Management Practice

16. Value and stage-gated management

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MPiE

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Course

Literature for the course:

Eisner, Howard. *Essentials of project and systems engineering management*. John Wiley & Sons, 2008.

Learning objective for this session:

- Able to describe a stage-gated process
- Able to setup a stage-gated process
- Able to describe what happens in each stage of this kind of process
- Able to describe dFMEA
- Able to describe design controls
- Able to reflect back on the different tools available to you

Value management

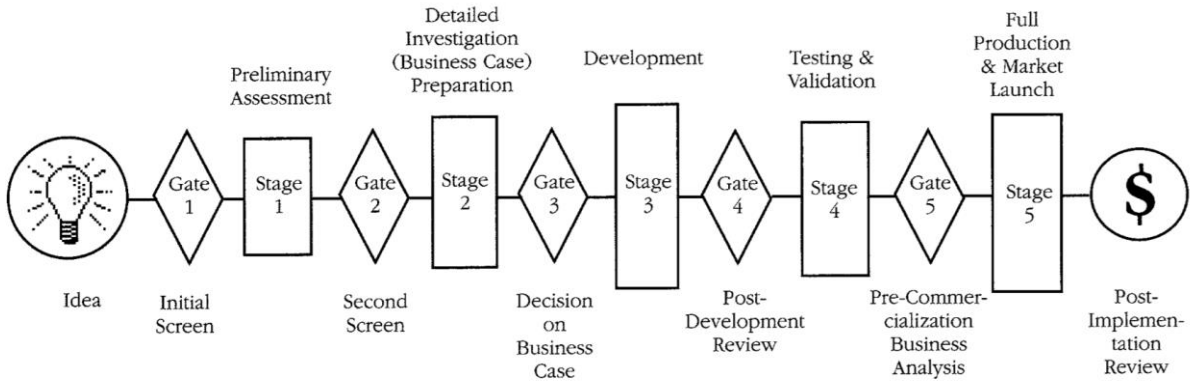
- Value Management is concerned with improving and sustaining a desirable balance between the wants and needs of stakeholders and the resources needed to satisfy them.

- This is made more challenging during the R&D process, due to the level of uncertainty.

- A gated process can be applied to support management of the process. An example of this is the product development.

Stage-gate systems

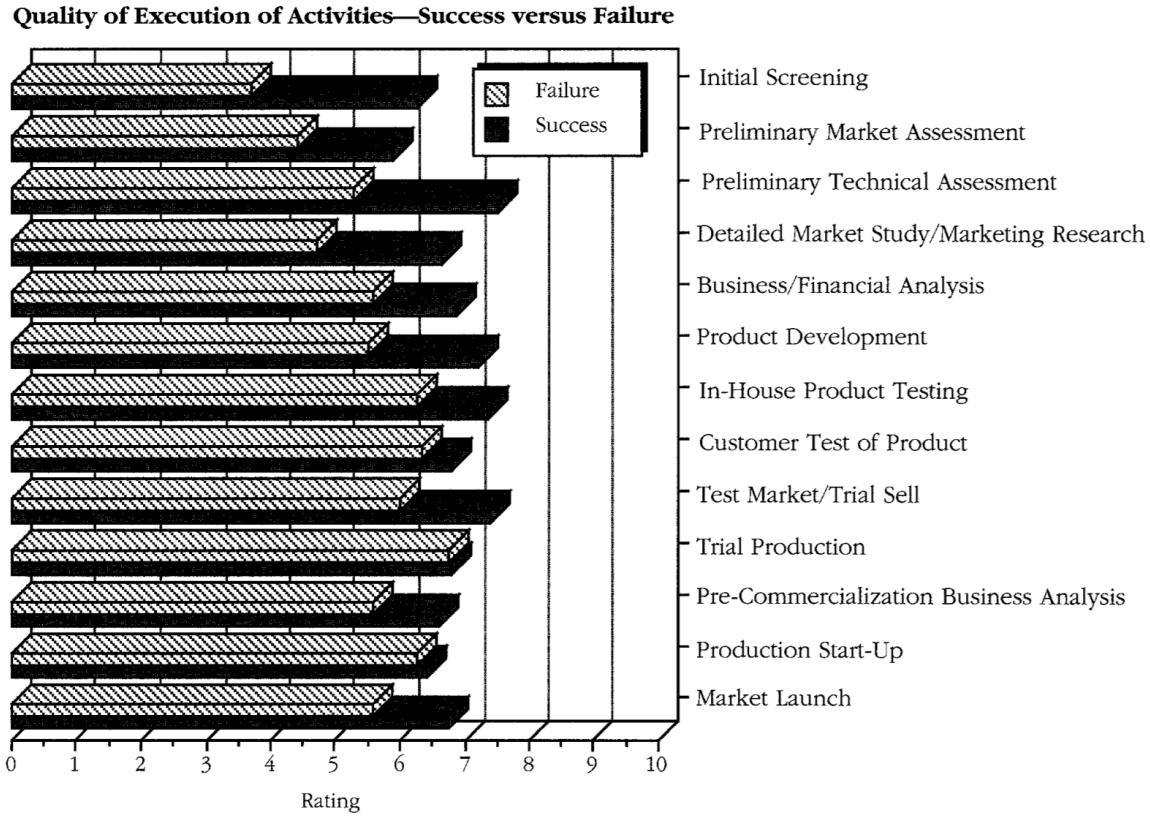
- Stage-gate systems simply apply process-management methodologies to the innovation process.
- The process is divided in a number of stages.
- A set of deliverables is specified for each gate. They need to be passed before moving to the next gate.



Source: Robert Cooper Stage-Gate Systems: A New Tool for Managing New Products 1990

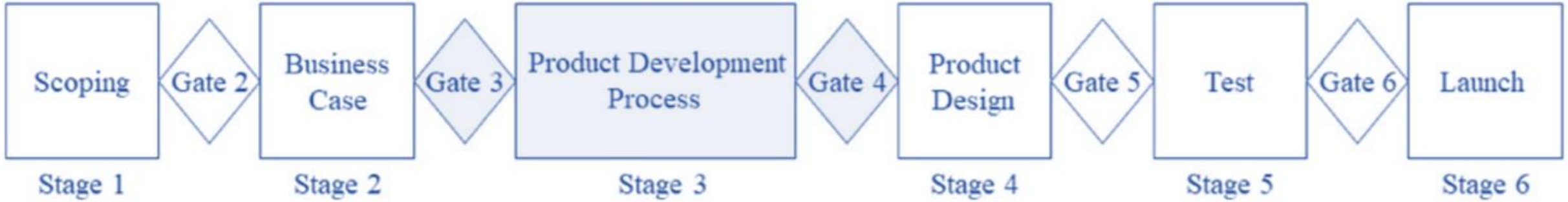
Quality as deliverable

- A research study of 203 new product projects (Cooper and Kleinschmidt 1986) suggests that quality processes are essential for new product development.
- The gates system should take into account quality of deliverables.



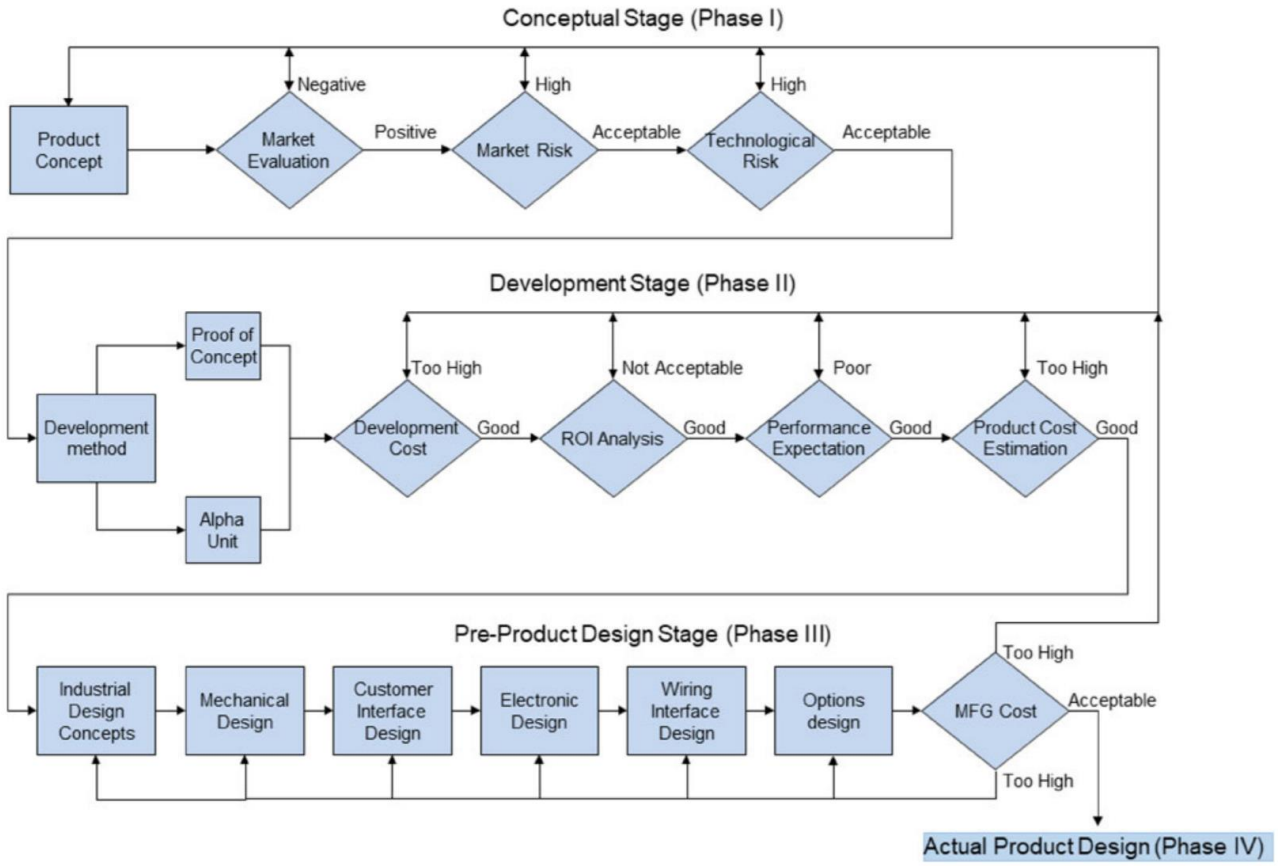
Source: Robert Cooper Stage-Gate Systems: A New Tool for Managing New Products 1990

Modified Cooper's stage-gate model



Source: JAMES MARQUIS & RUBA S. DEEB, IEEE ENGINEERING MANAGEMENT REVIEW, VOL. 46, NO. 4, FOURTH QUARTER, DECEMBER 2018

Product development



Source: JAMES MARQUIS & RUBA S. DEEB, IEEE ENGINEERING MANAGEMENT REVIEW, VOL. 46, NO. 4, FOURTH QUARTER, DECEMBER 2018

Practical stage-gated process example

- A practical overview can be provided by applying stages to the management model.

- An example will be provided to show some of the aspects of the stage-gated process.

Stage 1

Function	Stage 1 Initiation	G	Stage 2 Concept and feasibility	G	Stage 3 Design and verification	G	Stage 4 Validation and release	G	Stage 5 Post market activities
Core Development & Testing (DDT) – [part of R&D]									
Core R&D and Design	Start risk assessment (Design Failure Mode and Effect Analysis)								
Business development	Market analysis								
Regulatory	Review regulatory strategy								
Quality	Risk assessment								
Sales & Marketing									
Manufacturing									
Education and Training (E&T)	Start PDP								
Decision	Need & opportunity, feasibility, manageable risk and executional gaps								

Source: Daniel Voyce, CE marking forum 2017

Design Failure Mode and Effect Analysis (dFMEA)

Process Step	Potential Failure Mode	Potential Failure Effect	SEV[1]	Potential Causes	OCC[2]	Current Process Controls	DET[3]	RPN[4]	Action Recommended
What is the step?	In what ways can the step go wrong?	What is the impact on the customer if the failure mode is not prevented or corrected?	How severe is the effect on the customer?	What causes the step to go wrong (i.e., how could the failure mode occur)?	How frequently is the cause likely to occur?	What are the existing controls that either prevent the failure mode from occurring or detect it should it occur?	How probable is detection of the failure mode or its cause?	Risk priority number calculated as SEV x OCC x DET	What are the actions for reducing the occurrence of the cause or for improving its detection? Provide actions on all high RPNs and on severity ratings of 9 or 10.
ATM Pin Authentication	Unauthorized access	• Unauthorized cash withdrawal • Very dissatisfied customer	8	Lost or stolen ATM card	3	Block ATM card after three failed authentication attempts	3	72	
	Authentication failure	Annoyed customer	3	Network failure	5	Install load balancer to distribute workload across network links	5	75	
Dispense Cash	Cash not disbursed	Dissatisfied customer	7	ATM out of cash	7	Internal alert of low cash in ATM	4	196	Increase minimum cash threshold limit of heavily used ATMs to prevent out-of-cash instances
	Account debited but no cash disbursed	Very dissatisfied customer	8	• Transaction failure • Network issue	3	Install load balancer to distribute workload across network links	4	96	
	Extra cash dispensed	Bank loses money	8	• Bills stuck to each other • Bills stacked incorrectly	2	Verification while loading cash in ATM	3	48	

1. **Severity**: Severity of impact of failure event. It is scored on a scale of 1 to 10. A high score is assigned to high-impact events while a low score is assigned to low-impact events.
2. **Occurrence**: Frequency of occurrence of failure event. It is scored on a scale of 1 to 10. A high score is assigned to frequently occurring events while events with low occurrence are assigned a low score.
3. **Detection**: Ability of process control to detect the occurrence of failure events. It is scored on a scale of 1 to 10. A failure event that can be easily detected by the process control is assigned a low score while a high score is assigned to an inconspicuous event.
4. **Risk priority number**: The overall risk score of an event. It is calculated by multiplying the scores for severity, occurrence and detection. An event with a high RPN demands immediate attention while events with lower RPNs are less risky.

Source: isixsigma

	Stage 1
Deliverables and Key Tasks	Market Report – needs assessment; competitive analysis; SWOT; business opportunity
	Financial forecast and reimbursement strategy
	Investor relations
	Legal and IP analysis
	Technical risks and start development plan
	Regulatory plan and clinical path
	Overall business strategy
Decisions at Gate 1	Is there a market opportunity?
	Are regulatory and IP risks acceptable?
	Are the classification and essential requirements understood?
	Is the project feasible?

Source: Daniel Voyce, CE marking forum 2017

Function	Stage 1 Initiation	G	Stage 2 Concept and feasibility	G	Stage 3 Design and verification	G	Stage 4 Validation and release	G	Stage 5 Post market activities
Core Development & Testing (DDT) – [part of R&D]			Core team formation, project plan and timeline						
Core R&D and Design	Start risk assessment (Design Failure Mode and Effect Analysis)		Prototype design, dFMEA, initiate design history file (DHF) , manufacturability						
Business development	Market analysis		Business plan and strategy						
Regulatory	Review regulatory strategy		Prototype analysis, initiate regulatory strategy						
Quality	Risk assessment		Supplier and supply chain evaluation,						
Sales & Marketing									
Manufacturing			Review manufacturability						
Education and Training (E&T)	Start PDP		PDP						
Decision	Need & opportunity, feasibility, manageable risk and executional gaps		Value proposition, product risk, acceptance, feasibility, manufacturing & supply						

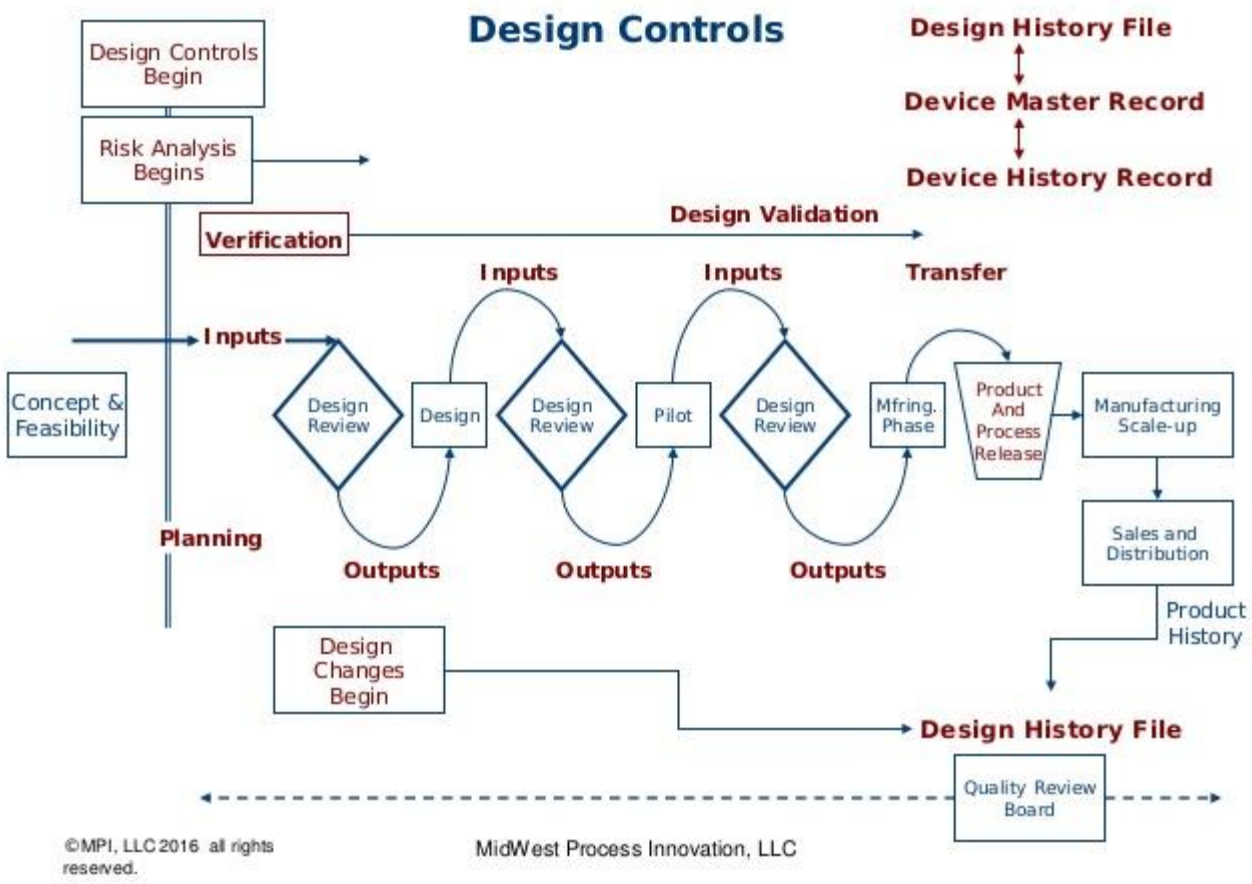
Design history file

- Information concerning intermediate design models, decision steps and the overall reasoning process are part of the 'design history' file.

- Design history files help:
  - explain how and why certain design decisions were made
  - verify that a product meets its specification is facilitated
  - explain how design changes might effect the specifications
  - the reuse of old design solutions

Source: JOHAN MALMQVIST (1997) Improved Function-means Trees by Inclusion of Design History Information, Journal of Engeering Design, 8:2, 107-117,

Design History File as part of control



	Stage 2
Deliverables and Key Tasks	Identification of CORE design and development team members
	Approval of project timelines
	Design inputs and target specification
	Initial regulatory plan & Design History File started
	Design review - prototype design and evaluation
	Initial design risk analysis assessment
	Design for manufacture and supply chain evaluation
Decisions at Gate 2	Value proposition acceptable?
	Product risks acceptable?
	Manufacturing supply chain established?
	Proof of Concept demonstrated?

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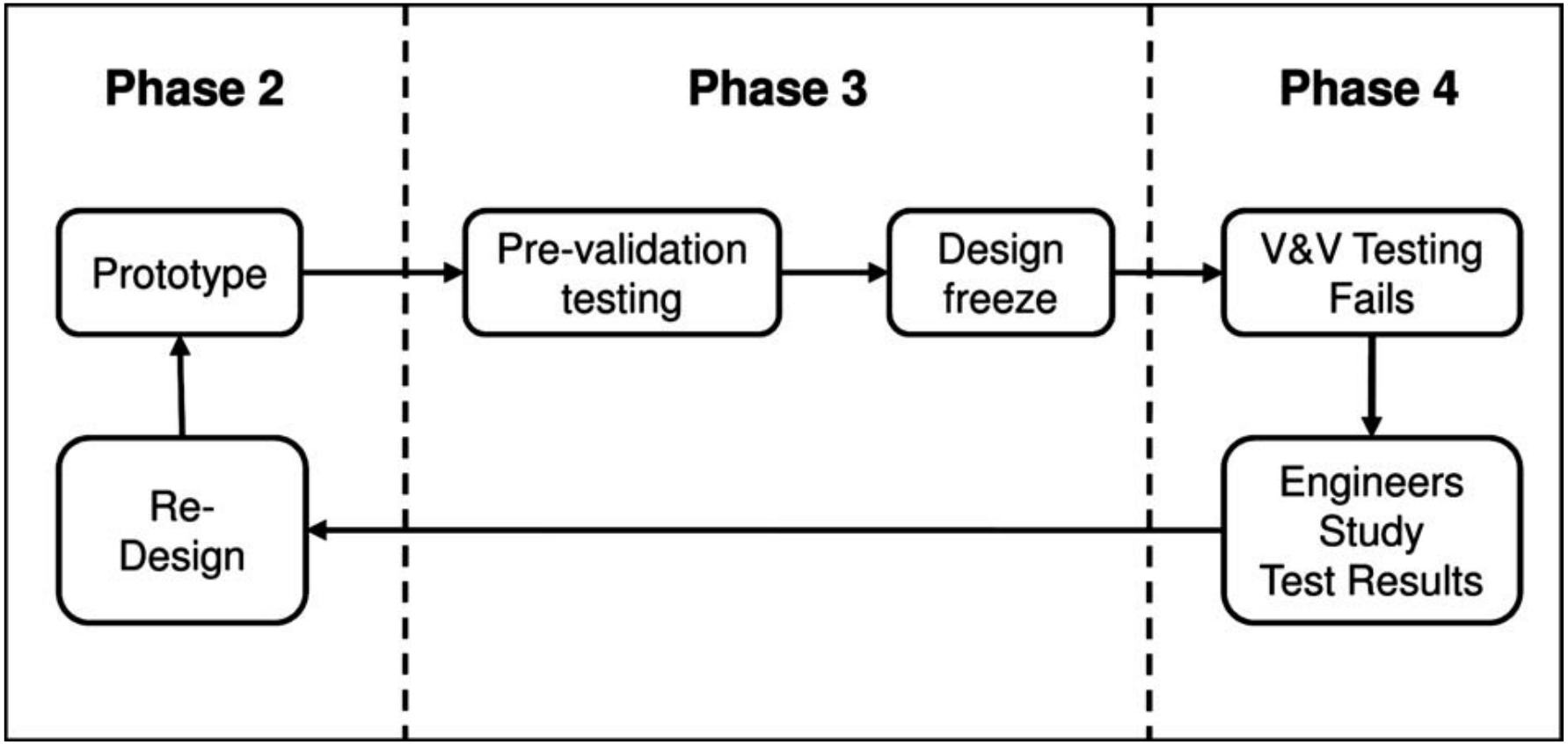
Core Development & Testing (DDT) – [part of R&D]			Core team formation, project plan and timeline		Finalise specification and verify plan, validation plan				
Core R&D and Design	Start risk assessment (Design Failure Mode and Effect Analysis)		Prototype design, dFMEA, initiate design history file (DHF) ,		Product verification, DHF				
Business development	Market analysis		Business plan and strategy		Business plan				
Regulatory	Review regulatory strategy		Prototype analysis, initiate regulatory strategy		Review design and risk, documentation				
Quality	Risk assessment		Supplier and supply chain evaluation,		Supplier approval				
Sales & Marketing					Sales and costumer strategy				
Manufacturing			Review manufacturability		Process risk				
Education and Training (E&T)	Start PDP		PDP		PDP				
Decision	Need & opportunity, feasibility, manageable risk and executional gaps		Value proposition, product risk, acceptance, feasibility, manufacturing & supply		Design freeze, verification report, risk mitigation, supplier approval, regulatory submission				

	Stage 3
Deliverables and Key Tasks	Finalised *PRS* - Performance Requirements Specifications, *SRS* - System Requirement Specifications, FRS - Functional Requirement Specifications, Uniform Replication Strategy (*URS*)
	Detailed designs completed
	Design risk analysis assessment updated
	Initial regulatory plan
	Verification plans, tests and reports completed
	Quality and process validation plans created
	Validation plan
Decisions at Gate 3	Design outputs satisfy inputs?
	Product risks acceptable?
	Design is ready to be frozen?
	Device is ready for regulatory submission?
	Supply chain approvals complete?

Handle of failures



Source: Jan B. Pietzsch et al, 2009

Function	Stage 1 Initiation	G	Stage 2 Concept and feasibility	G	Stage 3 Design and verification	G	Stage 4 Validation and release	G	Stage 5 Post market activities
Core Development & Testing (DDT) – [part of R&D]			Core team formation, project plan and timeline		Finalise specification and verify plan, validation plan		Product validation		
Core R&D and Design	Start risk assessment (Design Failure Mode and Effect Analysis)		Prototype design, dFMEA, initiate design history file (DHF) ,		Product verification, DHF		Technical support of testing		
Business development	Market analysis		Business plan and strategy		Business plan		Branding and marketing launch, negotiations		
Regulatory	Review regulatory strategy		Prototype analysis, initiate regulatory strategy		Review design and risk, documentation		Prepare regulatory submission		
Quality	Risk assessment		Supplier and supply chain evaluation,		Supplier approval		Process qualification, expire date testing, product life		
Sales & Marketing					Sales and costumer strategy		Sales and costumer support setup		
Manufacturing			Review manufacturability		Process risk		Scale up production		
Education and Training (E&T)	Start PDP		PDP		PDP		PDP – training of sales employees		
Decision	Need & opportunity, feasibility, manageable risk and executional gaps		Value proposition, product risk, acceptance, feasibility, manufacturing & supply		Design freeze, verification report, risk mitigation, supplier approval, regulatory submission		Evaluation report, launch plan, manufacturing process, post market plan		

	Phase 4
Deliverables and Key Tasks	Product validation complete
	Process risk complete, Manufacturing scale-up
	Design risk analysis assessment updated and reviewed.
	Risk management plan updated
	Product branding and literature Sales and marketing launch planned
	Revenue strategy finalised
Decisions at Gate 4	Device conforms to users requirements and intended use?
	Device is ready to be cleared for from a regulatory perspective? CE Submission complete?
	Design transfer complete?

Management Practice in Engineering

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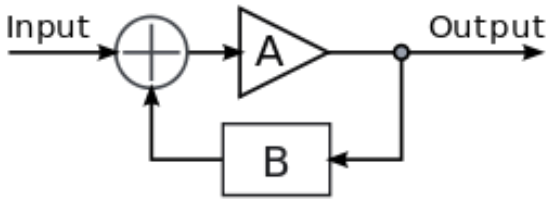
- A range of tools have been introduced and discussed.
- You will have to make decisions on (incomplete) best evidence for the selection of tools in a given situation.
- Make use of the background information provided and see if the problem can be seen as a system (of systems).

Feedback



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Questions?

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