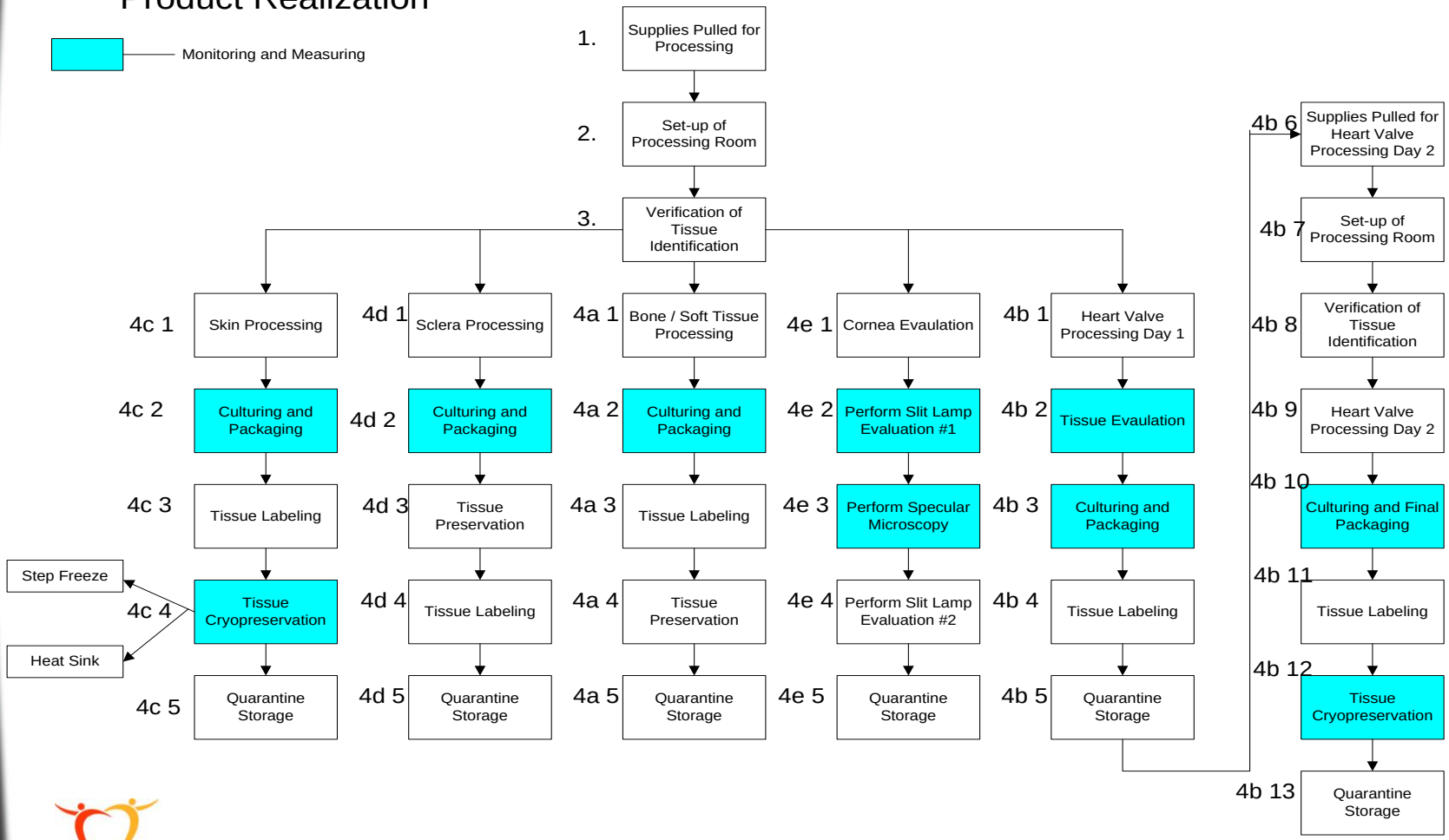
Perfect Devices, Inc. recently selected three new suppliers based on the following information:

1. Aim To Please, Inc.: Supplier audit documented an excellent quality system.
2. A-1 Plastics: Refused audit, highly recommended by other device manufacturers.
3. OK Parts, Inc.: Sole source of component! Supplier audit: No quality system!

Which approach to acceptance of incoming components would you recommend for each supplier?

Product Realization
Tissue Processing

Product Realization



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Product Realization
- Validation

•New validation

•Change in process that may affect quality or validation status

•Negative trend in quality indicators

•Change in the product design that affects the process

•Process is moved within facility or transferred from one facility to another

•Change in the application of the process

•May use historical data or lack of

Measurement, Analysis and Improvement

•Monitoring and measurement of processes are required to:

ensure product conformance

- feedback
- Internal audits (planned, spot, verification audits)
- M & M of processes
- M & M of product

– ensure conformance of the QMS

– maintain effectiveness of the QMS

These processes include measurement and analysis of products AND processes.

•Control of nonconforming product (quarantine, rework)

•Analysis of data (identify trends, suppliers, feedback etc..)

•Improvement (implement changes as a result of analysis, audits, QIR's etc..)

•**Corrective and Preventative Actions (**Root Cause Analysis**)**

Key component - Risk Management

Hazard is a potential for an adverse event, a source of danger. Risk is a measure of the combination of (1) the hazard; (2) the likelihood of occurrence of the adverse event; (3)

the severity or overall impact. Risk assessment begins with ***risk analysis*** to identify all possible hazards, followed by ***risk evaluation*** to estimate the risk of each hazard. In general, risk assessment is based on experience, evidence, computation, or even guesswork.

Risk assessment is complex, as it can be influenced by personal perception and other factors such as cultural background, economic conditions, and political climates.

In practice, risk assessment of medical devices is based on the experience of health care

Regional Tissue Bank

Control Number 2044

Quality Indicator Report

Section A: Discrepancy/Occurrence Information

Donor(s) Affected	Product(s) Affected	Recipient(s) Affected	Staff Affected	Other Affected
				SPD Supplies

Discrepancy/Occurrence Type

· Non-Conformant Equipment

Submission Date and Time 2010.07.06 10:25:27 **Reported By** Molly Spears

Occurrence Details:

3 Grinding wheels were found in the sterile supply room with holes in the package. They had been reconciled and placed on the shelf for use. They were in a clear bag containing approximately 12 grinding wheels. Lot number 4.6.10.06.2010 and initial K.

Immediate Corrective Action Taken:

Removed the grinding wheels from supply, informed Christian, completed QIR. Will inform Sterile processing of the issue as this is an ongoing problem.
(Molly Spears On 2010.07.06 10:40:09 AM) July 6,2010 Phoned Kim from SPD to inform her that the method of transporting the grinding wheels is causing them to poke through the package. She and I decided that it may be a good idea to only place 6 grinding wheel packages per bag. If this doesn't work, we could use a plastic container for transport. MS

Section B: Quality Management Review

[X] Action(s) Taken and Documented on this Form were Sufficient. Additional Corrective Action is not needed.

[ ] Medical Director Review Required.

[ ] Corrective Action Needed **Occurrence Severity (1 - 10)** 3

QSS/Quality Leader : Cynthia Johnston **Date:** 7/7/2010 10:30:40 AM

ities

Risk Level Estimator

Likelihood → / Severity ↓	Almost certain 5	Likely 4	Possible 3	Unlikely 2	Rare 1
Severe 5	25	20	15	10	5
Major 4	20	16	12	8	4
Moderate 3	15	12	9	6	3
Minor 2	10	8	6	4	2
Insignificant 1	5	4	3	2	1

Investigations of Complaints, Deviations, Recalls

- SAE's (errors, accidents)
- SAR's
- Sentinel Events
- CAPA (Corrective and Preventative Actions)

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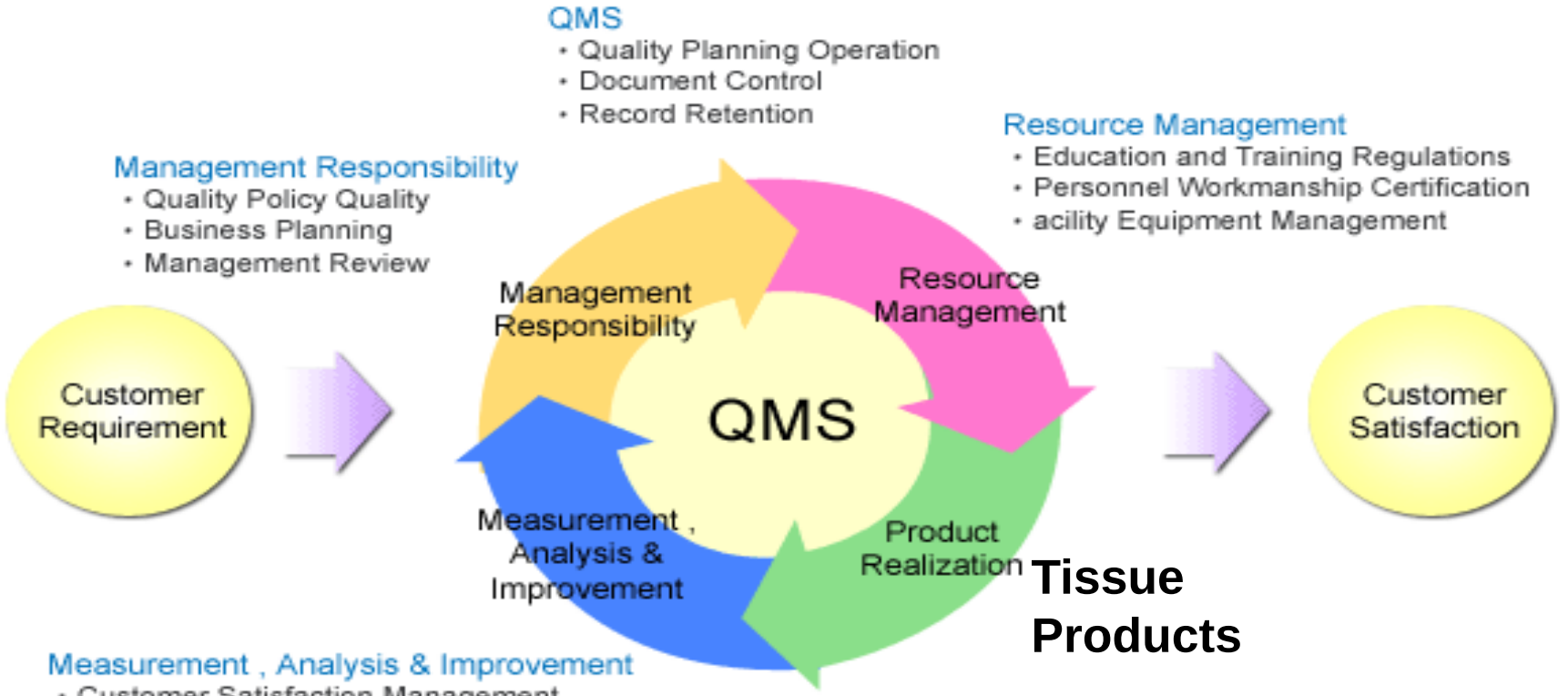

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RTB Quality Initiatives

- Validations – Disinfection for MS, CV and Skin
- Environmental Monitoring
- Supplier Qualification
- Package Expiry Dating
- IT - Incident reporting system modifications – Underway
  - Database reporting
- Partnerships with PEI, NFLD, enhanced NB relationships
- Donation Rate Targets