Reasons to use quality & reliability early and iteratively in new product development

and ways to do it

A look at common product development processes with a practical guide of how to make them better.

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The idea…

Speed the Product Design Process by incorporating Product Risk Management and Usability, Quality, and Reliability Engineering initiatives together with the design process.

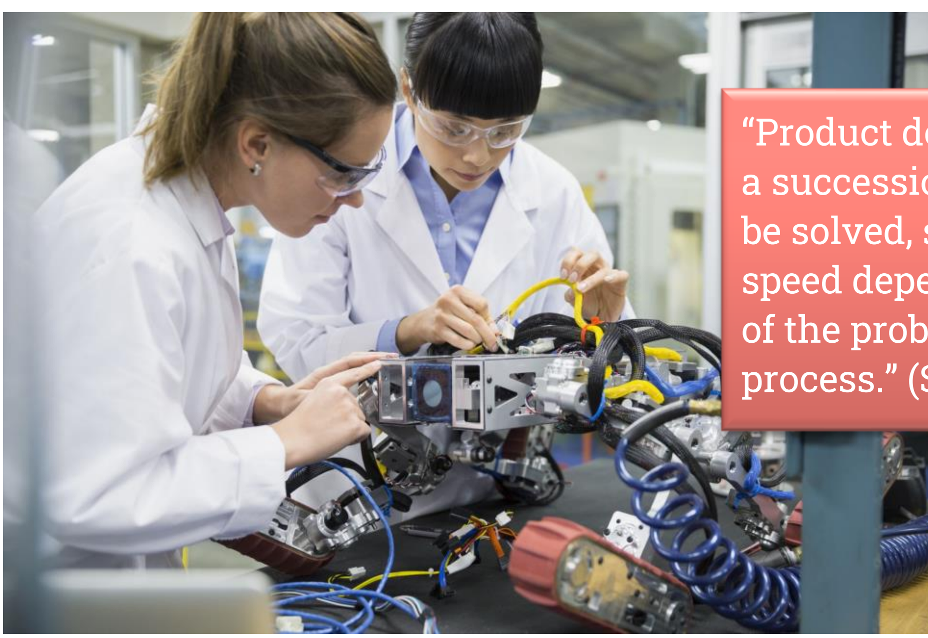
This optimizes the opportunities to make design decisions early. Typical tools in these fields are geared toward solving problems, and some can be iterative throughout the design process.

Early decisions positively affects

Safety Risk Mitigations Usability

Product Performance

and speeds the development of innovative ideas by reducing redesign and delays.



"Product development is just a succession of problems to be solved, so development speed depends on the speed of the problem-solving process." (Smith)

Table of Contents

Quality during Design SM

This document describes a design process model of iterative R&D, risk management, and usability, quality, and reliability engineering.

Information from presentations, articles, journals, books, and the author's professional experiences and case studies are represented.

The Current State of Design Development and its Challenges

A review of where current processes were derived and challenges with their application.

Design Development Processes

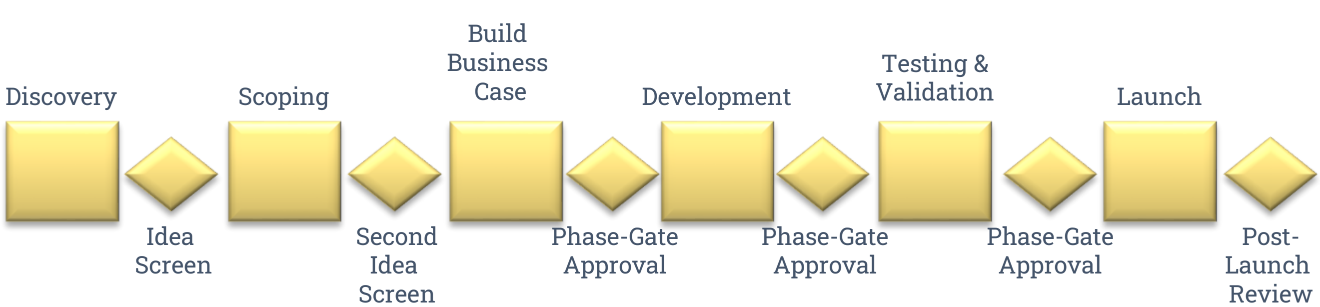
Processes for new product development started from NASA's Phased Review Process in the 1960s. They developed into later generations of formal phases of development separated by phase-gates, like the Product Launch Model (Cooper). These product development models are mostly linear, phased processes, with an understanding that there are development cycles within them, and feedback loops from testing.

A development to the Stage-Gate™ process was a Spiral process, where each stage contains a cyclical feedback mechanism that involves the customer. Team management also includes aspects of the Agile software development models (Cooper, R.G. "NextGen").

Project Management Process Groups (PMI)

Source: PMI (Project Management Institute)

State-Gate™ with Discovery and Post-Launch Review



Source: Cooper, Winning at Figure 5.4, pp 130.

User Centered Design

A User-Centered Design includes all user interfaces.

Early standards on user centered design focused on user interfaces with software applications. However, the idea of usability has expanded to all user interfaces.

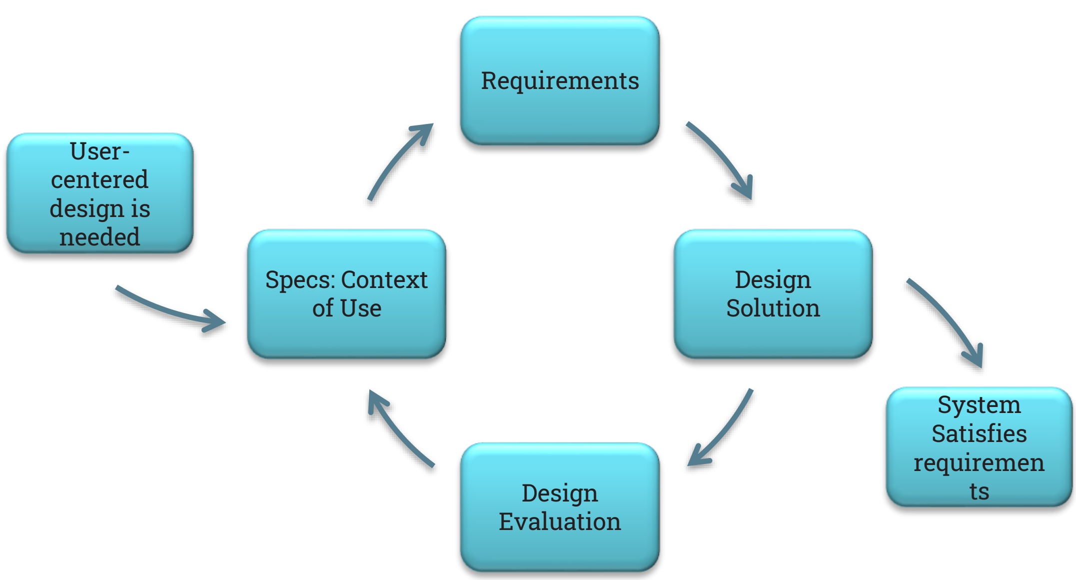
> *ISO 13407 "Human-centred design processes for interactive systems" was written for computer-based interactive systems. It has since been withdrawn and replaced with the ISO 9241 series of standards which have a broader scope.*

The accepted definition of usability for User Experience (UX) workers is from ISO 9241-11:2018 (Jokela, Iivari, Matero, Karukka)

> *"Usability: The extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use"*

A generic process for usability was defined in ISO 13407, but it was found that it does not adequately address different users and their needs/wants and does not help with determining measures of success. (Jokela, Iivari, Matero, Karukka)

Activities of a user-centered design



Source: adapted from ISO 13407

Other Regulations for Usability and Risk in Product Design

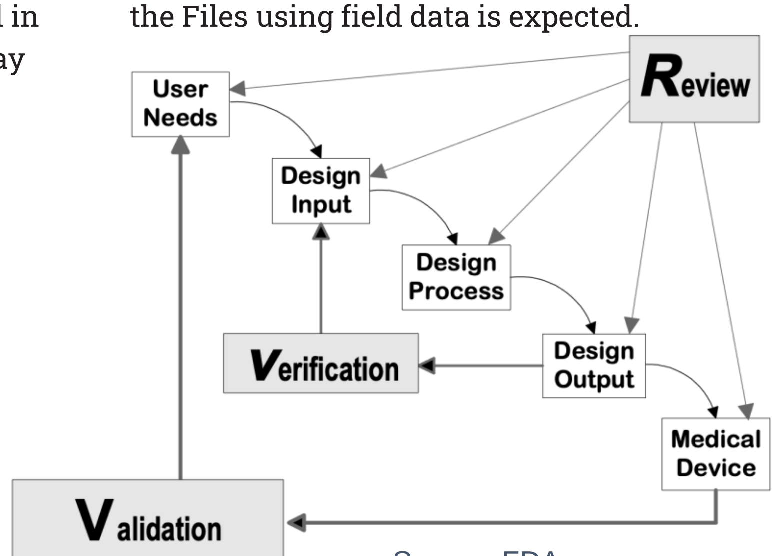
Current Regulations assume Product Risk Management and Usability, Quality, and Reliability Engineering methods are parallel or interspersed with the linear product development model.

One of the sectors of product designs that are regulated by standards are medical devices, because of their direct effect on public health and safety.

Usability engineering and risk management have been requirements for medical devices since 2015 (ANSI/AAMI HE74:2001 with the release of IEC 62366-1:2015.) Device manufacturers also need to be compliant with the longer-standing ISO 14971 (Application of risk Management to Medical Devices). With the advent of the MDR (Medical Devices Regulations) in the European Union (which was initiated in 1996, with compliance required by May 2021), the reporting requirements of post-market data increased in both frequency and scope, with a continued focus on usability, risk management, and an assessment if the technology is state-of-the-art.

Because of these regulations, a Usability Engineering File and Risk File (a collection of analyses and data that contain user and risk data that were used for product design) are increasingly prevalent as part of the device design cycle and field monitoring. Their presence as part of design history is required for compliance, and maintenance of the Files using field data is expected.

Even though these regulations are specific to medical devices, it's recognized that their application can be for product design, in their general sense.



Source: FDA

Issues with Application

There are issues when applying Product Risk Management and Usability, Quality, and Reliability Engineering to product design.

Teams delay Risk Analyses to later in the development process.

Product developers will create Risk Analyses after the design has been picked and decisions made, waiting to analyze risk until a vetted prototype is in-hand or hiring a third-party to analyze risk of an already-designed product. Delaying the Risk Analyses in this way impedes and may eliminate opportunities for the designer to prevent risk, or to eliminate or reduce a risk by product design. (Chao & Smith, Merrit pp. 10). There are also missed opportunities to prioritize design activities based on risk.

Customer insights are not gathered and used for development like technical activities.

Cooper performed benchmarking studies of the product development process. “The most poorly executed activities or tasks are the detailed market studies. These include user needs studies, building in the voice of the customer, and competitive analyses…By contrast, the technologically oriented activities…while not perfect, receive much better ratings” (Cooper, Winning at New Products, pp. 28-29)

Usability, Quality, and Reliability Engineering applied too late in the design process negates opportunities to design-in products’ safety and usability features.

Not understanding or communicating the usability aspects of the product to designers impedes their ability to design because they are missing a critical design input. Quality Engineering techniques applied to the use of the product can help drive design decisions, early.

Designers can use the results of Reliability Engineering techniques to better understand failure modes and predict reliability. They can use this information to make design decisions throughout the design process.

Design decisions with a cross-functional team are avoided.

“In only 12 percent of the projects did initial screening come even close to what it should have been: a multidisciplinary decision making group (in order to provide different inputs to the decision) armed with go/kill criteria upon which to base the decision.” (Cooper, Winning at New Products, pp. 35)

Timeline Concerns

The pace of new product development has increased, and leaders are looking for ways to improve their business models to speed the pace of their organization's innovations to remain relevant, increase their value equation, and maintain their rate of growth. [Keathly - Williams].

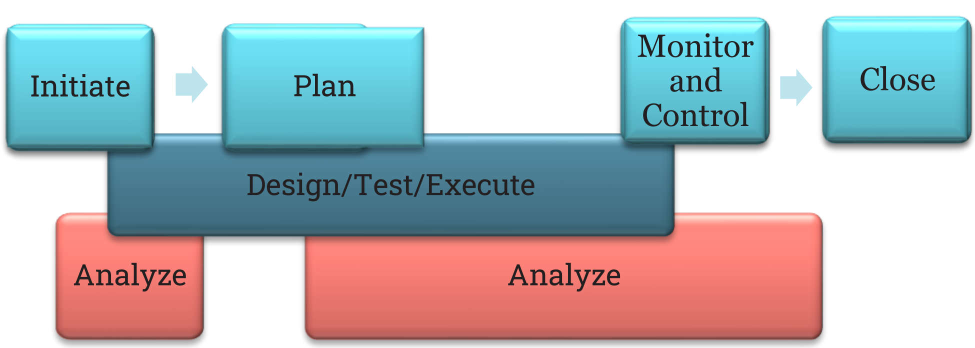
A linear approach to planning, analysis, and testing doesn't maximize resources, or take advantage of information and data to make decisions.

Project Management Process Groups (PMI)

Source: PMI (Project Management Institute)

Instead, techniques from risk management, usability, quality and reliability fields can be used during concept evaluation and planning to help a cross-functional team make decisions about a design.

Strategic Planning



Solution

Quality during Design[SM]

A map of the Quality during Design Development Process

Key highlights and methods

Solution

Quality during Design SM

The product development process incorporates at least four things:

1. the design process from concept through product retirement
2. Product Risk Management, and

Usability, Quality, and Reliability Engineering techniques

Quality during Design is adaptable. Incorporating quality and reliability early can fit into most any product development model.

The overarching application of these methods is to use them to make decisions during the design process, effectively pruning the process from design ideas that will not be fruitful in the end.

These aspects are important and beneficial to today's design process.

They help the design team make customer-centric decisions about the design.

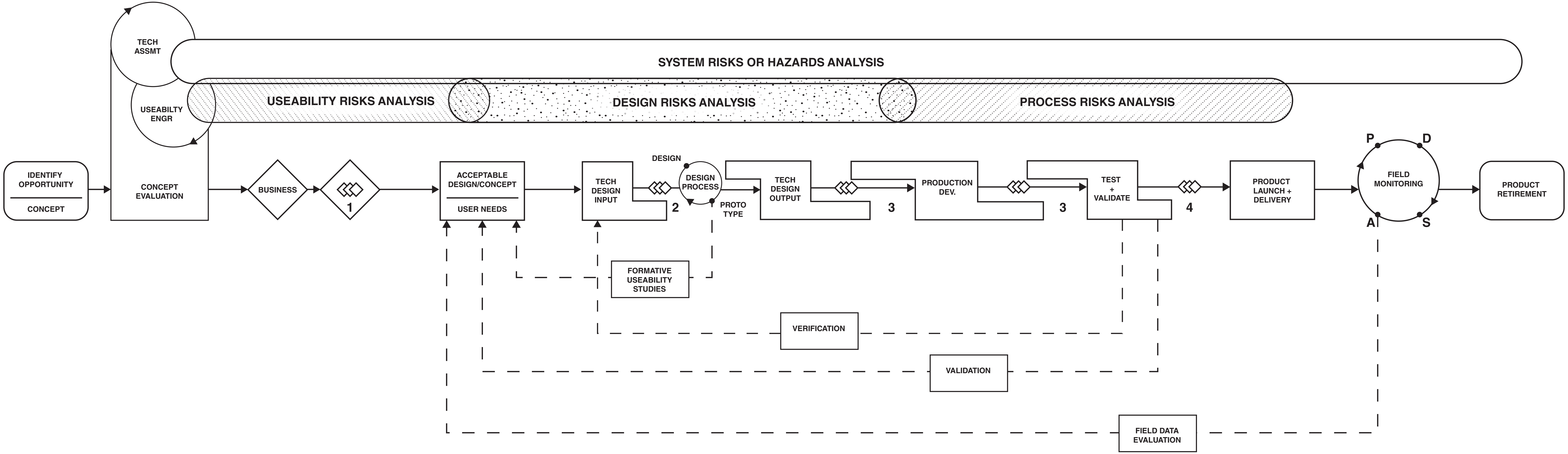
Their use can be prior to and during development and after the finished product is in the hands of the user.

The classical process of design inputs/outputs are combined with early-implemented risk management and usability engineering.

Quality and Reliability Engineering techniques and strategies are early inputs into the design process, in some cases using an iterative technique.

This process is adoptable to many business types and different product development cycles.

FUZZY GATES / ITERATIVE TECHNICAL DESIGN REVIEWS



Features of this Solution

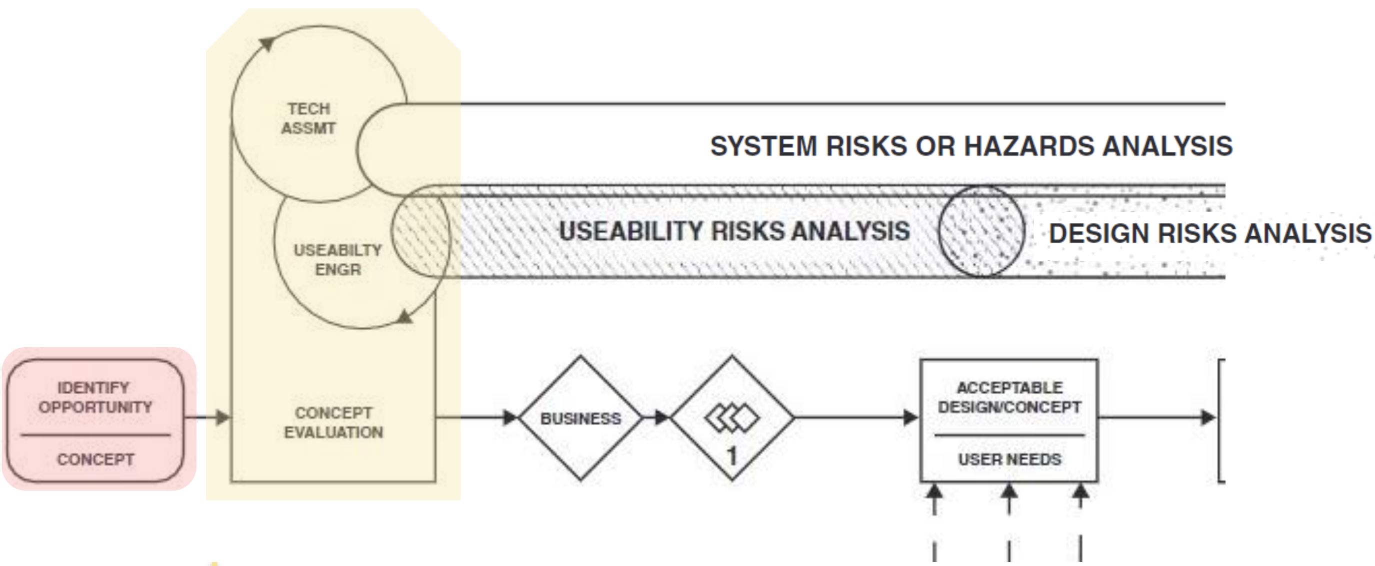
Quality during Design[SM]

How *Quality during Design* works.

How to have a Design Concept with Strong Foundations

The beginning of product design development is when the team identifies opportunities and design concept ideas.

Market evaluations, business assessments, and profitability are all things that are considered before venturing further into a proposed project. Of key importance to a new design is investigating user wants versus needs, analyzing competitive product, and understanding benefits and a value proposition.



The cross-functional team continues to evaluate the concept, still before technical development begins.

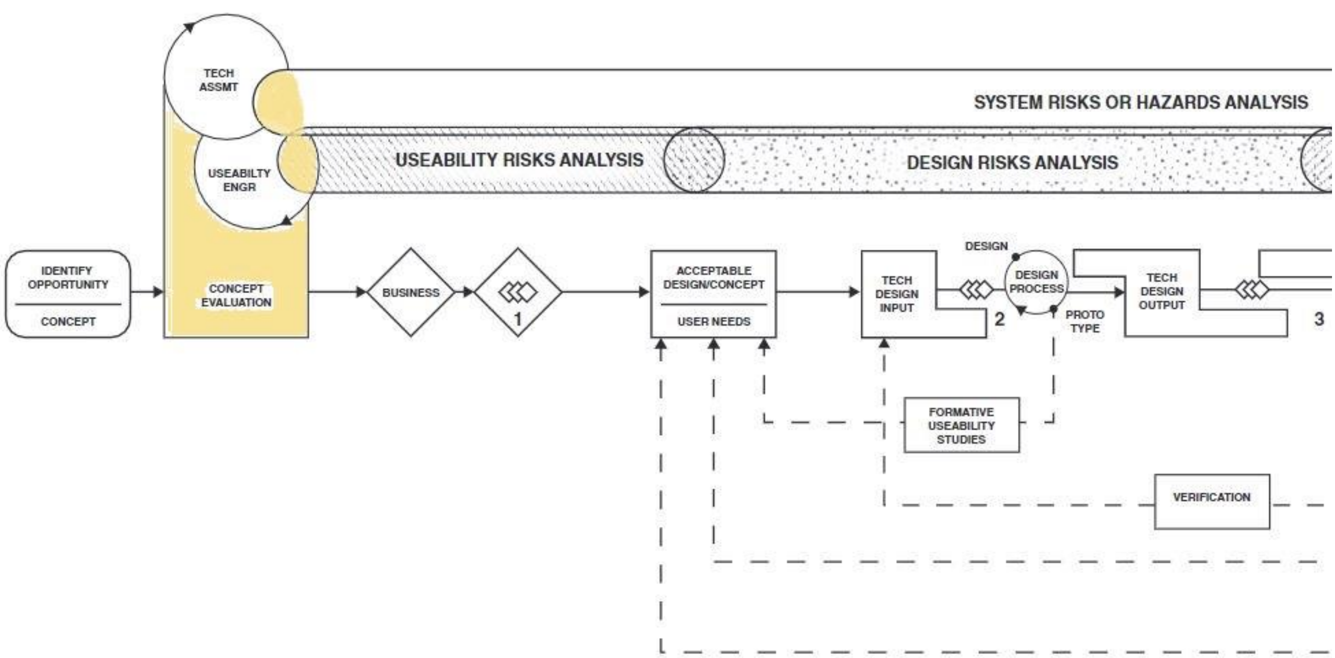
Within the Concept Evaluation phase are two, iterative development cycles that work together to evaluate and further refine the concept: the Usability Engineering cycle and the Technical Assessment cycle. Product risk analysis starts at the concept evaluation phase, with an over-arching evaluation of the risks associated with the full system. Quality and Reliability Engineering techniques are used throughout to help the team make decisions and set preliminary requirements. These up-front assessments and evaluations provide the designers a strong foundation of knowledge for the product's development.

Early Risk Analyses

Risk management starts at the concept evaluation phase, with an over-arching evaluation of the risk associated with the full system.

Risks evaluated at concept evaluation can include both technical risks ("the inability to satisfy the product specification) and market risk ("the inability to sell the product assuming it meets specifications") (Smith). Different, focused risk analyses may be used to evaluate the technical usability, design, and processing of sub-systems. (Marketing risks can be similarly assessed, but separately, and are not further described in this paper.)

This iterative technique is supported in other literature (Castaneda and Smith).

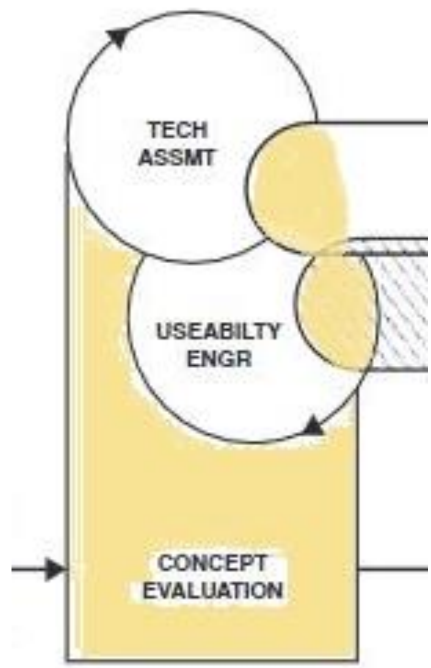


Early Use of Quality & Reliability

Quality and Reliability Engineering strategies and techniques are employed early, in the concept and concept evaluation phases.

They're used to help make decisions about the use, performance, and safety of design iterations. These methods can also be viewed as iterative, starting with what a team may know and further developing as the team learns more about the use case and design concept.

The team analyzes what they know to make decisions and prioritize development directions. The team must also balance being flexible and not over-analyze. Teamwork, iteration and movement are key.



Tools such as:

- flow charting the user process
- group activities with affinity diagrams
- reliability apportionment
- HALT (highly accelerated life test), and
- FMEA

can be used by the team to develop concepts and requirements that are controlled by the product design itself. Designing-out issues and designing-in features that will delight a customer is most easily done at the concept phase.

"A thorough understanding of customers' needs and wants, the competitive situation, and the nature of the market is an essential component of new product success." (Cooper, Winning at New Products, pp. 86)

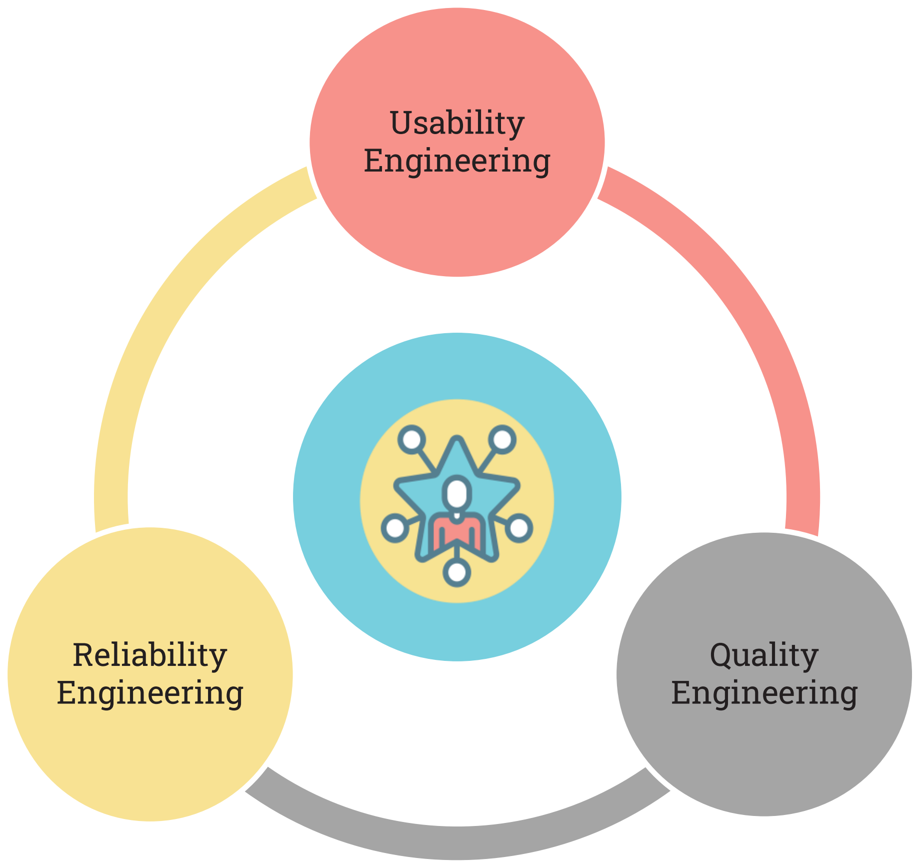
Design what the customer really needs

Usability, Quality, and Reliability Engineering methods are customer-centric, keeping the customer in the forefront of design decisions.

At the Concept Evaluation phase, the Usability Engineering process is incomplete. But, published case studies show success with iterative Usability Engineering cycles at the concept evaluation phase (Peijl and Beuscart-Zéphir).

And tools with a history in manufacturing can be similarly used by designers to evaluate the lifecycle of a product and the consumer's process in using a product.

"...traditional market research, such as large sample surveys, may not be appropriate for every project. But building in the voice of the customer, seeking customer insights, and getting the right market information before Development proceeds are vital requirements." (Cooper, Winning at New Products, pp. 25.



Cross-Functional Decisions

Quality during Design is do-able, approachable, and adaptable for teams.

Usability engineering can be started as an iterative cycle along with the technical assessment at the concept evaluation phase.

Doing this puts users at the forefront of design and in parallel with any technical considerations. This has the benefit of evaluating and capturing the important use aspects of new design in the early phases of development. Technical and user assessments are also aspects of the business decision to proceed with the product design, so utilizing user information by engineering early is not an undue burden.

"Involving multiple roles, for example users and developers in the risk identification process, will result in a more complete set of identified risks than if only one role is included in the process." (Lindholm)

Reliability and Quality data is used to help make decisions.

A team-approach to decision making can be used, using standard quality and reliability tools. These methods can be used early in the design process to make technical decisions for the design. And the approaches can be used to make decisions about the continued viability of the product in the market.

Before starting the iterative design/prototype process to develop a minimum viable product, the team works to understand the user and use environment.

Work is also done to develop potential risks and failures and translate them into functional, performance, operational, and reliability requirements. This work includes evaluating the potential risks to the system's function, performance, operation, reliability, and safety. Those systems risks can translate into potential usability failures and design failures. FMEAs can be used to understand and prioritize these risks so the engineer can implement design controls that are preventive, where possible.

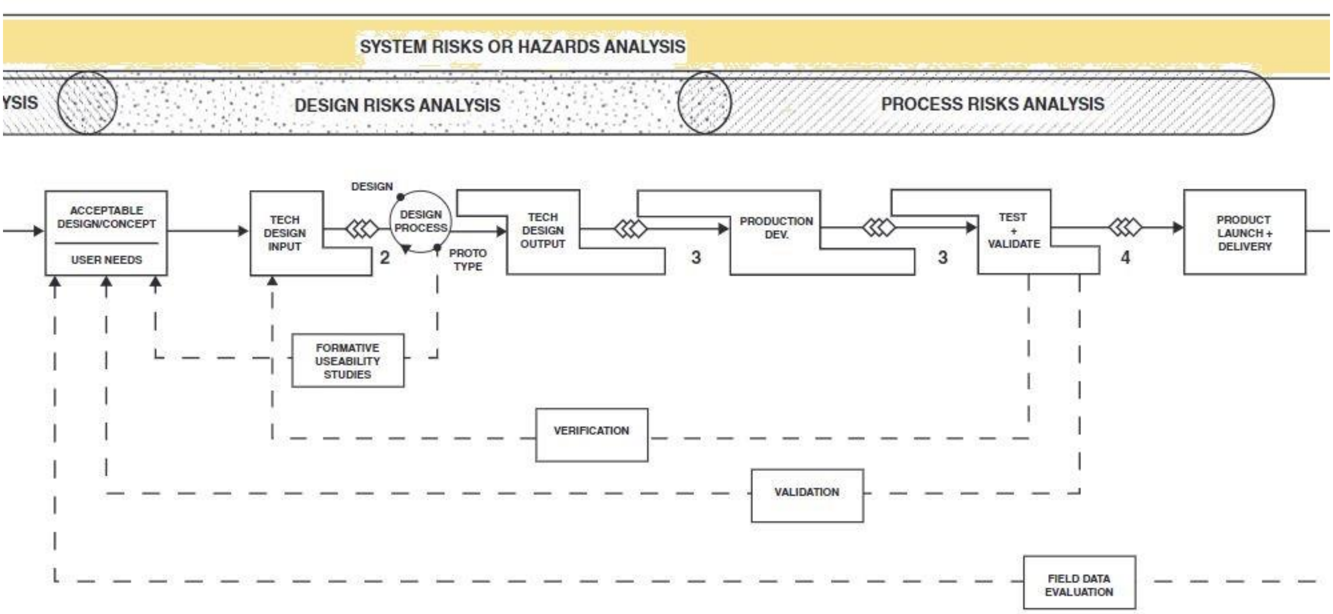
Iterative Design & Risk Management

The risk analyses are iterative with the development and honing of the product through its development and test, and as information is learned.

This approach is flexible; depending on the project, all levels of risk analyses may not be needed. The team can decide on the scope and level of detail they want to perform at the concept evaluation step. The results of the risk analyses are used to create action items for designs to reduce risk, prioritize design efforts, and assign a level of criticality with design, test, and inspection.

Even though the risk analyses are continually developed throughout, they are still able to help a team make decisions, especially if a fuzzy gate method is approached with the technical design reviews.

The process is a multi-tiered, iterative design and risk management methodology.



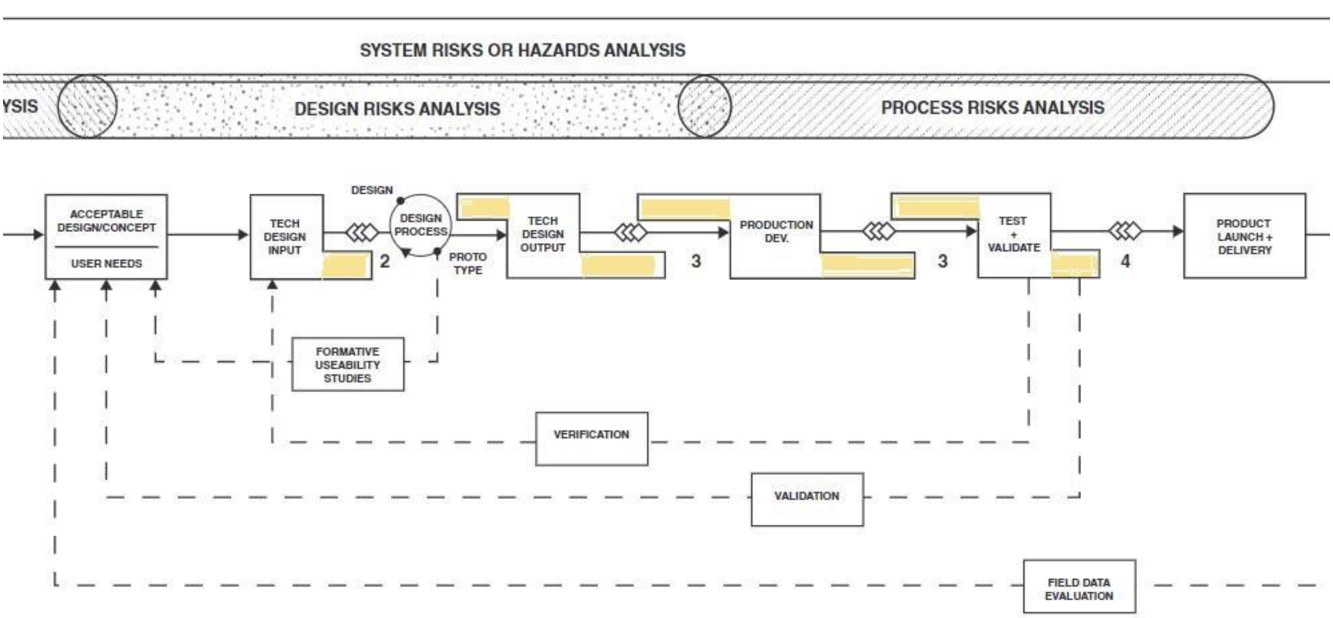
Flexible with Overlapping Phases

The system is flexible, allowing people to make decisions based on their experience with either the new product design itself (like a second-iteration of an existing design), or experience in design.

Part of the flexibility is that Phases of development can overlap.

Sub-systems or components may be developed and within production development at the time that other sub-systems are in their technical design output phase. Iterations of designs can be evaluated with formative studies to evaluate the usability and gather customer feedback.

Risk analyses can evolve with the design iterations.



A flexible system is promoted in literature (Cooper, and Smith).

Cross-Functional, Conditional Decisions

A series of technical design reviews with different focuses throughout the product development process involves cross-functional teams.

The approach of a cross-functional team is where no one function owns a step over another function, but they instead work together to produce results.

These reviews are used for the team to make decisions on the continued acceptability of the product being developed, given what is known at the time; this is how iterative risk management plays a role in product development.

The decision gates between Phases are represented as “fuzzy gates”. where conditional/situational decisions are made instead of a hard “go” or “kill” decision.

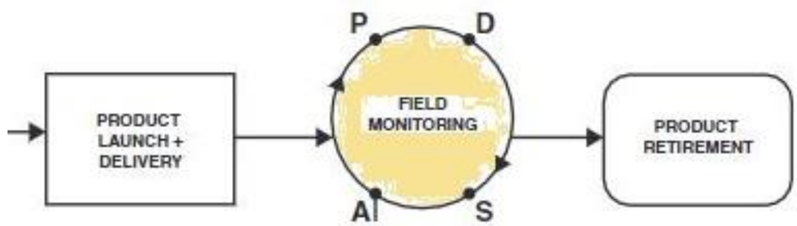
The conditional approval could be viewed as an agreement that the project looks good for now but is pending the completion of these other tasks by a certain date, and assuming the results of those tasks are positive. This keeps the project moving forward.

Source: A Fuzzy Gate concept was introduced by Cooper.

Continuous Field Monitoring

The cross-functional team continuously decides if the product should continue to be sold to consumers.

Points-of-view include usability, safety, performance, and business.



Field data is investigated using a PDSA (plan-do-study-act) cycle for continuous improvement.

There is a plan for data collection from field use and it is carried out and studied. The use of the product in the field is compared with the usability information that was used for design. Field failures are assessed for occurrences and compared with the risk analyses that were used to accept the product for sale. Competitive products are also evaluated.

The cross-functional team collects data from the field (post-launch) and compares that data to the information that was used to decide that the product was acceptable for launch: were there changes?

Examples are “Is the product still safe?”, “Are users using the product in the way that we had intended, or is a new user using it for a unique purpose?”, “Do we need to change our design because of new standards of technology?”, and “Is our product still relevant to the market?”

Process Phases

Quality during Design℠

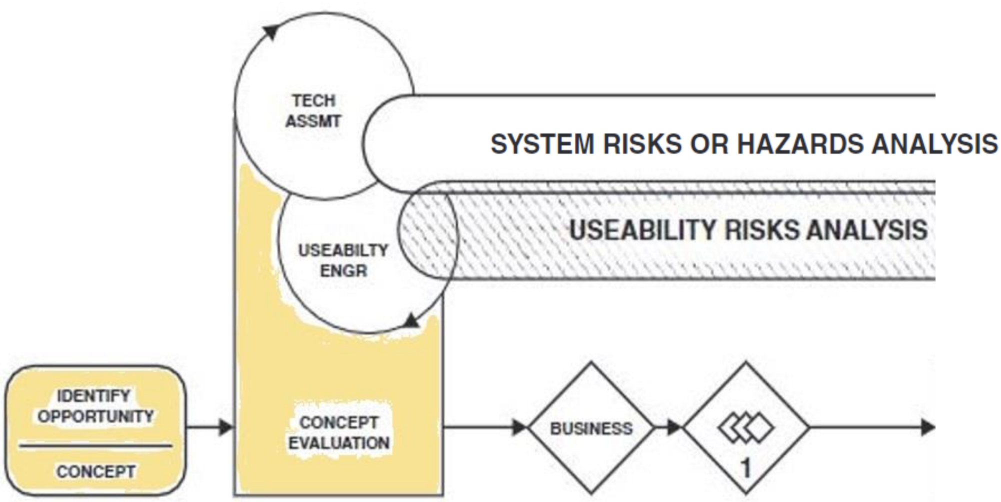
A step-through of each phase and how to incorporate product risk, quality, reliability, and usability at each step.

Process Phases Table of Contents

Identify Opportunities & Concepts

This phase is developing new ideas, opportunities, and design concept ideas.

Market evaluations, business assessments, and profitability are all things that are considered before venturing further into a proposed project. Of key importance to a new design is investigating user wants versus needs, analyzing competitive product, and understanding benefits and a value proposition. This paper does not address the methodologies used in this first step of new product development.



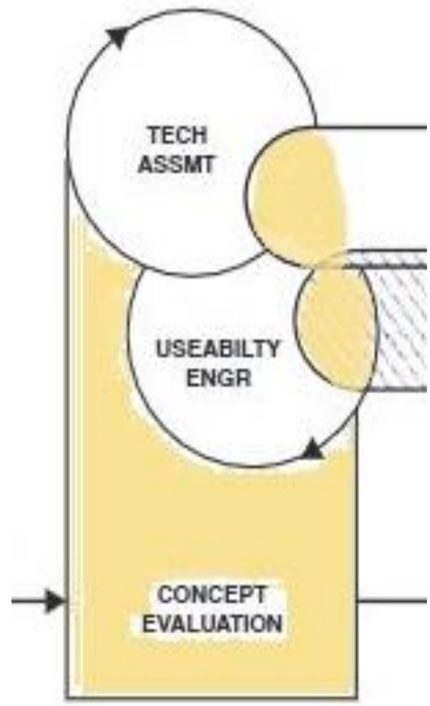
After the company identifies an opportunity and very high-level concept, the process moves into the concept evaluation phase, still before technical development begins.

Within this phase are two development cycles that work together to evaluate and further refine the concept: the Usability Engineering cycle and the Technical Assessment cycle.

Usability Engineering Cycle

The Usability Engineering (Human Factors Engineering) Cycle is an iterative process of developing the concept.

At the Concept Evaluation Phase, the Usability Engineering cycle is a participatory design cycle, with users or potential customers involved in the process. This cycle is used to test iterations of product ideas with customers.



Formative evaluations are tests that performed to get qualitative results about preliminary design options. The evaluations may be simulations using mock-up designs, interviews, or other real-world information gathering that helps identify design features.

Activities include customer-contact research, such as:

- Focus Groups / Customer panels
- Shadowing / day-in-the-life
- In-depth interviews, one-on-one
- Site visits
- Large sample studies

And may also include data research:

- Comment Cards and Formal Surveys
- Internet and social media marketing
- Field intelligence
- Complaints

And team activities:

- Design Sprint (Knapp)
- Structured brainstorming and evaluation with quality tools (multivoting, paired comparison, affinity diagrams, etc.)

Usability Engineering Cycle Outputs

Starting the Usability Engineering cycle at this early phase is essential to create design inputs that are directly linked to human factors engineering, an important step towards safety and usability.

At the Concept Evaluation phase, the Usability Engineering process is incomplete. But, published case studies show success with iterative Usability Engineering cycles at the concept evaluation phase (Beuscart-Zéphir and Peijl).

The team gets specific about its users.

Outputs are details that are clear and specific about:

- user groups
- use environment
- use cases or scenarios
- a preliminary process flow of the use of the concept device, and
- a preliminary task analysis.

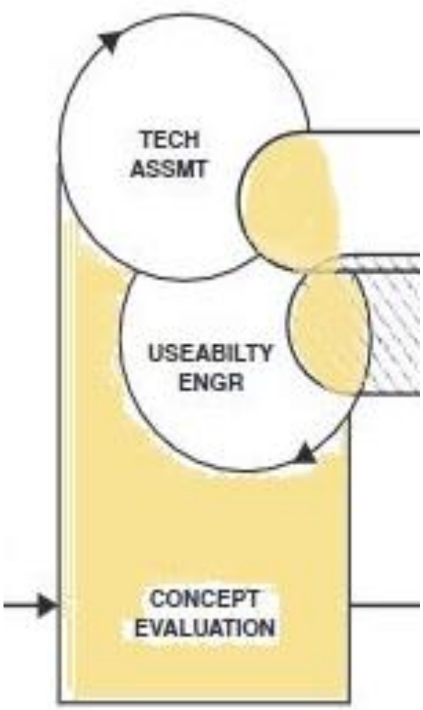
A task analysis lists use errors, or what could go wrong at which step of the user's process. Use errors include mistakes made by users either because of the device's design or because of the user's decision.

Technical Assessment Cycle

The Technical Assessment cycle is an evaluation of the feasibility and the market and patent capabilities of any new design.

The Technical Assessment includes the feasibility of design features, or what is available to be part of the device design. It includes a preliminary assessment of the reliability, manufacturability, and serviceability of a concept, including assessing any business partners that may be needed and their capability to deliver.

Identifying the technical limitations or options available is a high-level design input that affects the concept idea. It is linked to the Usability Engineering cycle at the Concept Evaluation Phase because the Technical Assessment affects the availability of design features. This cycle is identified at the start of the product development process but is an assessment; the details of development and control continue through the rest of the product development process.



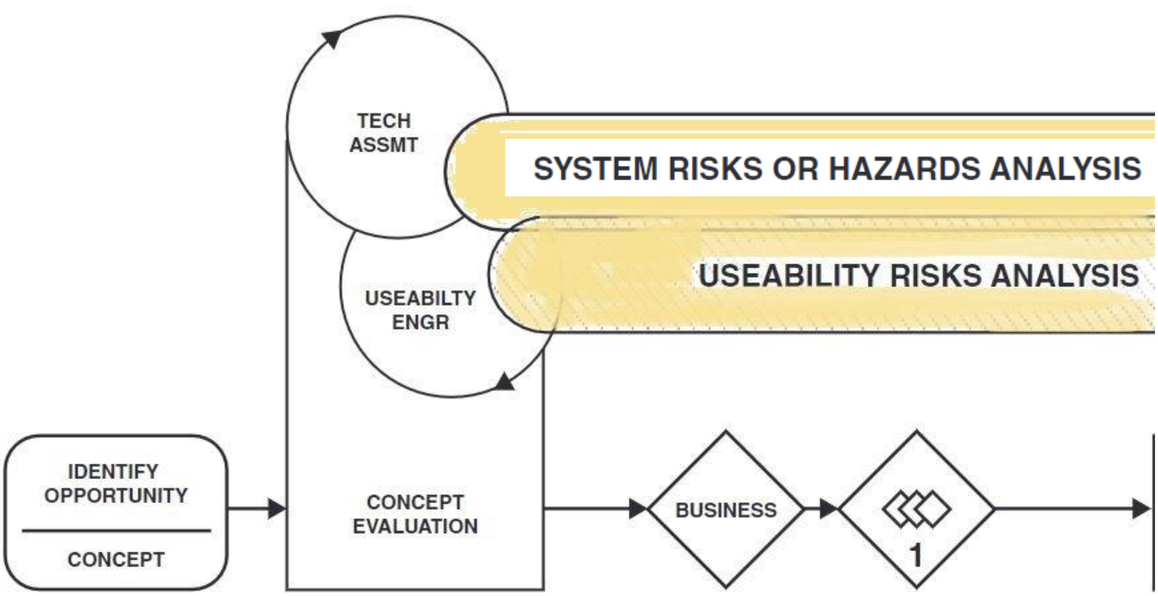
The Technical Assessment cycle also includes what is considered state-of-the-art in current design solutions and includes both applicable design standards that are mandated in the market and voluntarily accepted by the company. These other design solutions can be competitive products or the company's own assets. The other designed solutions that are state-of-the-art are used as a benchmark for new designs (for marketing or improved use) and as a source of field data for design input. Market data of existing products are assessed for use errors, performance successes and issues, and other safety and reliability data. The state-of-the-art must be defined at the end of this process (as part of Field Monitoring), so using the data up-front as part of the design input is important inclusion into the design process.

Product Concept Risk Management

At the beginning of the Concept Evaluation Phase, a Risk Management Plan must be approved, and Risk Analyses may be started.

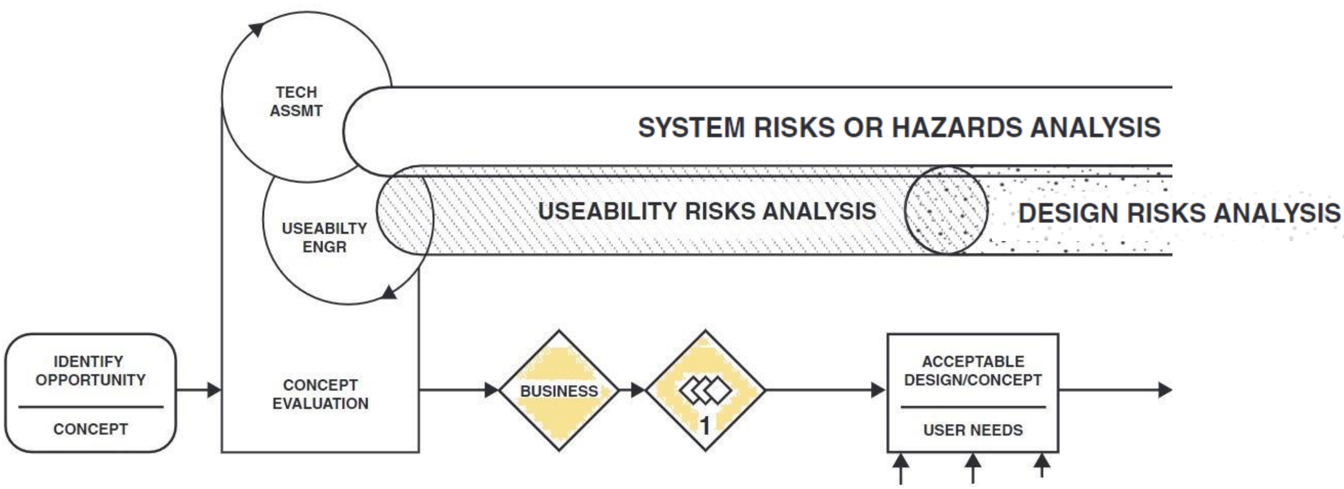
The plan outlines what types of risk analyses methods will be used and its rating scales and acceptability. The information generated from the Concept Evaluation Phase (both Usability Engineering and Technical Assessment cycles) begins to be analyzed in device Risk Analyses: specifically, the top-level System Risks FMEA and/or Hazard Analysis and

A Usability FMEA. The types of information that can be captured at the Concept Evaluation phase are the types of hazards; potential harms; the effects to the users, performance, or environment; and its preliminary ratings and acceptability. Outputs of the preliminary FMEAs include initial requirements for reliability, safety, usability, and information/labeling.



Team Decision: Do we proceed with the Concept?

The cross-functional team reviews the concept against business and technical merits.



Business considerations must take place and include market data analysis, profitability, time-to-market, and resource availability. The scope of the Technical Design Review is of the concept design's feasibility, reliability, manufacturability, serviceability, usability, and safety. A change point analysis may be performed against similar, previous designs, in-house and against competitive product.

The outputs of the Concept Evaluation's Technical Assessment Cycle and Usability Engineering Cycle provide the baseline or preliminary data from which to decide whether to pursue a design concept based on its technical aspects and its understanding of what is clearly known and what is estimated and how.

Phase: Acceptable Design/Concept

A Concept with Strong Foundations

The cross-functional team's up-front assessments and evaluations provide the designers a strong foundation of knowledge (use, risk, and technical aspects) for the product's development.

Deliverables/Outputs

Use Information

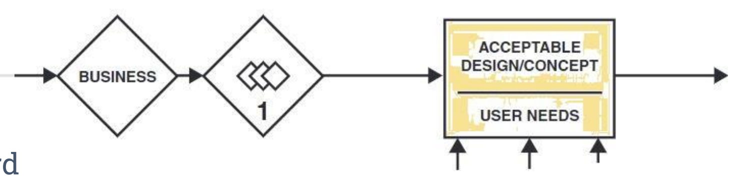
- User Needs, including the primary operation functions, performance, and usability (Ux) needs.
- definition of user groups and use environment (also considering end-of-life users)
- list of use scenarios
- preliminary process flow of the use of the concept device with a task analysis outlining potential use errors
- list of participatory users available to continue formative studies

Risk Information

- preliminary Systems Risks (or Hazard Analysis) and Usability FMEA showing potential harms and important use or design parameters relevant to risks
- Design FMEA
- list of potential harms; the effects to the user, procedure, or environment; and preliminary severity and occurrence ratings

Technical Information

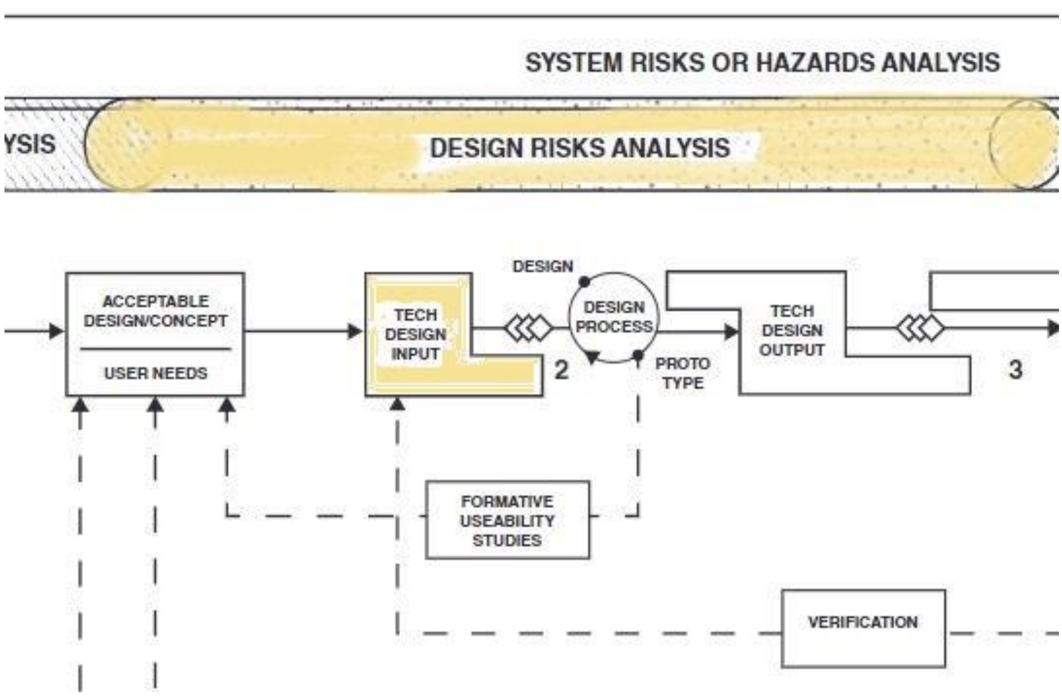
- Preliminary Requirements for quality, reliability, safety, maintainability, manufacturability, and serviceability
- list of design standards that are mandated in the market and voluntarily accepted by the company
- list of patent capabilities
- definition of state-of-the-art (competitive products or company's own assets) that is carried through to field monitoring



The Concept is Further Refined & Developed

Once a concept design has been approved, technical design inputs are further refined.

A Design FMEA is started, outlining the potential failures and effects of the system or subsystems by using the inputs from the Concept Evaluation phase.



This Design FMEA aligns with the causes and effects, and severities of the System Risk Analysis (or Hazard Analysis). The scope of the Design FMEA may be based on the results of the System Risk Analysis, where a Design FMEA is performed on the highest-risk subsystems only. Design features that act as preventive controls within the Usability FMEA are carried through to the Design FMEA. Additional requirements are developed as controls within the Systems Risk Analysis and Design FMEA. As the design becomes more defined, additional, published, technical standards may be added as voluntary requirements.

Goals are Set and Plans are Made

Safety, usability, performance, and reliability goals are clear and well-understood, against which design decisions can be made, including test methods.

Deliverables/Outputs

Clearly defined requirements for the system and subsystems (also called PRD, product requirement document)

- reliability requirements, including use environment and climate conditions
- preliminary product delivery conditions: shipping, vibration, handling conditions
- functional, performance, operational, and others
- Initial requirements for information/labeling

Iterative System and Usability FMEA

The Requirements for the system and subsystems are associated with the previous Phases' Inputs (including the user needs), published design standards, and the Risk Analyses performed (including the System, Sub-System, Usability, and Design Risks Analyses, created per the Risk Management Plan).

Risk Analyses should be viewed as driving the technical design inputs in both scope and level of control

Verification & Validation Test Plans

- Requirements Testing Plans
- Reliability Test Plan (focused on high-risk components or assemblies)
  - HALT (highly accelerated life test)
  - ALT (accelerated life test)
  - RDT (reliability demonstration test)
  - Need for warranty period predictions
  - preliminary ideas about production reliability tests (HASS, HASA, burn-in)
- Usability Test Plans
  - Formative Usability Study Plan
  - Summative Usability Study Plan

The plans use test methods that are developed to be relevant to the product design's use scenarios. The rigor of test is determined from the Risk Analyses: System, Design, or Usability, whichever analysis is using the requirement for test as a risk control measure. Relevant test standards that are considered pre-validated by the publisher may be used; if not, test method validations are required prior test, and may include gage R&R studies. A test plan will define how product will be tested, how it will be fixtured during test, and what constitutes a failure.

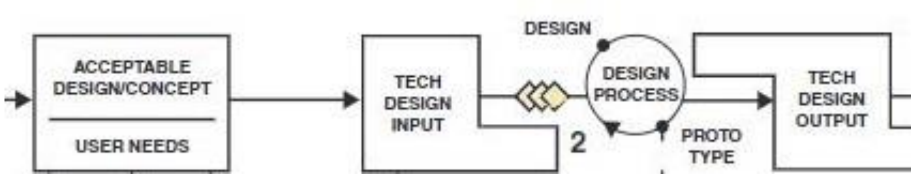
Phase Gate 2

Team Decision: Do we have the right plans?

Another series of Technical Design Reviews are conducted.

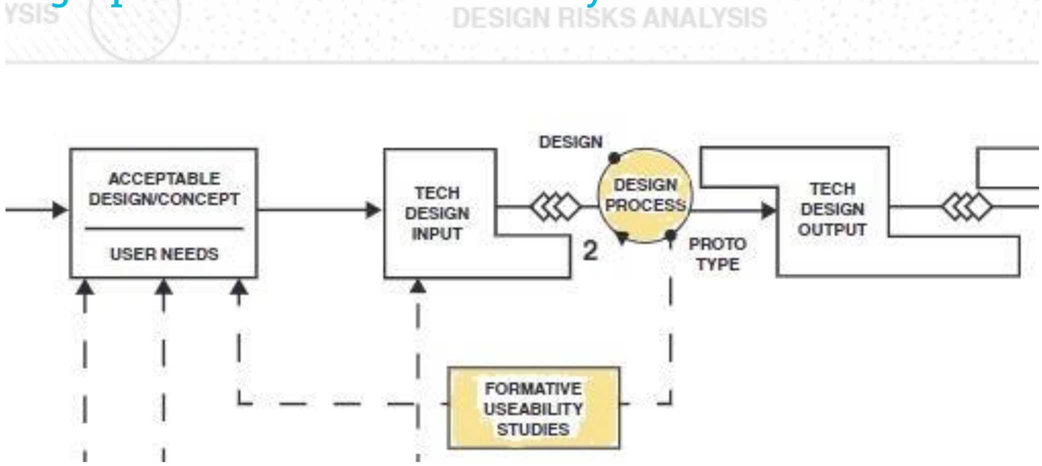
The team reviews the preliminary failure modes: their severity, occurrence, and controls. Controls are in the form of requirements for the system or subsystem, which are then also related to the test plan and test methods to use. Action items may be assigned to reduce or eliminate sources of risk.

The team reviews requirements to ensure they are mutually exclusive and exhaustive, and in alignment with the user needs. The team ensures that the test plans are written to align with requirements. A change point analysis may be performed against similar, previous designs, in-house and against competitive product.



Designing the Product

The design process is an iterative cycle.



The team proposes designs and engineering prototypes (EP) are made and evaluated (including product and labeling). Preliminary functional and performance tests, (sometimes called EVT - engineering validation tests and DVT – design validation tests) are performed to give engineers a level of confidence that the design will meet requirements. Positive results of this testing help engineers finalize the intended design. Reliability techniques such as life cycle costing, reliability apportionment, and HALT (highly accelerated life test) may be used to make design decisions and finalize choices.

For usability, a phase of prototype close to the proposed finished design (sometimes called MVP – minimum viable product) can be used as part of Formative Usability Studies, asking users to assess the prototypes. The design team performs these studies against the User Needs.

The design is also evaluated against initial manufacturing needs and capability assessments. Designs may need to be modified to match production needs and limitations.

The risk analyses (system, usability, and design) continue to be developed as new information is gathered. Failure modes and causes are clarified based on the new information provided by the prototypes and the preliminary benchtop testing that's been performed. Occurrences are further refined based on experience with the prototypes. Action items continue to be assigned to reduce or eliminate sources of risk.

Results from formative studies feed back into the user needs, to ensure that the product being developed is still going to be what the customer wants.

Creating Technical Design Outputs

Technical design outputs are generated for the system, subsystem, and components.

These outputs address the Technical Design Inputs and may be part of risk controls for the Design FMEA and other risk analyses.

As prototypes are developed and manufacturing methods are beginning to be applied, the process risks analyses are begun.

PFMEA are generated and may be chosen based on those processes that are associated with component features that have a high-risk level in the DFMEA. Preliminary risk control methods are created: special in-process testing, or inspections are identified. This information is fed into the design of the product because special product design features may need to be created to assist with in-process manufacturing, testing, or assembly. Process capability is more clearly defined and is an input into design tolerancing.

Specifications are defined to align with Quality Assurance inspection methods.

Quality Assurance inspection frequency and methods are defined and may be based on the level of risk (e.g. critical, major, minor). Inspection and test methods of the product are considered by the design engineer as part of product dimensioning.

Supplier requirements and controls are drafted to control risk within at least the Design FMEA.

Phase: Technical Design Output

Collect the Phase Deliverables

Safety, usability, performance, and reliability goals are clear and well-understood, against which design decisions can be made, including test methods.

Deliverables/Outputs

Engineering specs

- material requirements
- engineering drawings, tolerances
- reliability requirements for components/reliability block diagrams

Formative Usability Study Reports

Preliminary Process FMEA identifying controls

- in-process tests or inspections
- ongoing reliability tests
- assembly, manufacturing controls

Iterative System Risk Analysis, Design, and Usability FMEAs all showing risk levels and risk acceptability

- Design controls and manufacturing production controls are defined
- Information/labeling controls are defined
- Supplier controls are defined

Iterative Reliability Plan

- finalize plan for production reliability tests (HASS, HASA, burn-in)
- considerations for manufacturing environment and climate conditions
- considerations for shipping and handling conditions in-process

Manufacturing Plan, production requirements

- Resources: facility, equipment, staff/operators, materials
- Product movement [different phrase]
- Activities for development and transfer to production

Quality Control Plan focused on high-risk components or assemblies

- quality management controls (ref. company policies and procedures)
    - quality management systems
    - supplier relationships/management
- product-specific quality assurance requirements that may be risk-based
    - measure
    - criterion/threshold/tolerance
    - conditions of use, circumstances, etc.
    - criticality/level of confidence needed
- quality controls, monitoring
    - inspection/test methods
    - sampling
    - inspecting party (e.g. supplier, in-process, incoming)

Supplier Plan

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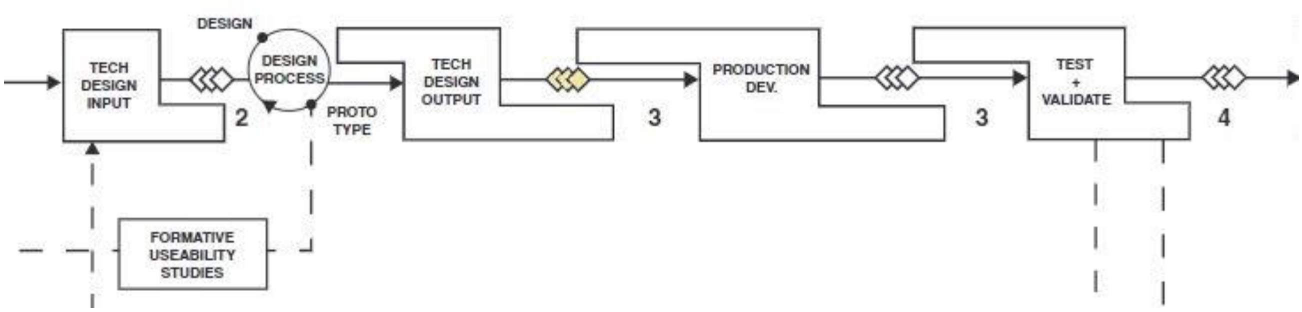
Team Decision: Are the Technical Design Outputs meeting the Design Inputs and the User Needs?

The cross-functional team reviews the deliverables, makes decisions about risk acceptability, and reviews the plans to control risks and to complete the project.

The team decides on the readiness of the project to continue into production development.

Different components may be reviewed for moving forward at different times; this is for the team to manage as part of project management.



The team reviews engineering specs for readiness for production, including quality assurance test and inspection.

Prototype test results are reviewed, including Formative Usability Studies performed with the users. Technical reviews may be based on failure modes.

The results of the preliminary Process FMEA failure modes are reviewed: their severity, occurrence, and controls. Action items may be assigned to reduce or eliminate sources of risk.

Failure modes and controls in the risk analyses are re-reviewed, and the team determines the risk acceptability of the System, Design, and Usability FMEAs. Action items to reduce risk are assigned, if needed.

Reviews are also held against the product development plans:

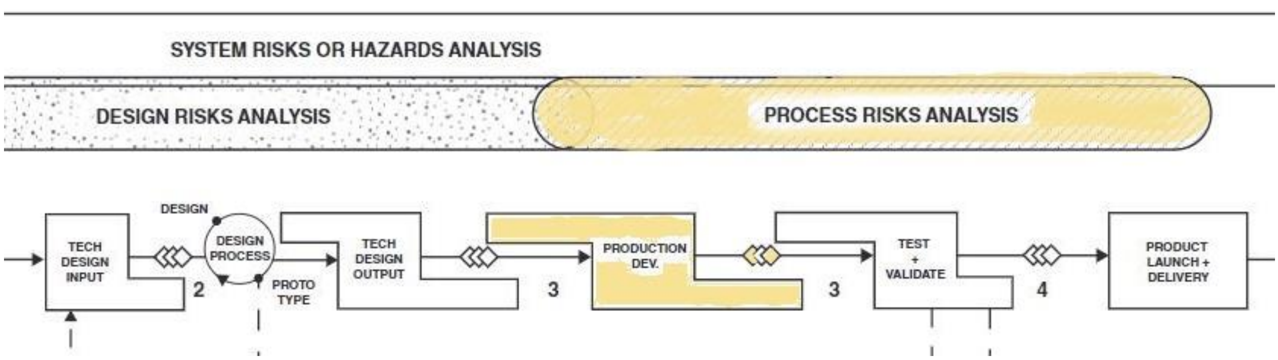
- Quality Plan
- Manufacturing Plan
- Iterative Reliability Plan, considering changes for adding production controls for reliability.

Phase: Production Development

Develop the Manufacturing Process

The Production Development phase is where manufacturing processes are further developed.

A Process FMEA is performed, associated with the causes in the Design Risk Analysis and the Systems Risks. The scope of the Process Risk Analysis may be based on the results of the System Risk Analysis or Design Risk Analysis, where a Process Risk Analysis is performed on the highest-risk subsystems only.



Deliverables/Outputs

Manufacturing Design Outputs

- process specifications
- training requirements
- equipment and tooling requirements
- process qualifications: IQ, OQ, PQ and tooling qualifications
- supplier validations
- in-process test and inspection methods are defined and implemented per Quality Plan and Reliability Plan
- Iterative System Risk Analysis, Design, and Process FMEAs all showing risk levels and risk acceptability

Technical Design Reviews are continued, with the same type of focus as performed from the technical design outputs. The focus is based on failure modes, causes, and controls in the risk analysis which includes results of process qualifications, supplier validations, and a review of the implemented controls like process specifications and training. Action items may be assigned to reduce or eliminate sources of risk.

Test Production-Equivalent Products

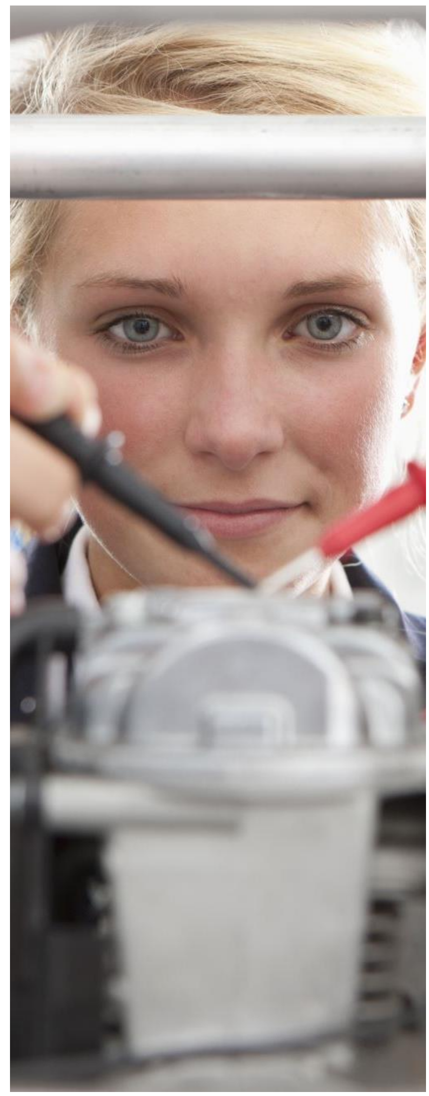
Product is manufactured for verification and validation tests.

Verification tests are those performed to ensure the product meets the technical design inputs or requirements, including functional and performance requirements.

Validation tests (sometimes called Summative Testing) is performed against the user needs. More validation (sometimes called PVT – production validation testing) is performed against other performance requirements.

Results of testing feeds back into the original needs and requirements of the product.

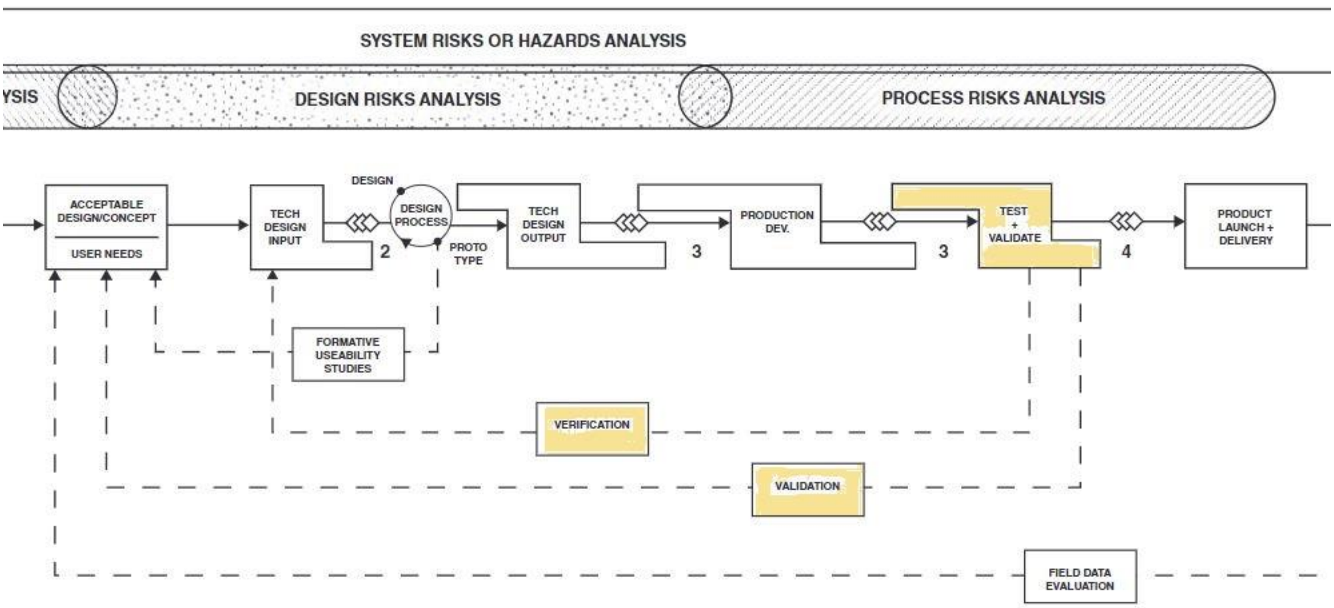
Test units are built in a way that is equivalent to the final production units or are final production units; this avoids introducing unknown variables. Prototype units that are not produced in the same way as production product can perform differently in functional and performance testing because of different material and design properties. Products made on a bench top may be assembled by technicians with a different level of experience or expertise than what would be made in a mass production environment. Production environment may also influence the test performance of product: humidity, temperature, cleanliness, and exposure to other chemicals or agents as examples.



Phase: Test and Validate

Analyze Test Results

Results of testing are compared against the User Needs and the Technical Design Inputs.



Deliverables/Outputs

Revised

- user training requirements
- user labeling
- Iterative System Risk Analysis, Design, Usability, and Process FMEAs all showing risk levels and risk acceptability.
- Iterative Reliability Plan, edited to include Field Data to be collected for Life Data Analysis

Technical reviews are performed to review the results of the testing: verification, validation, and summative usability studies (4). The focus of these series of reviews is of the test results. Test failures and their root causes are reviewed, as well as how they are addressed. Risk analyses are reviewed for any updates to failure modes, causes, ratings, and controls. New information about the types of failures, likelihood of occurrence, and the overall risk acceptability given this new information is reviewed.

Phase: Product Launch and Delivery & Field Monitoring

Launch and then Monitor the Product in the Market

The design is continuously evaluated against measures of performance, with team decisions about the continued acceptability of the product within the market.

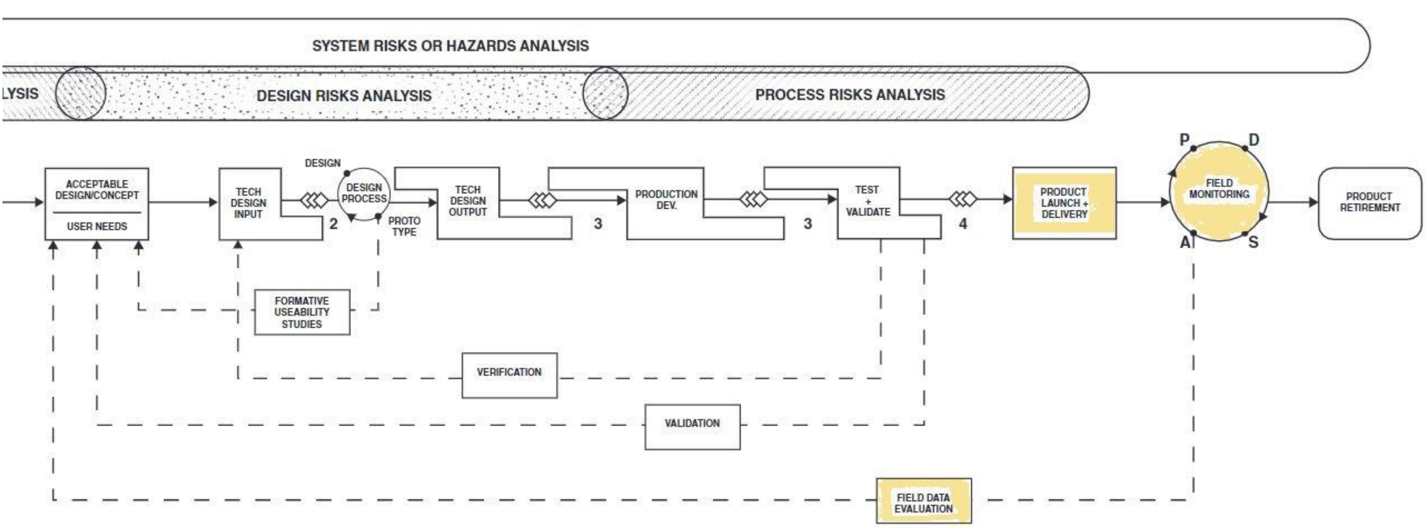
Product launch and delivery is approved once the design controls are completed, testing and validation phases are complete and acceptable, and the risks are acceptable based on the acceptance criteria established in the Risk Management Plan.

A quality plan is finalized for how the product quality will be maintained. A risk management plan will continue to define risk management activities after product launch. Field monitoring is planned for what will be monitored, how often, and by whom.

Deliverables/Outputs

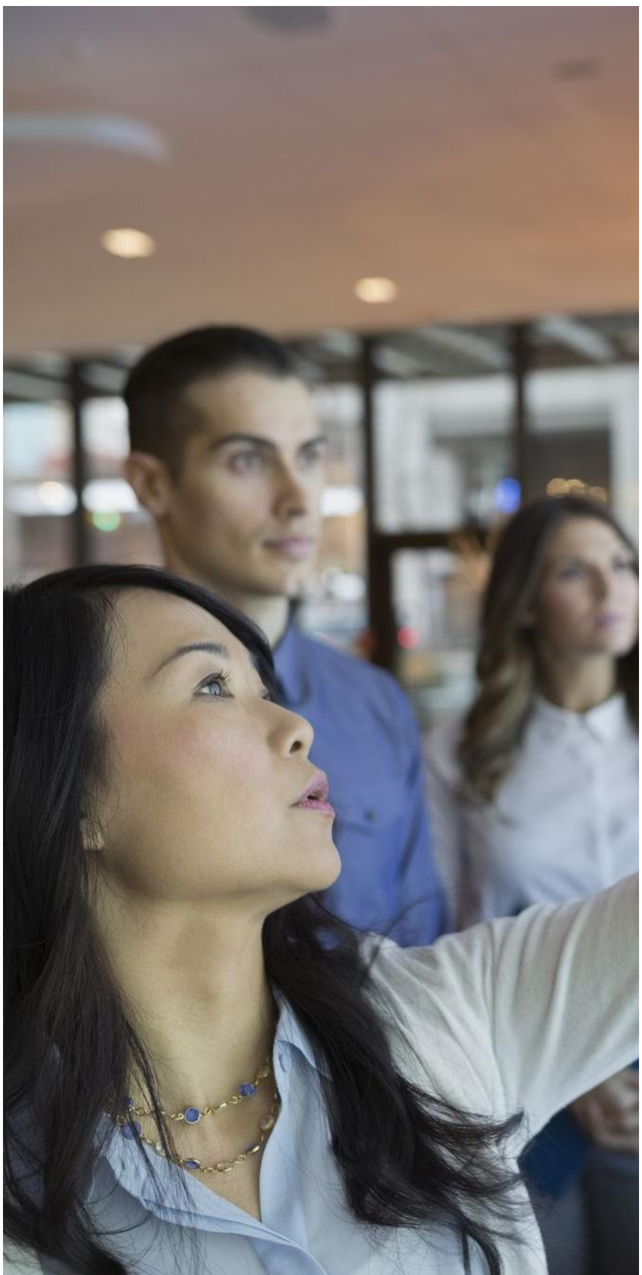
- Iterative Quality Plan
- Risk Management Plan
- Post-Market Surveillance Plan

Field monitoring follows the PDCA cycle for continuous improvement. It can be defined based on ways to collect data to monitor for the types of failures seen at test, the potential systems failures that are high-risk, to monitor the field reliability, and the use scenario. Trending can be performed against the types of failures and compared against the measures established in the risk documents, adjusting severities or occurrences and re-evaluating the risk acceptability, if needed. Monitoring can be performed to ensure that reliability and use scenarios continue to match what was used for the product's development; if changes are occurring, it is a cause to investigate the design's safety and reliability in the field.



Retire Products

Information from existing products is used in the design of the next products.



Products may be retired due to economic, manufacturability, or business decisions. Or for field performance issues in quality, safety, reliability, or usability.

The data from field monitoring can be used as an input into the next product. This information was produced and collected by the business and is an important design asset that should be utilized.

Field data can be compared against the usability file. What changes happened since we produced the product? What are areas we need to further investigate or better understand with this new design?

What were the potential risks we identified when we designed the product? Are there new risks that were identified in field monitoring? Are there new preventive design controls we can implement? How effective were the design controls we had in place?

Were there complaints or issues related to the performance of the product? Were there recalls because of quality issues? What changes do we need to make to improve the quality of this next product, if any?

Next Steps

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Get started with next steps to implement.

Next Steps

Stop Waiting

Start practicing Quality during Design and begin realizing benefits today. Contact me.

Quality during Design℠

Sign-up you and your team of engineers for the *Quality during Design Journey.*

Know how to use quality and reliability to capture early information and then iterate on it through development. Make team decisions based on data and move forward.

Train your brain for Quality Thinking.

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Quality during Design[SM]

Product designers can achieve greater success with early concept development and iterative application of quality and reliability throughout the development process.

Benefits

optimize the opportunities to make design decisions early

Prioritize Design Efforts

Focus on the right things

Design what the customer really needs

More easily communicate important features

With other, downstream customers

Like Procurement, Supplier Management & Quality Assurance

Make decisions for test

What to test

Risk-based sampling

Root causes of failures

Acceptability of test results, etc.

...and more Benefits

avoid delays and identify features

Reduce surprises

During late-Phase testing

Test for and eliminate failures

Get to the root cause

Decide on preventive controls

For failures, at the start

Design-out

Design for test

Design for manufacturability

Get cross-functional buy-in and input, early

Avoid the “stop” button

Save time, resources, and design the right thing

12 things you should have before a design concept makes it to the engineering drawing board

Applying quality thinking early leads to a strong foundation for design with use, risk, and technical information.

Use Information

- ❑ user needs, including the primary operation functions, performance, and usability (Ux) needs.
- ❑ definition of user groups and use environment (also considering end-of-life users)
- ❑ list of use cases or scenarios
- ❑ preliminary process flow of the use of the concept device with a task analysis outlining potential use errors
- ❑ list of participatory users available to continue formative studies

Risk Information

- ❑ risk management plan, outlining what risk analyses measures will be taken
- ❑ preliminary list of potential harms; the effects to the user, procedure, or environment;
- ❑ preliminary product risk analysis showing potential harms and important use, labeling, or design parameters relevant to risks and preliminary severity and occurrence ratings
    - Systems Risks and/or Hazard Analysis
    - Usability FMEA (if planned)
    - Design FMEA (if planned)

Technical Information

- ❑ preliminary requirements
    - quality
    - reliability
    - safety
    - maintainability / serviceability
    - manufacturability
- ❑ list of design standards that are mandated in the market and voluntarily accepted by the company
- ❑ list of patent capabilities
- ❑ definition of state-of-the-art that is carried through to field monitoring: competitive products or company's own assets

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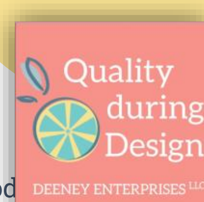

About the Author

Dianna Deeney is president of Deeney Enterprises, LLC and founder of *Quality during Design*$_{SM}$. She coaches product development engineers about awareness and use of quality and reliability methods during the design development process.

She has worked in manufacturing for over 25 years, developing an engineering career from the manufacturing floor to manufacturing process engineering, product design, quality and reliability engineering, and quality management systems. She is senior quality professional and an active member of ASQ, holding certificates as a CQE, CRE, CQA, and CMQ/OE.

Through her experience, she recognized a gap in understanding between people that design products and the quality techniques and input from quality professionals. She recognizes that bridging this gap could make a significant, positive difference in the outcome of product design as well as save on total costs by solving design questions earlier and help design engineers to be star performers.

Dianna founded *Quality during Design*$_{SM}$ with a mission of using the company as a communication and education tool, to bridge product managers and designers (entry-level to seasoned) to the world's quality initiatives and quality-minded people. Her vision is a world of products that are easy to use, dependable, and safe – possible by strategically using *Quality during Design*$_{SM}$ for products others love, for less.

She hosts the *Quality during Design*$_{SM}$ *Podcast* and publishes under QualityDuringDesign.com and DeeneyEnterprises.com. She also co-hosts the *Speaking of Reliability* podcast and is a contributing author to *Quality Disrupted (Working It®- Future of Work Series)* published by CERM Academy (available on Kindle).

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