DESIGN AND OPERATIONS QUALITY

an introduction

By Frede Jensen

Design and operations quality: an introduction

First edition

Cover by the author

Published by the author; distribution through lulu.com.

Lulu.com book ID: 21207193

ISBN: 978-0-244-02171-9

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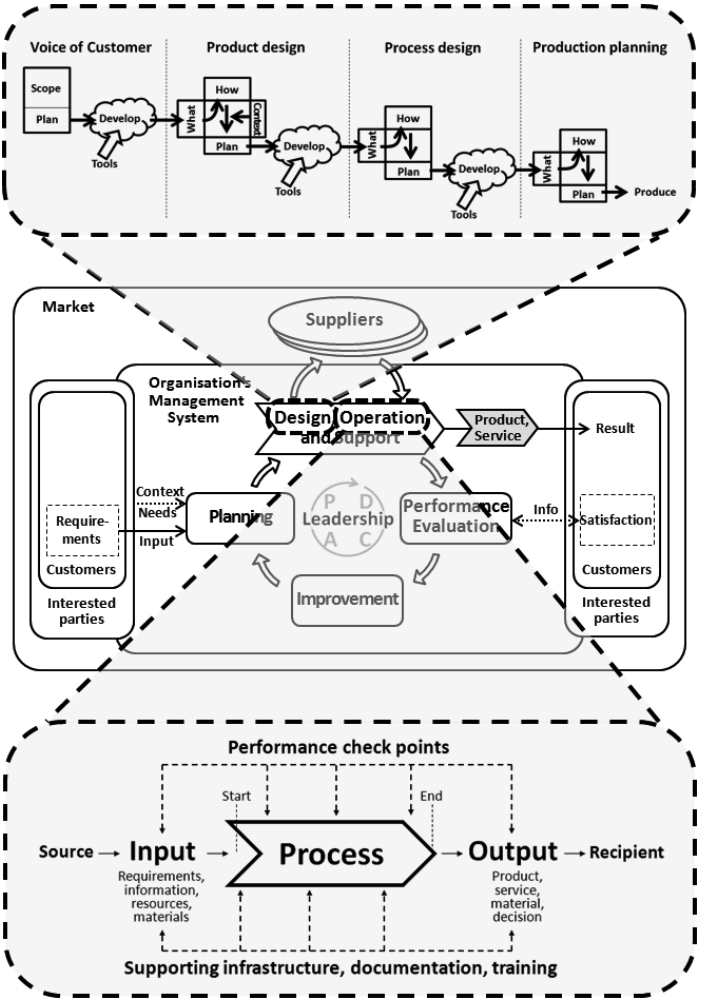
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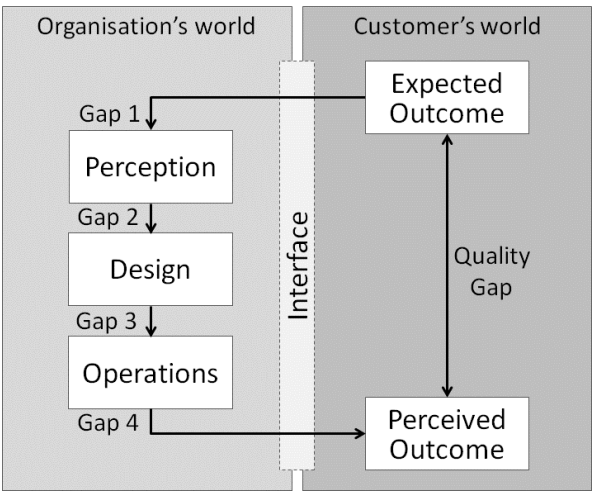
Requirements, information, resources, materials
Process
Output
Product, service, material, decision
Recipient
Supporting infrastructure, documentation, training

INTRODUCTION

The gaps analysis teaches that quality must be inherent by design, of both the product and its operational processes.



Customer quality gap

The customer perceived quality gap results from an additive combination of several organisational gaps:

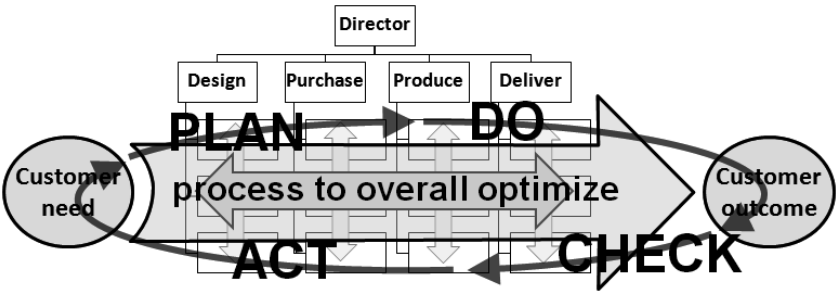
Gap 1: Listening gap: Not knowing current expectations, including legal and other stakeholder requirements, resulting in an imperfect perception of customer needs.

Gap 2: Specification gap: Poor translation into design requirements. Misinterpreting the standards.

Gap 3: Design gap: Poorly designed or under-developed product. Lacking solution. Lacking testing and validation.

Gap 4: Operations gap: Inadequate resources and/or poor performance in the delivery system.

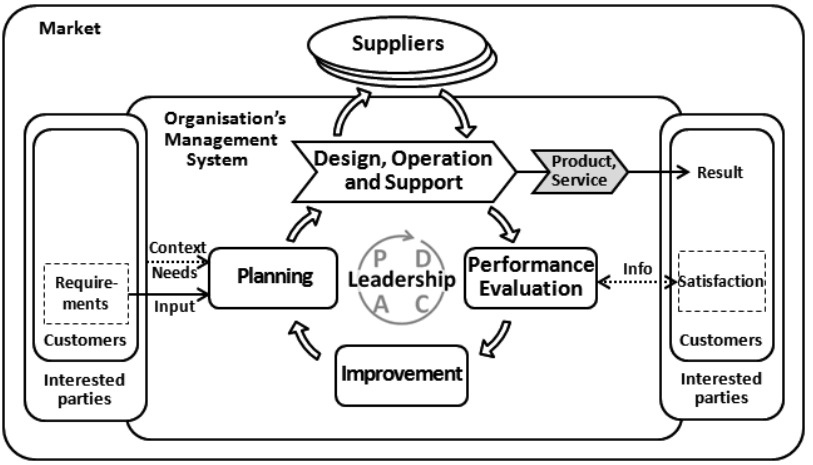
Everything that interacts has variability and represents points where a deviance can creep in. At best we can maintain the variability within limits that are unnoticeable or easily tolerated by the customer. However, organisations and their operating environments are dynamically complex. It is utopian thinking that excessive variability can never happen. The risks of poor quality must be optimally reduced and continually managed. Operations do more than simply conforming to the designer's specification. Operations will also experience, control and instigate the correction of any flaws in the designer's original work, to continue the systematic improvement of quality – after the product design project has closed.



The integrated process-based organisation

The total flow from perceiving the customer needs to customer outcome should be managed as one integrated whole, in a wider management system evolving around the Plan-Do-Check-Act cycle. Fixing any problems post-launch should be done in context of the original development and will typically involve the original

designer, as opposed to becoming a bolt-on solution. This can be a difficulty when design and operations activities occur in separate organisations or locations. For example, a designing organisation may have the product manufactured by a far-away sub-contractor; or a retailer may use a third party for designing and developing its online shop. Clients in such a relationship depend on compatibility between the inter-organisations methods, for collectively assuring effectiveness in the contract designed or contract produced product. The increased potential for disjointedness can be addressed by adopting and communicating from the perspective of a standardised approach. The designer can then become just as much team with purchasing, production and delivery functions, as he or she is with other designers. There is hence merit in a standardised approach to design and operations. This book introduces a design and operations concept based on the principles of standards ISO 9001 and ISO 16355.

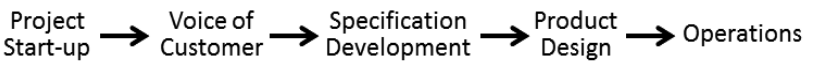


Process-based management system model,
based on ISO High Level Structure (HLS)*

*) In the ISO 9001 HLS model, Design is actually defined as a sub-process under Operations. Design is separated out here for illustration purposes, but the model remains true to the ISO 9001 version of the HLS.

ISO 9001 defines a set of descriptive requirements for what is universally recognised should be contained in a management system that seeks to achieve and continually enhance quality. It does not prescribe how these requirements shall be met. It is for the organisation self to determine how it will meet them, in a way that best suits its particular situation. The standard is based on a generic process approach and simply defines product as the "*result of a process*". This makes it universally applicable to any type of organisation, regardless of size and product or service provided.

Quality Function Deployment (QFD) is a systematic approach to addressing the 'design' element within the wider management system. Standard ISO 16355-1 on "*General principles and perspectives of Quality Function Deployment*" defines a generic design process flow chart, which includes the hand-over to operations.

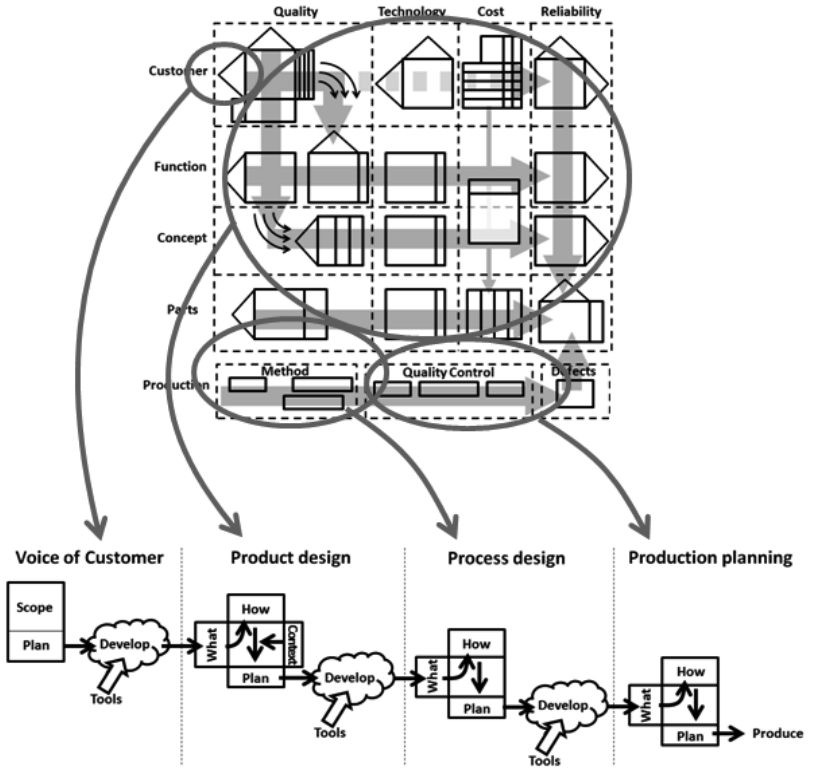


Flow chart for the QFD approach
(adapted from ISO 16355-1, Clause 5.2.2)

ISO 16355 does not provide any ready-made model for implementing QFD. The standard "*is descriptive and discusses current best practice but is not prescriptive by requiring specific tools and methods*". Compared to ISO 9001, which has been 50 years in the making, ISO 16355-1 was first published in 2016. Establishing a new standard is a consensus-based process, where the first edition is often a compromise between the different schools of thoughts. The QFD standard is yet to evolve into being something more descriptive and less 'discussive' than the current revision is.

DESIGN QUALITY

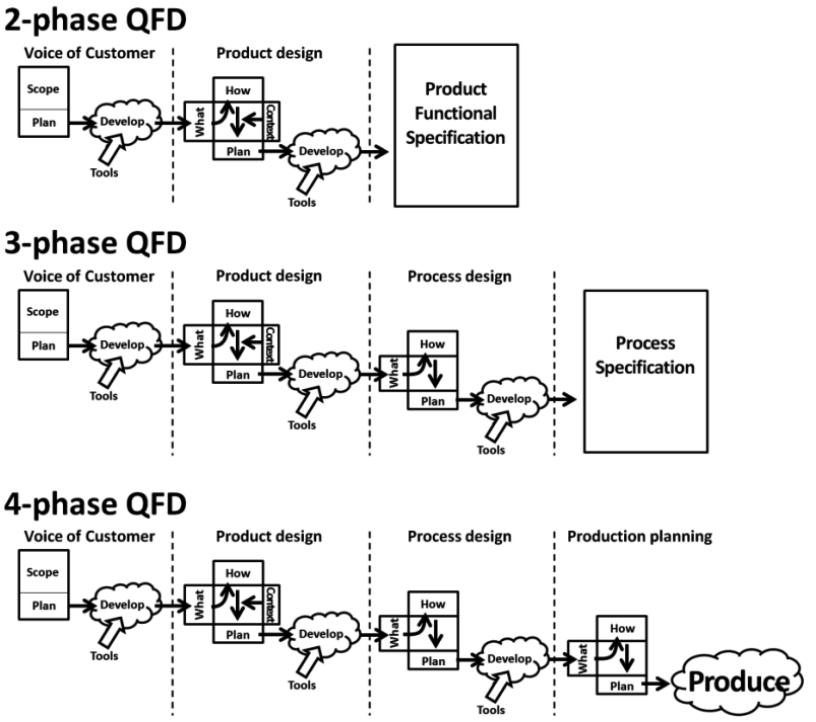
The introduction has already highlighted Quality Function Deployment (QFD) as a systematic approach to design, including its transfer to operations. QFD is an approach that coherently and systematically maintains in focus what is most important to customers and stakeholders, thereby assuring quality and reducing development time. QFD addresses all the organisational issues identified by the gaps analysis – as seen on page 1.



The 4-phase QFD model is a truncated variant of the original 'comprehensive' approach for larger, more complex projects.

Even if you will never use QFD other in a conceptual sense or in a mental process, its principle approach holds true for any type of design project, whether hardware, software, parts or services.

Standard ISO 16355-1 informs of some example QFD approaches, ranging from 'comprehensive' to simpler application models. The evolved 4-phase model is a truncated form of the 'comprehensive' model and has today become the most widely used QFD approach. As we represent it here, each the 4 design phases consists of 2 steps – namely planning of the phase specification, followed by development against this specification. The interlinking, with the output from a preceding phase feeding into the planning of the next phase, maintains integrity of customer and stakeholder requirements through the 4 phases.



QFD design projects can have differing spans

The QFD approach may be used with a reduced span, in which not all of the 4-phases are necessarily being applied. For example, the development may be a software product, for which the production process is already well-developed. The organisation can then use the QFD approach phase 1 and 2 only, before a straightforward transfer to 'operations'. In another example, the QFD project may omit phase 4 and instead hand the process specification to the production team under a program of Kaizen – a philosophy for collaborative continuous improvement.

PROJECT SCOPING

When starting-up the design project we essentially seek clarity and communicate awareness about:

a) Purpose of the project.
b) Who the customers and stakeholders are, and what we aim to do for them.
c) Who in the organisation influences the design or project context, and what their involvement in the project will be.
d) Project time line.
e) Allocated resources and aids.
f) Responsibility and authority.

Sharing the project scope helps people who are not directly participating, but may be relied on for support during the project, understand what is going on and become prepared for the outcomes. In larger organisations, in particular, there is likely to be a number of cross-cutting activities, which can all influence the design project. Each such activity is pursuing its own objectives, within a wider context, and will sometimes place a limitation on or conflict with the goals of the design team. For example, the designer may consider using a new better component part that is not available from an existing strategic supplier, with whom the organisation's procurement department has established good

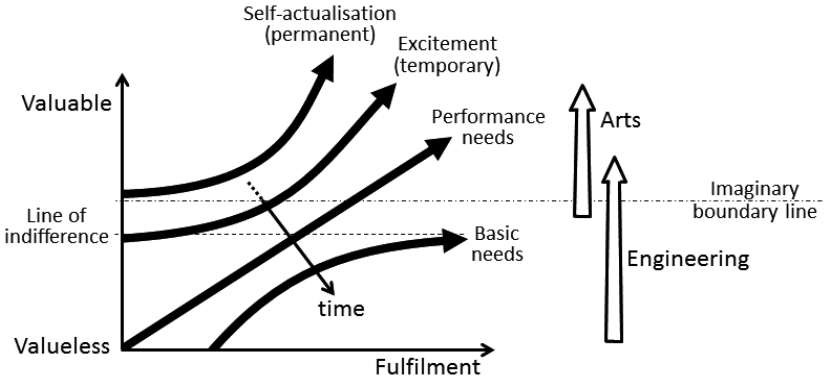
relationships and a favourable wider discount deal. Selecting the new component could thereby destroy the deal that the organisation benefits from more widely in the many other products it produces. The co-operation around an optimum trade-off between the design team and the cross-cutting functions is therefore important to overall success.

VOICE OF CUSTOMER

The 'Voice of Customer' (VOC) phase is about clearly defining what customers and stakeholders need and what they want, and also understanding what they could tolerate less of and what they do not want at all.

The term 'need' could be wrong in some context. Customers tend to express their 'wants', and are often not aware of or ambitious enough about their needs. People can possess a short horizon-span, where they see their needs and wants mainly in relation to solutions they already know. If we are to excite customers towards our product or service, then we must find new opportunities for answering needs that are not yet fully realised or addressed – in effect turning unmet needs into new wants. However, be mindful of not selecting something we think that customers need, but that is too alien in concept and they are in fact not yet ready for. Another abnormality in defining the VOC is that sometimes we are commercially forced to try make the customer mostly want what we can realistically provide them with, from our current capability.

Standard ISO 9001 defines quality as "*the degree to which a set of inherent characteristics fulfils requirements*". As already mentioned, customers are not always aware of or ambitious enough about their requirements. They do also not attach equal importance to their various needs.



Value diagram combining Kano[1)] and Maslow[2)]

Line of indifference: The value point where customers are neither satisfied nor dissatisfied.

Self-actualisation needs help people realise their personal growth potential. Maslow puts it: "*What a man can be, he must be*". It follows a sub-conscious meaning of life, to become the most complete self. Customers will attach high value to product features that support self-actualisation.

Excitement needs create an emotional engagement or unexpected spontaneous desire.

Performance needs are what customers will ask for and against which they intent to measure their buying decision – unless overruled by influence of an excitement or basic need.

Basic needs are threshold needs. Although basic needs may not be asked for, their omission will result in rejection. They are taken for granted and do not add any particular value.

1) Kano, N., Nobuhiku, S., Fumio, T., Shin-ichi, T., "Attractive quality and must-be quality". Hinshitsu (Journal), Vol.14, No.2: 39–48, April 1984

2) Maslow, A. H. (1968). Toward a Psychology of Being. New York: D. Van Nostrand Company.

Correctly identifying and addressing all the explicit customer needs may still not be enough. The product will also require some excitement or 'flair', which exceeds expectations and makes the customer take notice, saying: "*Wow, I must have that*". In our product context, design is about applying engineering and arts in creating or improving function, usability, ergonomics or aesthetics, to make products more marketable and their production more efficient.

Art is defined as *"a deliberate arrangement that excites or influences the senses, intellect or emotions"*. Engineering is defined as *"a discipline for acquiring and applying science"*. Although good engineering can be beautiful to the intellect – i.e. an art – engineering is in most products concerned with the nuts and bolts hidden from view. In the main, good engineering is essential to assuring the foundation for product value – i.e. to avoid devaluation by insufficiency or unreliability. However, it is the art contents that create the higher levels of product value.

There will be many different views and priorities on what the customer needs. We must seek evidence for correctly quantifying the strengths of wider needs, and wants. When presented with the same evidence, anyone looking at it should practically reach an equivalent conclusion. The evidence effectively makes the decision. This is particularly important to the VOC, which can otherwise easily become influenced by bias and subjectivity. When faced with decision information, think about where the evidence-base is on the information quality scale and think about where it should ideally be, to provide sufficient confidence in making the right decision. If the main source of evidence cannot establish the full extent of required confidence – say, if only a partial data set is obtainable – then supplement with other sources of evidence. The multiple sources will complement each other and add up to an overall level of quality. When multiple sources of partial confidence evidence agree, then it adds strength

to the overall quality of evidence. Similarly, say, if two sets of data are in conflict then it weakens the overall quality of evidence and more factual decision information will be needed. Tools such as Analytical Hierarchy Process (AHP) will help rank priorities in situations that contain uncertainty or are complex by multiplicity.

Even with factual information at hand, the designer will still see the design problem in his or her individual way, which if done distantly can differ in perception to that of real customers. Designers should go through a formal process of meeting customers and experience the new product's use environment. The acclaim is that the first-hand experience of customer needs and wants in the use journey, when combined with the designer's technical skills and knowledge, represents an opportunity for creating value beyond what could otherwise be achieved.

PLANNING

The QFD approach may emphasise development work by different functional groups at different stages, but it is planned under the same umbrella project where everyone in the project team have oversight of and contributes to the end-to-end master plan. This contrasts a traditional over-the-wall planning approach, where designers interpret and develop the product in isolation of other organisational functions.

The QFD planning activity is about the collective team accepting the output from a previous phase and then deploying it into fresh specification objectives, for the following phase activity that is currently about to commence. The plan addresses:

What source requirements are we to address?

How should we go about addressing them?

Normally, for very simple design problems, we can perform this deployment in a mental exercise. However, as the complexity of unknowns and contradicting multiplicity sets in, we will need a system for ensuring that we best predict the causal argument for our actions. Individual gut feel is important, but it is better to produce a robustly evidenced plan for the more complex phases in a development project. Selecting an appropriate depth of planning relies on our understanding of risk-based thinking.

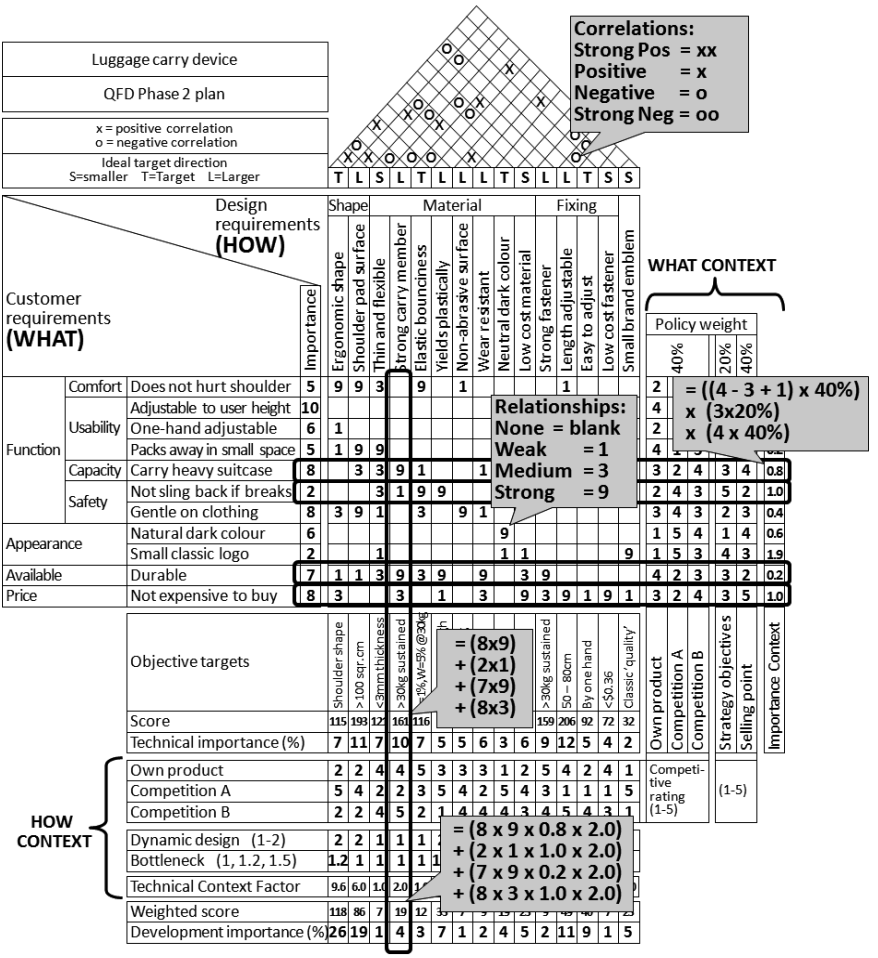
The 'plan' step is where the QFD matrix tool adds strength. The deployment matrix, which in some form is called the 'House of Quality', is partly constructed from what we obtained as the outputs in the previous phase. This assures the 4 phases are interlinking. The fresh set of characteristics that are being worked on within any one phase will inherently link back to the very original set of customer input requirements. It is worth reminding that the House of Quality is not necessarily the only planning tool that can be used at this point. Once we deeper understand the house workings then we may find different ways to perform or approximate the same function.

HOUSE OF QUALITY

The House of Quality is simultaneously a transfer tool and a container for the planning activities. The House of Quality does two things:

1st Records the (prior) translation of a set of input requirements into a corresponding set of derived output requirements, helping us to visualise if anything in the translation is missing or overemphasised.

2nd Procedurally transfers the importance of characteristics in the input requirements into the characteristics in the output requirements, establishing a prioritised development plan. The plan is effectively a specification for what to do next.



The house of quality

The ‘what context’ defines the direction the organisation wants and needs to take, with regards to meeting the customer requirements. The ‘how context’ defines the degree of ambition, or necessary trade-offs, in term of workload and technical creation to be achieved. The business case, sponsoring the QFD project with time and money, will normally have predefined the required degree of ambition, in terms of the minimum value

creation that is required. In case of any doubt, it would normally be a good idea to test the contexts assessment with the project sponsor, to ensure that it meets the original business case.

DEVELOPMENT

The development activity is where the value-added is created – as opposed to previously, where it was being specified and planned. It is here the design project spends most of its time and resources. The development will focus its resources according the plan, such as the 'development importance' output that was calculated in the House of Quality. The QFD team will periodically refer back to the House of Quality for evaluation and visualisation of progress against the prioritised plan. The output from the development activity is evaluated against and must match the input requirements.

Products and the approach to developing them will of course vary. QFD does not define any specific tools or techniques for the activity. The following lists some suggestive development tools, which are often seen associated with the development processes. However, their selection is not obligatory. Other tools could in fact be equally or better suitable:

- Picture board.
- Translation table.
- Sketching.
- Design re-use.
- CAD modelling.
- Cost Function Analysis.
- TRIZ.
- Design for Manufacturing.
- Engineering optimisation.
- Rapid Prototyping, build and test cycles.

- Robust Engineering Design (RED).
- Failure Mode and Effects Analysis (FMEA).
- ... and many more

TRANSLATION TABLE

A technique for translating a set of input requirements ('whats') into a set of output requirements ('hows'), or a specification.

There is often more than one functional way of satisfying an input requirement. In order to attain competitiveness, it is important to identify and develop the one with most advantages over the others. The human mind in disposed to draw assumptions from past experience and to copy the behaviour of others. In some way, we are thereby naturally pre-conditioned to produce stereotypical solutions. The translation table compels the design team to think laterally and record how else an input requirement can possibly be met. When using the tool, the team will consider other man-made or natural systems where similar kinds of needs are met. They will ask themselves: *"What are the functions, features or activity that satisfies the input requirement"?* and they will document the answers in a solution neutral language as is possible. The table should also try to stimulate lateral thinking by considering an abstract or nature analogy. Lastly, it should also consider if there are any mandatory or relevant standards requirements that must be adopted.

The translation table will eventually present sets of alternative information in a way that stimulates new thinking across and down them, as well as presenting them for evaluation and selection. What we finally select as output requirements should match the business plan ambition and 'difficulty budget' from our planning phase (see House of Quality 'how context'). We must be as creatively inventive or as conventionally conservative as the market and business context demand. Looking at the wider

options helps opening up the team's collective mind and makes it more receptive to lateral new thinking. Looking across and down the table of example solutions, the QFD team can realise a duality from combining related functions into one multi-functional output requirement.

The selected output requirement (right column) can be either:

a) New-found way of fulfilling the input requirement, or
b) Combining an existing solution with a new aspect, or
c) Keeping or strengthening an existing solution.

What		**Example design solutions**					***How***
		For each cell ask: What are the functions, features or activity that satisfies customer requirement?					
Customer Requirement ***(input)***	Importance	Existing own solution	Competitors' 'best' solution	Related 'state-of-art'	Abstract analogy	Design rule, standards and regulatory requirements	**Design Requirement** ***(output)***
Not rusting	7	Zinc plated mild steel material	Stainless steel, but at higher cost and more difficult to work	Aircraft grade aluminium alloy	Water system corrosion protecting by biological antioxidants	None	Anodised aluminium material
Colour red	3	Paint	Paint	Mountaineer equipment is colour coded by anodising. Doubles to rust protect	Flower has in-material pigments	Must not be confused with yellow	Red anodising

Translation table (partial)

In the portion of an example translation table shown here, we consider what a strong competitor is doing and what a related state-of-the-art response could be. We also try to stimulate lateral thinking by considering an abstract or nature analogy. Lastly, we consider if there are any mandatory or relevant standards requirements that we must adopt. There is no product standard for "not rusting" in this case; but the customer requirement for "colour red" relates to a product safety standard that says the red colour is classed as a warning indicator and must therefore be clearly distinguishable from the lesser alert level indicated by a yellow colour. What we finally select as design requirements

should match the business plan ambition. Developing something novel in rust protection, such as using plant-based biological antioxidants to inhibit the galvanic corrosion process, could be too far-stretched for our particular 'difficulty budget'. However, just looking at such far-fetched option helps opening up the team's collective mind and makes it more receptive to lateral new thinking. In this scenario, it turns out that 'borrowing' part of the solution from state-of-the-art aircraft design is a more realistic solution. Looking across and down at the example solutions, the design team can realise that aluminium (not same alloy grade) is easier to work and that anodising has a dual function of providing both colouring and protection. The selected solution remains cost competitive and it will be easier to control in manufacturing.

Failure Mode and Effects Analysis

A risk management tool for analysing potential failures and their effects on a system, and for evaluating the development of countermeasure to prevent these effects from being realised in the design – or in the related operations processes.

The FMEA method is to, firstly, clarify (mentally or document) the function of each system component. Then investigate the potential failure modes or possible deviations from the intended performance, within each the components over the full life of the system. Ask: *"What could potentially go wrong"?* Investigate and record the important effects on the system for each failure mode. Then further investigate to determine their root causes, by asking: "*Why would the failure happen*"? The definition for failure is a "*shortfall between performance and expectation/standard"*, or *"loss of ability to perform to some defined performance criteria*". We are considering single-failure modes and cascade-events only, meaning we do not consider the additive "*what if*" for two or more independent (i.e. unrelated) failures occurring at the same time. This would be far-fetched and results into much work.

Failure Mode Effect Analysis (FMEA) Worksheet															01/01/2017
System	Television model XYZ12345												Owner		Development Manager
Severity: 1 = failure effect is negligible (no harm done); 10 = devastating (catastrophic harm is done)															Urgency of actions should reflect the risk score. Consider it irresponsible to operate systems under intolerable risk
Likelihood: 1 = highly unlikely (practically impossible); 10 = highly likely (occurring frequently)															
Detection: 1 = obviously detectable for easy/timely action; 10 = undetectable before action is too late															
Score: Above 100 = intolerable; below 100 = moderate; below 40 = tolerable; below 20 = negligible															
	Original condition (assuming no controls)											Countermeasures and resulting condition			
Description	Failure Mode	Effect	Root cause	Severity	Likelihood	Detection	Score	Controls	Actions	Severity	Likelihood	Detection	Score		
Remote Control	Button press doesn't make change on TV	Customer dissatisfaction. Complaint. No repeat purchase.	Battery power loss	2	10	8	160	User manual advises to check	Add battery low warning indicator transmitted to TV for display on screen	2	10	1	20		
			Dirt ingress onto PCB contact pad	4	4	7	112	Rubber button pad designed to wrap over PCB to create seal	None	4	1	7	28		
			Firmware program/data memory error.	4	2	9	72	Best 3 of 5 EEPROM read/write routine	Continual creeping program checksum, with auto-reset	2	1	9	18		
	Unintended selection	Customer dissatisfaction. No repeat purchase.	Button symbol worn away in 36 months. Inappropriate marking solution.	3	5	2	30	Marking validated to established design standard	Improve design standard when opportune. Review solution accordingly	3	3	2	18		
		Uncomfortable loud sound. Complaint.	User misinterpret the button symbol	4	2	2	16	Use 'harmonized' terms and conventi...	None	3	2	2	12		

FMEA chart for a higher-level components analysis

Evaluate each root cause potential in terms of severity, likelihood and ease of detection, to produce a Risk Priority Number (RPN), which signifies the magnitude of risk.

- Severity rates the adversity of the failure effect (if it occurs), where 1 = failure effect is negligible (no harm done) and 10 = devastating (severe harm is done).

- Occurrence relates to the likelihood that the root cause of the failure mode will occur, where 1 = highly unlikely (almost impossible) and 10 = highly likely (frequent).

- Detection relates to the difficulty in catching the failure before it reaches the customer, where 1 = not difficult at all and 10 = undetectable beforehand.

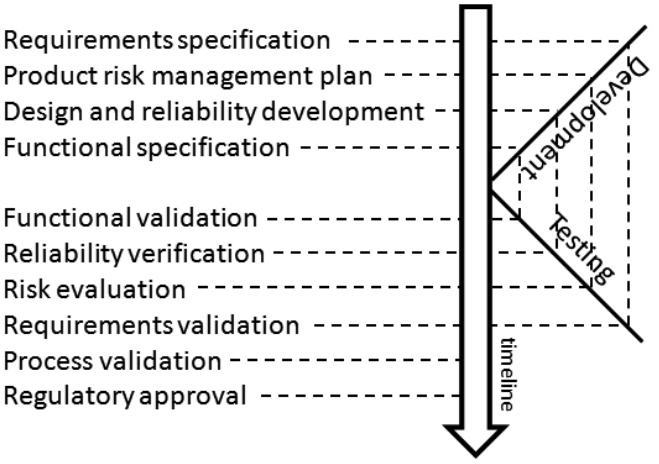
Determine and record the countermeasures and then re-assess the resulting RPN for the failure now being realised. An RPN of 20 or less is generally acceptable. For example, if severity is high, say a full 10, then we would want to assure that sufficient controls are put in place to make the occurrence and detection scores their very lowest. If, on the other hand, severity is negligibly low, then we can practically tolerate investing less in the associated controls.

DESIGN VALIDATION

Validation tests are distinct by being post-development and are concerned with made samples that are representative of the final design. The post-development testing will confirm and establish evidence for conformance of the design output to input requirements, before the product is launched to market. Although the validation helps assure against shortfalls in the design, it must be noted that it does not necessarily help assure against any shortfall in the specification of input requirements. If the VOC was

wrong, then the validation might merely assure that the design is equally wrong. This highlights the importance of the VOC activity.

There is a relationship link between the requirements and the testing activities that verifies the result. The relationship can be depicted by the V-model.



Relationship links between the inputs and tested outputs

The Functional Specification consists of the final description, calculations, tolerance/assembly drawings or software code representing the finished design, which came about by the QFD approach.

Functional validation: Tests and documents that pre-production units meet the performance and tolerances defined in the Functional Specification, including requirements identified in the reference standards*.

* Note: The input specification, defined in the VOC phase, required the developer to complete a detailed search for relevant regulatory standards. For products, such as electrical equipment, toys, medical, for example, actual sales cannot commence until a legally defined conformity assessment procedure is completed. This additional procedure may stipulate independent examination.

Reliability evaluation: Repeatability and durability qualification tests, such as accelerated life and stress testing, to establish the intrinsic life of the designed product and to understand its wear profile. The units under test may be produced in the developer controlled environment, but should otherwise be fully representative of the final production units.

Risk evaluation: Performs a hazard analysis, risk estimation and acceptance evaluation for the final design, against the policy and criteria defined in the Risk Management Plan. The evaluation identifies and evaluates any residual risks and concludes on overall design risk acceptance – i.e. evidence that the product or service is safe to sell.

Requirement validation: Review by sales and marketing teams. For example, the organisation may present samples to distributors or customer representative focus groups. It is essential to catch any unforeseen shortfalls at this very final stage, as opposed to once launched for sale.

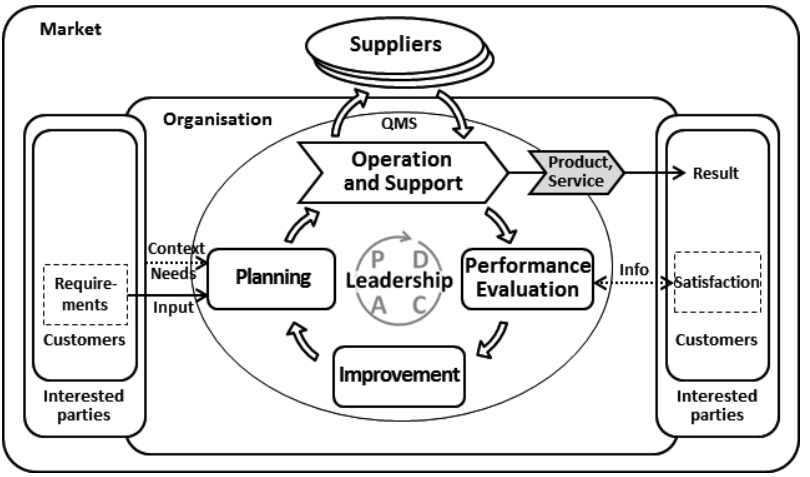
Any serious design flaw identified in the design validation process should halt the new product launch, and instead iterate the project back to the design and development process. Hopefully, this will not happen in a systematic process. Minor, manageable design flaws may be tolerated, subject to a plan for addressing them at the next opportune design review or for handover to an ongoing product maintenance process for continual incremental improvement.

OPERATIONS QUALITY

Operations assure quality by adhering to the design specification. However, learning from the processes and evolving customer feedback will likely identify unforeseen shortfalls and new improvement opportunities in the original design. The operations shall therefore maintain a system for instigating corrective actions, to continually evolve the product and processes design.

QUALITY MANAGEMENT SYSTEM

Standard ISO 9001 defines a quality management system (QMS) as *"coordinated activities to direct and control an organisation with regard to quality"*. The standard relates to the QFD approach in two ways. Firstly, it describes best practices in operational delivery processes. It can thereby provide some of the input requirements into the QFD Phase 3 and 4 plans, for which the output will transfer into operations. Secondly, the QFD approach is itself a sub-system within the QMS 'operation' element.



QMS model (adapted from ISO9001:2015)

The QMS is structured with the following elements:

Leadership
Drives the effective implementation and ongoing execution of the PDCA cycle across the system. Sets a unified direction and promotes the coherence to planned objectives. Maintains conditions for achieving the objectives. Unblocks any obstacles.

Planning
Determines the customer input, any mandatory requirements and their organisational context, for translation into planned objectives. The context influences the objectives for making maximum use of opportunities for improvement and efficiencies as they arise. Planning also considers and incorporates countermeasures to risks of deviation from the objectives.

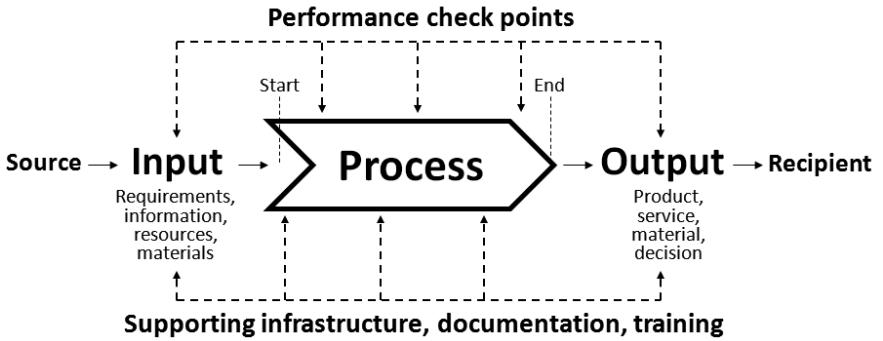
Operation and support
Organises and controls the multiple activities and linkages in the processes-chain and resources, for producing the planned result – e.g. transforms the input requirements into a corresponding output. This includes both design and operations activities, within an integrated process. The support element develops and maintains the appropriate competencies, capability and capacity in people, equipment, infrastructure and work environment.

Performance Evaluation
Measures, investigates and analyses the processes, product and outcomes, including customer satisfaction, for purpose of verifying that planned results are met and for identifying new risks and opportunities. Periodic audits objectively measure effectiveness and verify conformity to requirements.

Improvement
Reactive and proactive activity for assuring the ability to meet requirements and for enhancing the satisfaction of customers and other interested parties. Improvement relies on evidence-based decision information.

The ISO 9001 standard provides a descriptive (as opposed to being prescriptive) model for an end-to-end process-approach to achieving an organisation's policy and objectives, and for managing risks and opportunities. Risk-based thinking means to ensure that risks are identified, considered and controlled by a proactive approach. An opportunity is defined as a set of circumstances that makes it possible to do something positive.

The term 'process approach' refers to the "*systematic definition and management of processes and their interactions so that to achieve the intended overall results in accordance with policies and strategy direction of the organisation*" [source: ISO 9001]. The process approach enables the organisation managing the system and its value creation as an integrated whole, including the risks and opportunities that span across the organisation.



Single process model (adapted from ISO 9001:2015).

A process is "*an activity or set of activities using resources, and are managed to enable the transformation of inputs into outputs*". Generally, the output from one process forms the input to the next. The process should therefore be considered as part of an extended, interlinked value-chain – starting and ending with the customer and other interested parties.

A process is defined by describing the step-by-step tasks that it performs, together with their interactions with the various elements shown in the 'single process model' diagram above. The definition should also identify who is responsibility for performing and overseeing the process, and it should have some result criteria attached – i.e. definition should be telling: "*This is how we want to perform the activity and this is what we want the output to look like*". In this way, everyone can be clear about the tasks and how they link to the organisations objectives.

To use the process approach, the organisation should understand and define the processes that are important to its objectives. The definitions should appropriately balance both risks and opportunities within the system overall. For example, defining a 'performance check point' may help prevent a deviance from the original intent and, thereby, protect against the realisation of a failure. However, if this control is over-rigidly defined then it may simultaneously prevent an opportunity for improving the process, by not allowing or by de-motivating a potentially useful deviation contained in a new value-enhancing idea.

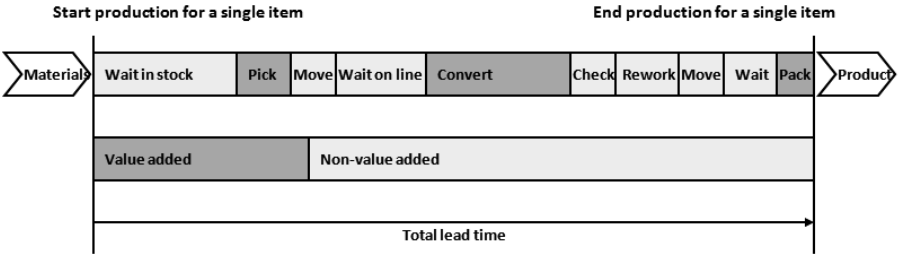
The number of check points shown in our 'single process model' here are simply to illustrate what might be. It is preferable for a process be so well developed and implemented that its performance does not depend on any checks at all. Only use a check point if there is a real lack of confidence in the activity or where we must produce and record a measure, for use in the ongoing performance evaluation or for, say, legal evidence reason.

LEAN PRINCIPLES

The lean concept is a systematic iterative approach to identifying and eliminating non-value added activities waste, through a continual perfecting of the work flow to the pull demand of the customer.

Lean principles do not solely apply in manufacturing, but they are equally oriented toward services sectors, healthcare, education and government, with variant approaches such as 'lean enterprise' and 'lean accounting'. The most basic lean thinking is to simply consider that whenever an item is being worked on then it creates value; while when an item stands still (waits), is being carried or transported, is checked or reworked then value is being destroyed. This does not mean that value creation and destruction occurs at the same rate – but just that it occurs.

- Value added activities are those that are worth paying for having done.
- Non-value added activities are those that nobody can see any worth in paying for.
- Non-value added required are those that do not add value but must be done – say, for legal safety reasons.



Process-chain summing up the
value and non-value added activities

It is not unusual that only 5% to 30% of activities time and effort in an operation are truly value adding. There tends to always be significant scope for reducing waste. One way of managing the value improvement is to implement value stream mapping, measurement and costing tools, which enable the tracking of waste in the organisations continual Plan-Do-Check-Act cycle.

Lean principles distinguish 8 wastes and their typical causes, which should be targeted for reduction.

Waste	Causes
1. Inventory Any supply in excess of what is needed for the single next customer order.	• Poor forecasting and scheduling. Not operating to pull demand/kanban. Traditional MRP (materials requirement planning) is not lean. It is utilisation and not cycle time focused, resulting in large static batches and scheduling at each supply chain stage. • Lack of stock visibility. • Large batches or in-process inventory. • Safety stock buffers against unresolved problems. • Unreliable supplier shipments.
2. Transportation Moving materials, products and documents within the facility, from suppliers and to customers.	• Poor layout. • Poor process flow. • Larger than necessary facility. • Distant suppliers. • Distant warehouse. • Distant customers.
3. Motion Any movement by people or machines at a work station, which does not add value to the product or service	• Poor workspace organisation. • Poor housekeeping. • Inconsistent work methods. • Lack of individual tools and equipment, where operators waste time in searching for the shared tools/equipment.
4. Waiting Idle time waiting for parts or waiting to commence the next task.	• Unbalanced workload and takt time. • Unplanned maintenance. • Quality problems. • Unreliable suppliers. • Poor scheduling. • Lack of visibility about what is next. • IT problems.

Waste	Causes
5. Defects Bad parts, mistakes and rework.	• Weak process definition. • Tolerance of poor quality. • Bad suppliers. • Inadequate maintenance. • Inadequate training. • Poor morale. • Lack of or diluted responsibility - e.g. in a multi-phased system. • Poor equipment. • Poor housekeeping.
6. Over-processing Effort that adds no value to the product or service, from the customer and organisation's point of view.	• Poor communication. • Unclear customer requirements. • Bad directions. • Redundant inspections. • Redundant approvals. • Excess unnecessary information and copies.
7. Over-production Making more than required, earlier than required, or faster than required – and then risk it passing its sell-by-date.	• Lacking confidence. Unnecessarily planning for 'just-in-case'. • Long process setup. • Poor scheduling. • Unbalanced workloads. • Redundant inspections. • Lack of visibility and responsiveness.
8. Under-utilized people Not making the most of people's mental, creative and physical abilities.	• Poor recruitment practices. Over-capacity of the wrong skills. • High staff turnover. Always inexperienced people in the system. • Command and control management (only do what and when you are told!). • Sub-ordination to systems. • Blame culture where good intentions risk-taking is punished.

PROCESS RELIABILITY

We would want the developed operations process to continually assure quality. Reliability, R(t), can be measured in terms of an item's capacity for meeting the required performance over a defined period of time. Related measures are mean-time between failures (MTBF) or mean down time (MDT).

Design principles for reliability:

a) Use components with known well-established failure profiles – e.g. through components and design validation.
b) Exceed system stress with adequate safety margins.
c) Minimise complexity and unpredictability. Consider using known well-established modules/platform solutions.
d) Add active or conditional standby redundancy or duplication, including error-checking and self-initiating correction.
e) System distribution and diversity. Avoid multiple sub-systems relying on a single common critical component that can result in a common-mode failure.
f) Robust engineering design (RED). Determine design parameters through experimentation, to establish best possible insensitive to uncontrollable random effects – e.g. deviance in raw materials, environmental or human noise factors.
g) Calculate and justify system reliability. Make R(t) subject to design and process validation testing.
h) Assess failure risks (e.g. by process FMEA) and assure they are reduced to within acceptable levels.
i) Place mistake-proofing devices in the process flow, such as a physical obstruction or automatic failsafe that prevent incorrect working or assure against faulty items leaving the process. Good mistake-proofing devices do not add complexity or delay.
j) Manage suppliers and inventory, to reduce probability of deviance, deterioration and compromising shortfall. Control

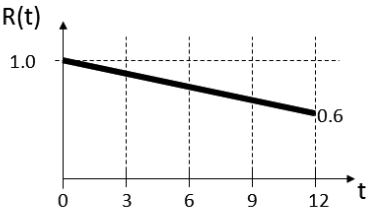
the flow of materials, methods and changes. Control processes and standards.

k) Support customers with adequate user instructions and training, to prevent inadvertent misuse.

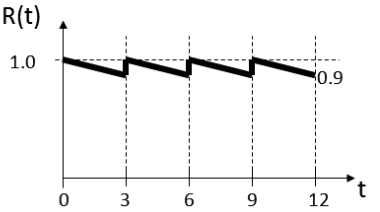
l) Define preventative maintenance requirements and maintainability. Good design should minimise maintenance time, ease condition monitoring and diagnostic.

Whereas some unreliability can be guarded against by preventative maintenance, we must be careful in prescribing maintenance as the standard solution to possible breakdowns. In some instances, maintenance can potentially reduce reliability. Every time we take apart and put back together a system during maintenance, we risk introducing a new mistake. Occasionally, the old saying "*if it isn't broke then don't fix it*" will hold true. Preventative maintenance should focus on what is critically important and what has a quantified wear profile. For the lesser critical or input related (e.g. raw materials) elements of the process, it may be better to simply monitor and develop fast reactive solutions for responding to potential failures, such as with readily accessible spare parts and/or a (small) standby safety stock or backup device.

Without any preventative maintenance, R(t) is 0.6 after 12 months



With quarterly preventive maintenance, R(t) is 0.9



When things do go wrong, or awareness is raised that there is a risk they could go wrong, then proactively or reactively trace the identified defect back to its root cause. Consider each part of the wider process both in isolation and as part of the whole. Do not assume that a solution that worked well for one part of the process will automatically be a good solution for another part of the process. In particular, we ideally want to minimise the reliance on controls and preventative maintenance – not increase them. Better, if it can be done, iterate back to the design phase and resolve the matter as a robustness issue. A robust design should be insensitive to normal process variability.

PROCESS VALIDATION

The concept is a systematic investigation for purpose of establishing evidence that the process is capable of consistently delivering a quality result. It is performed before ramping up to full production/service capacity. The process owner, or an independent party, collects and evaluates data in order to judge whether there is sufficient understanding to have a high degree of confidence in the process. This includes:

- Knowing the presence and the degree of process variability.
- Understanding the sources of variability.
- Understanding the impact of variability on the process and how this cascade into impacting on product quality.
- Control the variability, proportionally to the magnitudes of risks they present to the process and product quality.

The process validation is performed over a series of staged activities:

Stage 1: Process design, during which knowledge of the risk factors and a strategy for their control is established (e.g. by FMEA). Some process quality attributes are

inherited from product design – i.e. the design robustness to process variability will determine the attention to tolerances and controlling that is required.

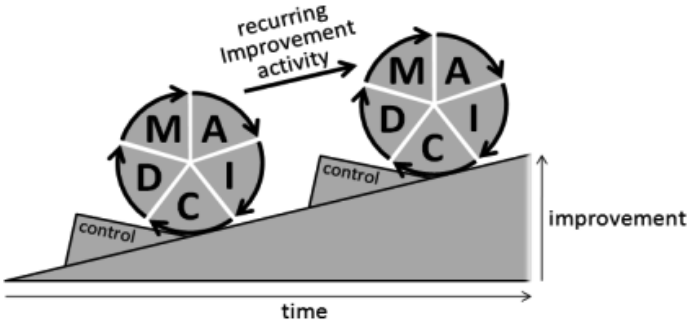
Stage 2: Process qualification is the validation of facility and equipment installations (IQ); operational stability, capability and sensitivity (OQ); and process performance (PQ). This stage will quantify the risks and will qualify their controls.

Stage 3: Process verification is the on-going assurance that the process remains in a state of control.

Various methods or techniques may be used for collecting and evaluating data at the different stages of the process validation. It is important to the producer that the validation methods are both reliable in their results and economical in application.

SIX SIGMA

The approach can be thought of as a project based, statistically analytical, data-centric parallel to the PDCA management system cycle. Six Sigma is based on the DMAIC cycle.



The 'Define, Measure, Analyse, Improve, Control' cycle

Define: Describe the issue or problem to be solved, including the project scope and goal – such as a new quality yield or cost saving target to be achieved.

Measure: Identify and clarify all the potential factors that can influence the issue or problem in scope. Collect input, in-process, output and result data relating to the influencing factors. Verify the measurements accuracy.

Analyse: Apply statistical, experimental and/or visualisation tools to examine, quantify, evaluate and uncover interrelationships in the influencing factors. Identify the causes for shortfalls against the project goal.

Improve: Develop and test candidate solutions. Decide on a prioritised action plan and implement. Validate that actions produce their intended results, without causing any unintended side-effects.

Control: Update the product specification and/or processes definitions, to reflect the new state. Communicate to and train people. Verify that improvements remain stable and are sustained.

Due to its statistical technical nature, Six Sigma is often being 'done to' the system by an expert practitioner. This can potentially make it difficult for people to feel involved. By comparison, the PDCA cycle relies on the deeper involvement of people, maintaining their ownership of the problem and the solution. This difference does not devalue Six Sigma. The analytical evidence-based technique can yield superior improvement solutions in certain complex scenario. Although it is not universally suited for every situation, Six Sigma is proven by successes in many diverse industries.

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