Training Quality Engineers – Practical Approaches

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Limited Information in the regulations

- ISO 13485

6.2 Human resources

6.2.1 General

Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

- FDA Guidance to Design Control

This guidance is intended to assist manufacturers in understanding the intent of the regulation. Design controls are based upon quality assurance and engineering principles. This guidance complements the regulation by describing its intent from a technical perspective using practical terms and examples.

- 21CFR820.25

(a)*General*. Each manufacturer shall have sufficient personnel with the necessary education, background, training, and experience to assure that all activities required by this part are correctly performed.

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Terminology

- Quality :
  - Degree to which a set of inherent characteristics fulfills requirements (ISO 9000:2008)
  - Fitness for use (Joseph M. Juran)
  - Quality management is not about meeting regulations....it is about not being able to make bad stuff. If you have that mindset and follow through on it, meeting the regulations is not an issue. Compliance becomes the result, not the goal, of quality management (Constance Ace, Ph.D., Xylos Corporation).
- Engineering
  - Engineers work to develop economical and safe solutions to practical problems, by applying mathematics and scientific knowledge while considering technical constraints (www.wikipedia.org).

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Terminology

Quality Engineers

- Certified Quality Engineer, often abbreviated CQE, is a certification given by the American Society for Quality.

  These engineers are professionally educated in quality engineering and quality control.

  They are trained in researching and preventing unnecessary costs through lack of quality, lost production costs, lost market share due to poor quality, etc.

  They possess the knowledge needed to setup quality control circles, assess potential quality risks, and evaluate human factors and natural process variation.

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Quality Engineering

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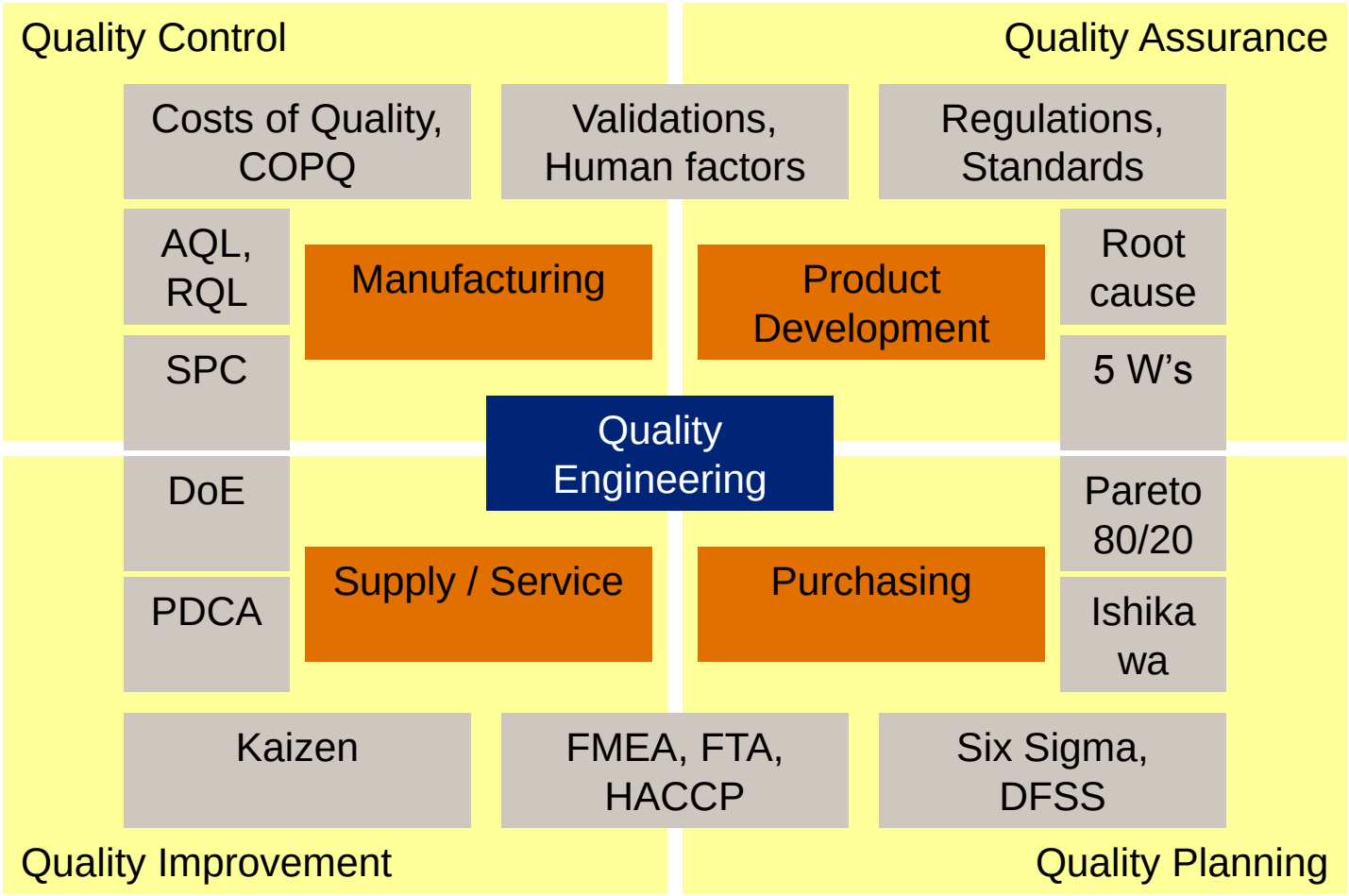

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Quality Engineering

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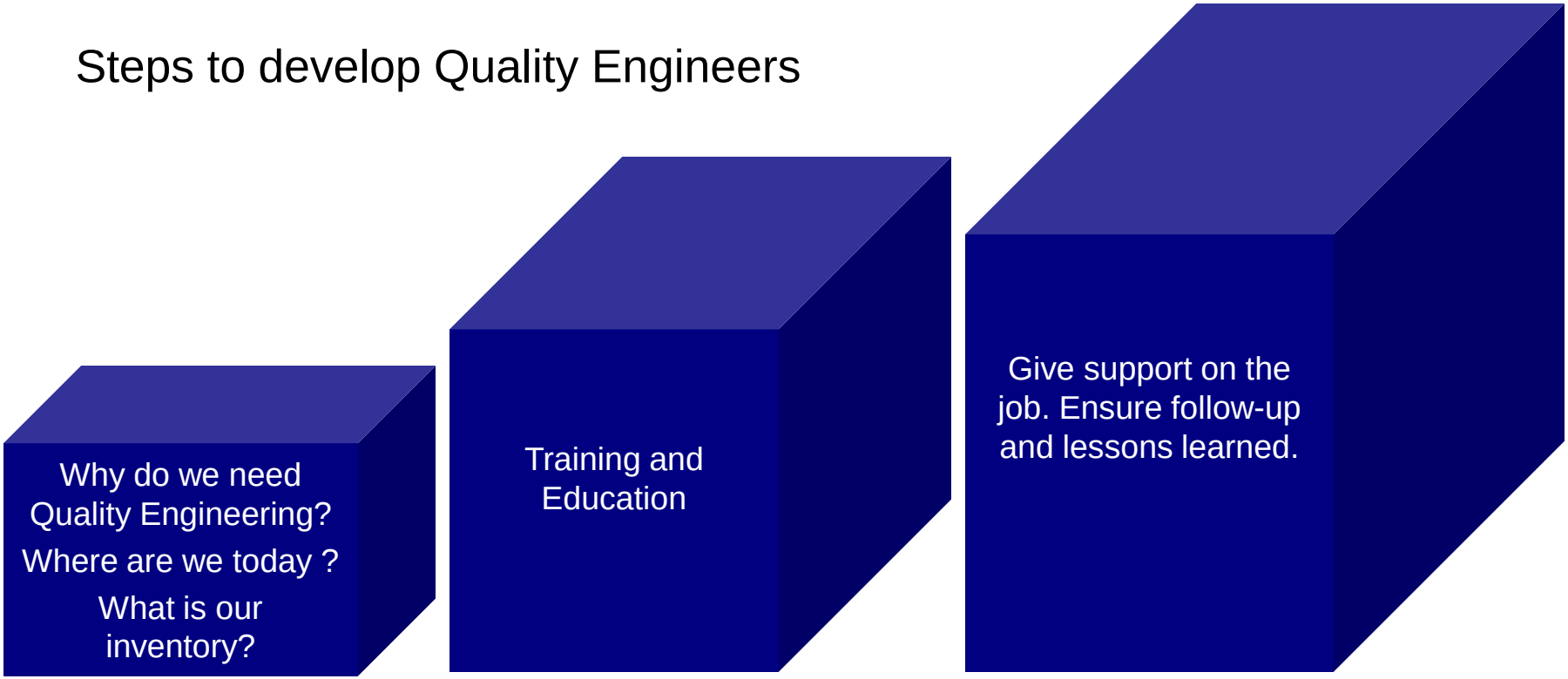
Steps to develop Quality Engineers



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Before planning and initiating any training programs, the existing inventory needs to be evaluated:

- What is the experience and background of your Quality Engineers?
  - Experience in medical devices? In Quality? In Validations ? In statistics?
- Did they already receive internal / external trainings?
  - Could you re-use the training packages? Any lessons learned? Good trainers & bad trainers?
- Where are the current gaps and deficiencies?
  - Which knowledge is missing? Are the candidates experienced?

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Three Approaches

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#1	#2	#3
Class Room Trainings followed by learning-on-the job	Assignments in R&D and Manufacturing.	Dedicated training programs like six-sigma, quality systems, regulatory affairs
Which classes? What is “on-the-job”?	Which project or which responsibilities? How long?	External or internal? Which focus areas?

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Class room

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#1 Class room trainings followed by learning-on-the-job

- Which classes?
  - Design control
  - Product Risk management
  - Validations
  - Supplier qualification
  - Statistical techniques
  - Root Cause Analysis
  - CAPA, T&I
- What is “on-the-job”?
  - Where should they be located?
  - Which tools will the get? When are they ready?
  - Who supports them?

Place your QE’s where the “rubber meets the road”: In the clean room in the shop floor, in the center of the project landscape offices….

Measure success, use checklists, make exams to identify *QE-readiness*

Give them the best support they can get. Take them by the hand and guide them to success.
SPEND TIME

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Class room

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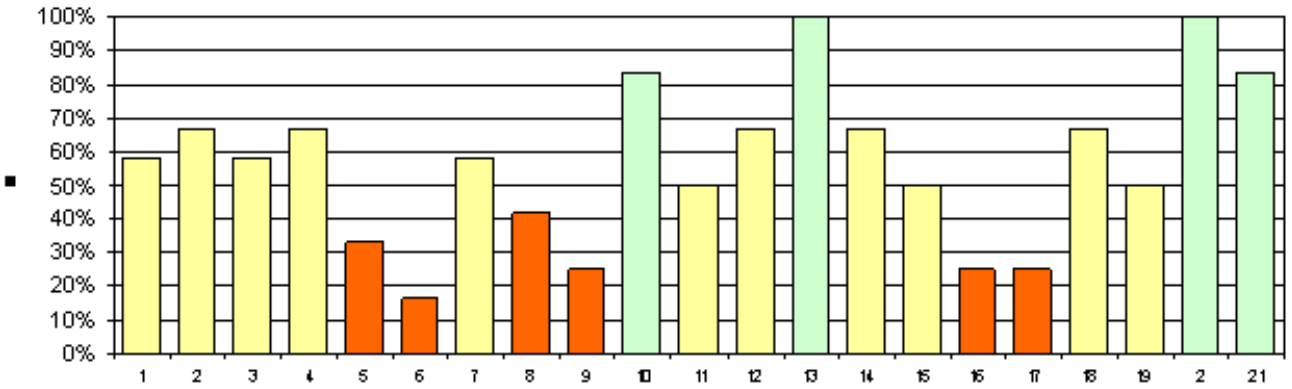
QE - Readiness

- One example to measure objectively is the use of “driver licenses”
- Compare and Benchmark the candidates

Criteria Value	(Factor)	Good 6	Satisfactory 3	Poor 0	Score
Validation planning	Content (3)	☐ All required validation activities and deliverables are correctly identified. • IQ,OQ,PQ • Process OQ • Test methods • Computerized systems • Facilities/utilities Rationale for decision if validation was required is included/discussed	☐ All required deliverables are identified • IQ,OQ,PQ • Process OQ • Test methods • Computerized systems • Facilities/utilities	*Dead end:* ☐ Required deliverables are missing.	
	Comments:				
	Relationship (2)	☐ Describes • Relationship between different deliverables (sequence of IQ/OQ/PQ, ...) • Relationship to existing qualified systems or previous validations or VMP's	☐ Includes only one of the following relationships • Relationship between different deliverables (sequence of IQ/OQ/PQ, ...) • Relationship to existing qualified systems or previous validations or VMP's	☐ describes no relationships, decision making process is not included or insufficient	
	Comments:				
	Presentation (1)	☐ Validation plan and its scope is clearly described and protocols/requests are compiled to one package. (Does not leave the reader with question and states why it is important and explains the relationship).	☐ Validation plan is clearly described. (Leaves the reader with some questions.)	☐ Validation is not transparent. (Leaves the reader with questions and concerns.)	



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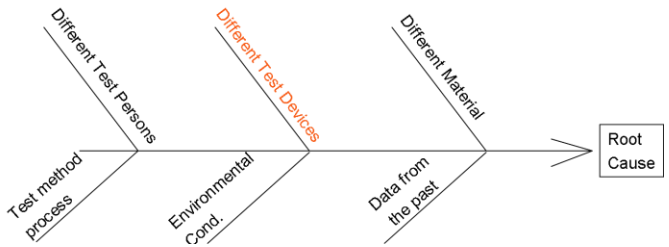
Example for a class room training

- Root Cause Analysis for quality issues
  - Be able to write a focused problem statement
  - Be able to utilize the Pareto 80/20 Principle to analyze data for “vital few” identification
  - Given a focused problem, be able to construct a cause-and-effect diagram that demonstrates causal thinking
  - Given a focused problem, be able to create a tree diagram with at least four levels of depth for a least one path (5Why’s)
  - Be confident that most likely root cause has been determined
  - Proof reproducibility



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Assignments

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#2 Assignments in R&D and manufacturing

- Which projects?
  - Participate as R&D Engineer
  - Work in-line
- How long?
  - 6 months assignments
- Which responsibilities?
  - Be responsible for the work which an QE will review afterwards

Each QE must experience the *responsibility and challenges* of innovative R&D engineering.

Each QE must have the understanding of manufacturing tools & constraints.

Be progressive and set-up a x-functional training program.

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Assignments

Experiencing responsibility and difficulties

- Within a x-months R&D assignment, a Quality Engineer will act as R&D team member, being responsible for Design Development
- Within another x-months Manufacturing assignment, a Quality Engineer will act as manufacturing team member, being responsible for production, materials, equipment, processes
- After the x-months he will surely have a different view on things and he will have much better insight and understanding.

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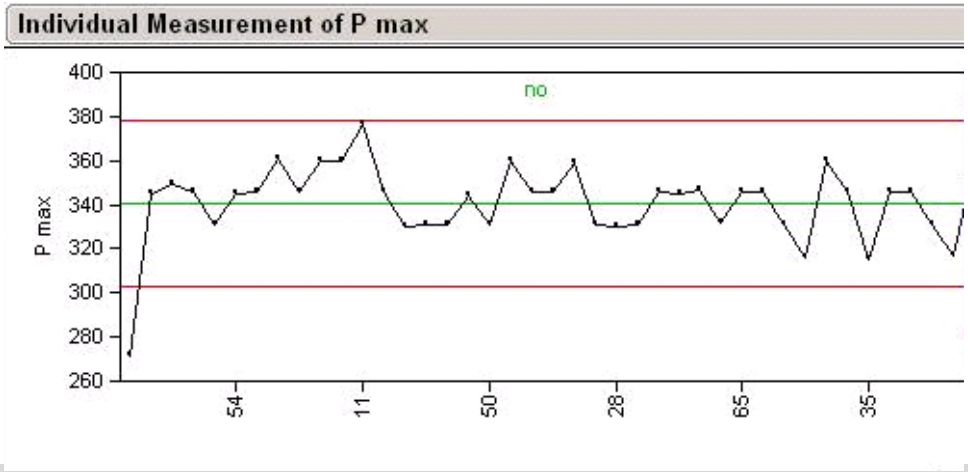
Assignments

Example for a manufacturing assignment

- Implementation of a dedicated software for SPC for two manufacturing lines
  - Sourcing and Purchasing
  - Installation and qualification
  - Statistical background, calculations and Training material
  - Operator's manual
  - Training
  - Support the go-alive
  - Report statistics



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Dedicated programs

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#3 Dedicated training programs like six-sigma, quality systems, regulatory affairs

- External or internal?
  - Internal Advisors?
  - Your notified bodies (BSI, TÜV, …)
  - Quality organizations (DGQ)
- Which focus areas”?
  - Identify the focus area suiting to the field of work
    - Synergies between Quality and Regulatory? Go for RA trainings
    - Product & Process Design ? Choose the right six sigma colors (Green, Black, …)
    - Strengthen your Quality System? Go for system managers and auditors

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Dedicated programs

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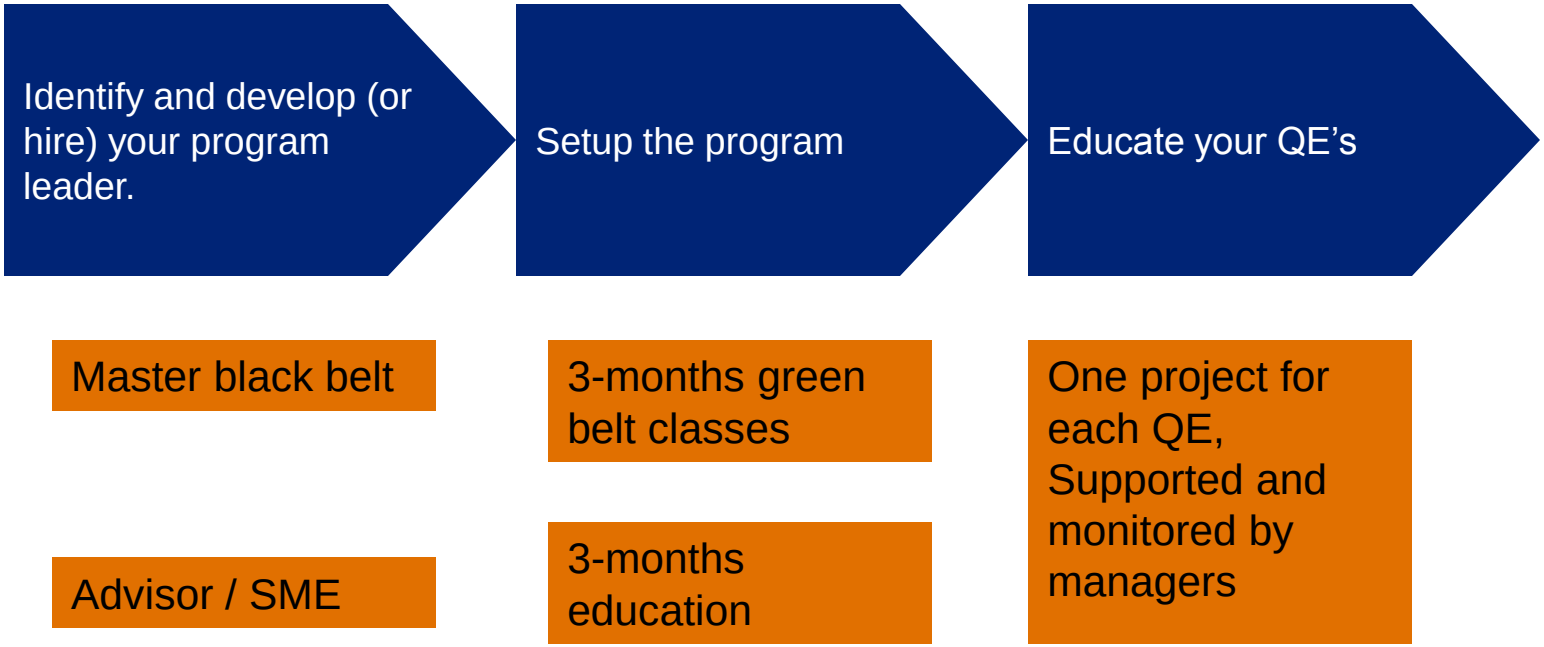
Why not setting up internal programs?



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Dedicated programs

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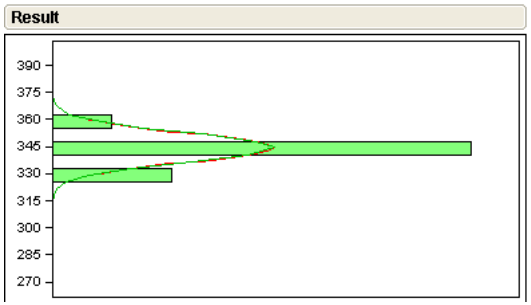
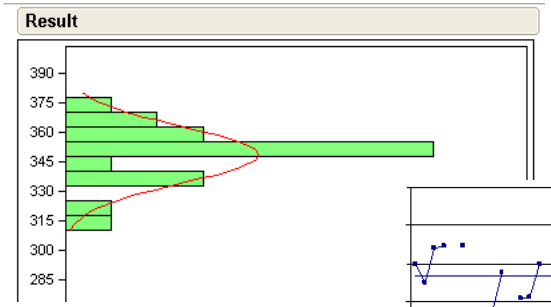
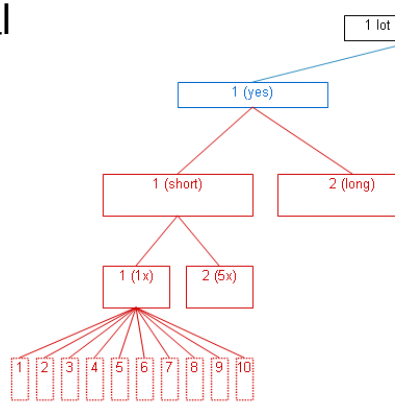
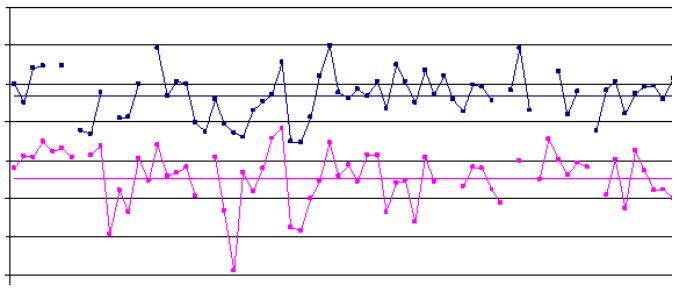
Example for a green belt project

- Correlate test results of a subassembly with the results of the final release test.
  - Identify data distribution
  - Review test methods, DoE
  - Correlate data and revise test practices









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Lessons learned

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- Define your own value-adding understanding of Quality Engineering
- Evaluate your Inventory and determine the gaps.
- Identify the tools and resources needed
- Train, educate and support

SPEND TIME | SPEND MONEY | **GET QUALITY**

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