



Overcoming Quality Challenges ASQ Toronto Chapter

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Overcoming Quality Challenges

Introduction – What is Quality?

- It is a word that we have most commonly use as a noun to describe a product characteristic
- As a noun, we think in terms of a product or an attribute
 - That product has high quality
- (n) The totality of features and characteristics of a product or service that bears its ability to satisfy stated or implied needs – ISO 8402



Overcoming Quality Challenges

Introduction – What is Quality?

- However, it can also be used as an adjective to describe an outcome of a **process**
 - They are a quality organization
- (a) The ongoing process of building and sustaining relationships by assessing, anticipating, and fulfilling stated and implied needs – Quality Digest.
- (a) An organization that has a *demonstrated commitment to process and product understanding* toward the goal of customer satisfaction
- Perhaps thinking of it as an adjective will help us change from a product to process focus

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Introduction – What it isn't





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Introduction – Why is Quality Important?

- **Helps maintain a solid customer base**
- **Can attract new customers**
- **Reduces costs**
- **Protects reputation**
- **Protects the public**
- **Opens new markets**

- **But if this is true, why do so many organizations struggle with it?**



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Leadership (Passion)

- Does the senior leadership understand Quality?
- Do they recognize that quality processes should improve the bottom line?
- When does the leadership involve Quality in new initiatives?
- What is their motivation for having a quality group?
 - Compliance or best practice?



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Management (Consistency)

- How consistent is the management team in their application and adherence to Quality processes?
- Does management genuinely buy in or are forced adopters?
- Do managers attempt to implement processes from other organizations, industries?
- How aggressively pursue quality data and how do they use it?



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Quality Personnel (Capable, driven)

- What are the credentials of the head of Quality? Do others listen to them?
- Does the organization have sufficiently experienced staff to drive Quality?
- How capable is Quality able to navigate the gray zone?
- Do all Quality personnel understand the quality standards and are they uniform in their application?
- Does the Quality organization have a strategy and is it be being followed?



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Quality Personnel (Capable, driven)

- **Key Attributes**
 - Committed with a vision
 - But don't take it personally
 - Customer-focused
 - Effective communicator at all levels
 - Keen interest to learn
 - Can work in the gray zone
 - Objective
 - Have higher standards for their own area
 - Self confident
 - Mentor



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Registrars (Challenge or Support)

- Is your registrar adding value to your organization?
- How does your auditor review and identify issues?
- Does your registrar rotate auditors?
- Do they provide and/or maintain a compliance matrix?



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Organization Structure and Authorities (Aligned with Quality Imperative)

- To whom does quality report? Does it have the authority to drive quality?
- When a significant issue is identified, can QA stop the bus?



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Quality Planning (Planning BEFORE Doing)

- **Misunderstanding what it is and when it is used**
- **Not a living process**
- **Fail to understand the various required quality plans**
 - **Design and Development Plan**
 - **Product Quality Plan**
 - **Risk management plan**
 - **Supplier control plan**
 - **Master validation plan**
 - **Equipment calibration plan**



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Culture (Supports Quality)

- Does the organization advocate Quality Control or Quality Assurance?
- Is the organization serious about improvement?
- Does the organization reward quality?
- Does the organization solicit employees for improvement ideas or initiatives?
- Does the organization live its Quality Objectives?



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Culture (Supports Quality)

- Does the organization encourage or require employee participation?
- Is the Quality group considered overhead?
- Are inter-facility quality comparisons made?
- How is quality staffing defined? In terms of % of manufacturing?
- Are procedures and work instructions used and adequate? Are the pages dog-eared?



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Culture (Supports Quality)

- When a new product is being launched, how does the organization process last minute problems?
- How well is QA integrated into the organization?
- How closely does QA liaise with HR and IT?
- Do organization politics hinder quality initiatives?
- Do job descriptions define quality system responsibilities for all employees?



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Time/Resources (Invest wisely)

- Can be the biggest factor an effective Quality Management System
- Does financial payback trump implementing or following quality processes?
- Does the organization provide the time/resources for systems like internal audits/corrective action?
- Does the organization take the time to find the root cause or the first identified cause?



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Suppliers (Should be Partners)

- Does the organization have legacy suppliers that have historically been poor?
- Does the organization utilize scorecards to periodically review the performance of suppliers?
 - Are performance requirements appropriate?
- Are meaningful supplier metrics maintained and shared?



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Suppliers (Should be Partners)

- How does the organization perceive suppliers?
As a partner?
- How does your organization and supplier resolve quality issues?
- Has your organization established a Quality Agreement for critical suppliers?
 - How detailed is the agreement?



Overcoming Quality Challenges

A Lack of Quality Tools (Infrastructure)

- Does your organization have an active system for introducing new employees to quality and maintaining awareness of existing employees?
- Does the organization have an effective internal audit programme? Are internal audits welcomed or adversarial?
- Is your CAPA system well integrated with other systems such as NCs, internal audits, supplier management, complaints, etc?



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A Lack of Quality Tools (Infrastructure)

- **Are meaningful metrics established and maintained?**
 - Are they posted for all employees?
 - Are they maintained in real time?
- **Are the reporting processes effective? Limited to Management Review?**



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Maintaining the Momentum (Results)

- Has the organization identified some easy fixes to help challenge the processes?
- Does the organization understand its process flows and how much time is spent correcting problems?



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Maintaining the Momentum (Results)

- Does QA communicate to the entire organization?
- To what extent do non-QA people speak to quality?
- Does it post its quality successes and failures?



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In Summary

- **Implementing an effective quality management system shouldn't be difficult...**
- **...but it is**
- **Achieving quality improvements doesn't need to take a long time...**
- **...but establishing the right culture will**

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And Finally





Overcoming Quality Challenges

Aristotle

- Quality is not an act, it is a habit

Steve Jobs

- Be a yardstick of quality. Some people aren't used to an environment where excellence is expected



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Questions and Ideas

Thank you for your time!

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