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Writing a quality policy, quality manual and the role of the quality manager

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Quality Policy

- What is a Quality Policy?

- Who should write it?

- How long should it be?

- How does it differ from the Quality Manual?
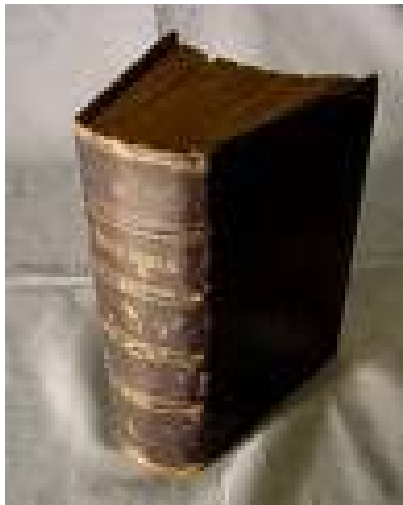
Components of a Quality Policy

- Mission Statement

  – What you do when things run smoothly

- What service will be delivered to stakeholders

- Vision Statement

  – Where you aspire to be

Vision statement – be careful what you wish for…

WISHES

WHEN YOU WISH UPON A FALLING STAR, YOUR DREAMS CAN COME TRUE.
UNLESS IT'S REALLY A METEOR HURTLING TO THE EARTH WHICH WILL DESTROY ALL LIFE.
THEN YOU'RE PRETTY MUCH HOSED NO MATTER WHAT YOU WISH FOR. UNLESS IT'S DEATH BY METEORITE.

Quality Manual

- What does it contain?

- How long should it be?

- Who should write it?

What the Quality Manual is NOT

- Unchangeable
- Unreadable
- Unusable
- Bought off the internet
- Written by a consultant (and never read)
- The Technical Manual

Components of the Quality Manual

1. Background
2. Quality Management System
3. Organisation and management responsibility
4. Resource management
5. Product realisation
6. Evaluation and Improvement

Quality Manual: Background

- Purpose and scope
  - Why you exist and what you do..
- Terms and Definitions
  - PGD is full of jargon
- Background
  - Surprise yourself
- Activity
  - Start crying!

Q Manual: Quality Management System

- General requirements
- Document requirements
  - Categories, style, format, etc
- Document control
  - How your system works (pdf, hyperlinks, review and revise schedule, authorities SOP, etc)
- Control of records
  - Retention, storage policy, etc

Q Manual: Organisation and management responsibility

- Customer Focus
- Quality Policy
- <u>Quality Objectives</u>
- Quality Planning
- Organizational Chart
- <u>Individual Responsibilities</u>
- Internal Communication
- Management review (frequency, output)

Q Manual: Resource management

- Human Resources
  - General (job descriptions, induction etc)
  - Competence and training
- Infrastructure, Premises and Facilities
- Equipment and materials management

Q Manual: Product Realisation I

- Planning
- Requirements related to the product
- Review customer requirements/communication
- Design ± Development
  - Planning, inputs, outputs, review, verification, validation and change control
- Purchasing
- Third Party Agreements and service provision

Q Manual: Product Realisation II

- Control of Operations
- Validation of processes/service
- Identification and traceability
- Preservation of product
- Control of measuring and monitoring devices

Q Manual: Evaluation & Improvement

- Evaluation
  - Customer satisfaction (questionnaires, log)
  - Complaints (log, investigation, resolution)
  - Internal and external audit
  - KPIs and Quality objectives
- Non-conformances
- Data analysis
- Continual Improvement
  - Corrective and preventive action (risk assessment)

Q Manual: Appendices and References

- Relevant documents (with hyperlinks)
    - Technical manual(s)
    - Relevant ISO standard (or local equivalent)
    - Relevant regulatory or legal documents
    - Glossary
    - Other useful publications
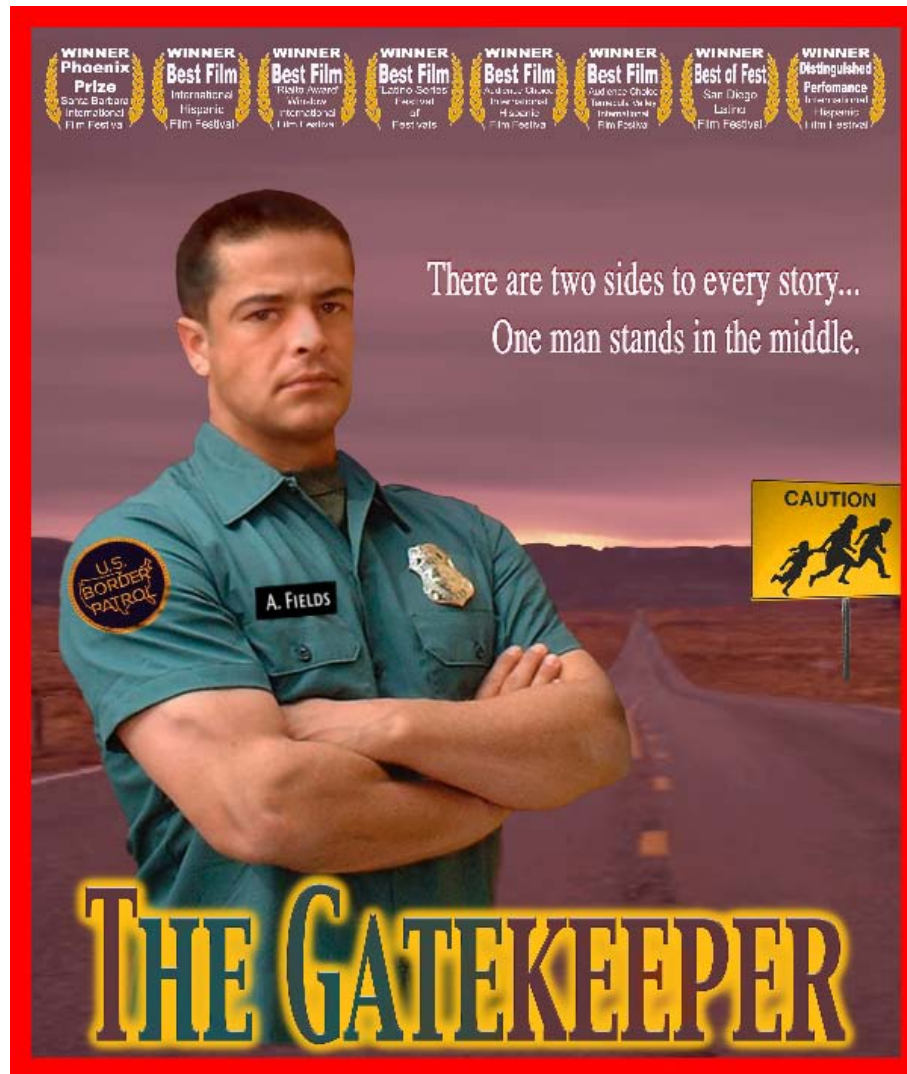
Quality Manager

- Who should it be?
- What is required from the Quality Manager?
- What are his/her roles and responsibilities?

Quality Manager

- Who should it be?

- CEO or junior technician?

- Is there a Quality Manager in the house?

Your next Quality Manager...?

Quality Manager

- What is required from the Quality Manager?

  - Understanding of most (if not all) processes

  - Authority and power to enforce compliance

  - Implement change (when required)

  - Ultimate Guardian/Gatekeeper of QMS

Quality Manager - roles and responsibilities

Project manage/oversee/coordinate QMS

Compile ± Maintain Quality Manual and Policy

Schedule ± complete internal/external audits

Train staff in QMS

Reviewing QMS and reporting to senior management

Quality Manager – NOT responsible for:

- Writing **all** SOPs

- Completing **all** audits

- Doing **all** the work to prepare for inspections

- Single-handedly maintaining quality

"A teacher is someone who talks in our sleep!"