

# Medical Device Project Management Best Practices

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New Product Development –  
Automotive, Aerospace, Defense, Medical Device

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## Our Agenda Today

- Evaluate key aspects of leading NPD processes
- Identify common themes/ elements
- Determine valuable, key differences
- Review these elements in a case study

**The Best Design is about: Decisions, Priorities, Options**

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## Typical Improvement Attempts

- Stage Gate (control)
- Design For Six Sigma, DFSS (tools)
- Toyota Product Development System/ Fast Cycle Time (speed) (sometimes called Lean)
- Agile (flexibility)
- APQP (Big 3 Automakers, not discussed today)

No one process is going to be a magic solution

## Planning

Approach	Requirements	Risk	Schedule
Stage/ Gate	Firm/ deliverable	Decision points	Checklist
DFSS	VOC	FMEA	Detailed
Toyota	Use case	Transparent	Hard
Agile	Evolving	Rapid prototype/ learning cycles	Variable
Commonality	Deep understanding with flexibility	Quick, honest learning to allow timely decisions	Focused end date, but flexible and simple communication

## Requirements

- **Issues come from missing or wrong requirements.**
  - The User Story can help this
- **Majority fixed with ability to evolve at lower levels**
- **Some need to be flexible**
  - As technology evolves
  - As customer understanding evolves
  - Test and evaluate unknowns early
- **Track status**
  - How many flexible
  - How many new
  - How many changes of fixed items
- **Understand basis and test approach**

## Risk

- **Honest with self**
- **Any tool only provides a relative risk (*priorities*)**
- **Learn about high risks early**
- **Focus on actions to take**
- **Have trigger dates for back up plans, if not going parallel path**

## Schedule

- Based on decisions to be made
- Firm, predictable end date
- Decisions on critical path early
- Rolling wave/ evolving as we learn
- As deep as useful
  - For this project
  - For the next project
- **“If we knew what we were doing, it wouldn’t be called Research.” Albert Einstein**

## Execution

Approach	Concept	Testing	Management
Stage/ Gate	Focused	Phases	Project Manager
DFSS	Pugh Concept Selection	Decrease variation	Sponsor
Toyota	Set based design	Early/ often	Chief Engineer
Agile	Minimum viable product	Cadence/ pace	Product Owner
Commonality	Multiple with layers of <i>decision</i> points	Early learning	Knowledgeable leader with broad ownership

## Concept

- **Flexible early**
- **Set based design, with one *option* the minimum viable product**
- **Understand *decision* points and what will trigger them**
  - Tooling
  - Vendor selection
  - Critical technology

## Testing

- **To make *decisions***
- **High risks early**
  - Instead of later because we are not sure how to solve them
- **For learning. Early and often**

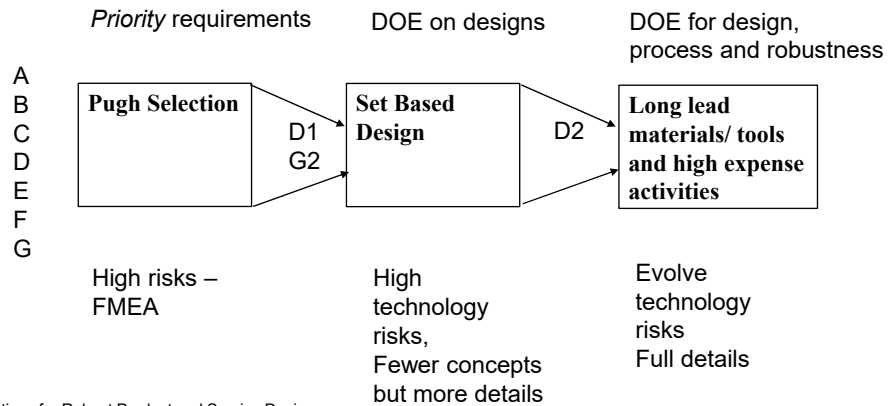
## Management

- Knowledgeable leader with a system perspective
- Understands customer and needs
- Understands capability of solutions
- Able to remove road blocks
- Comfortable with uncertainty

## Contradictions/ Conflicts in NPD

- Flexibility with control
- Focus with *options*
- Predictable advancements with risk taking
- *Decisions*

## Convergent/ Divergent Concept



Derived from Best Practices for Robust Product and Service Design  
Parendo, 2019, PDMA, <https://bit.ly/318zgB0>

## Practices

- Failure Modes and Effects Analysis (FMEA)
- Design Of Experiments (DOE)
- Pugh Concept Selection
- Set based Design
- Convergent/ divergent
- Learn or confirm
- Decoupling technologies
- Requirements
- Risk Management
- Monte Carlo Analysis
- Quality Functional Deployment (QFD)
- Triz
- User Experience (UX)

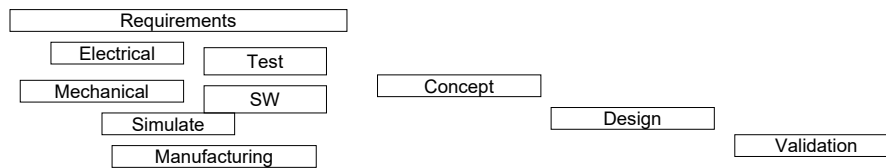
Only the top 5 are considered best.  
All are important, but some  
only in certain circumstances.

## Practice Links

Topic	Video Link
FMEA	<a href="https://bit.ly/2y0F6XS">https://bit.ly/2y0F6XS</a>
Design of Experiments	<a href="https://bit.ly/2peWLdi">https://bit.ly/2peWLdi</a>
Concept Selection - Pugh	<a href="https://bit.ly/37ay2EA">https://bit.ly/37ay2EA</a>
Convergent/ divergent	<a href="https://bit.ly/2wlotUu">https://bit.ly/2wlotUu</a>
Set up for Innovation	<a href="https://bit.ly/13FB8vP">https://bit.ly/13FB8vP</a>
Requirements	<a href="https://bit.ly/1ciEAGP">https://bit.ly/1ciEAGP</a>
Risk Management	<a href="https://bit.ly/17q0v7g">https://bit.ly/17q0v7g</a>
Monte Carlo Analysis	<a href="https://bit.ly/1ileFNp">https://bit.ly/1ileFNp</a>
Quality Functional Deployment (QFD)	<a href="https://bit.ly/1mJgoGu">https://bit.ly/1mJgoGu</a>
Triz	<a href="https://bit.ly/1qdOM9r">https://bit.ly/1qdOM9r</a>
Statistics/ Decision Making	<a href="https://bit.ly/10qWaF3">https://bit.ly/10qWaF3</a>

## Medical Device Program Management

- Organization needed critical Program Management help
- Came into an organization with no background in the product technology, no knowledge of the underlying therapy and no experience with systems/ processes for this organization.





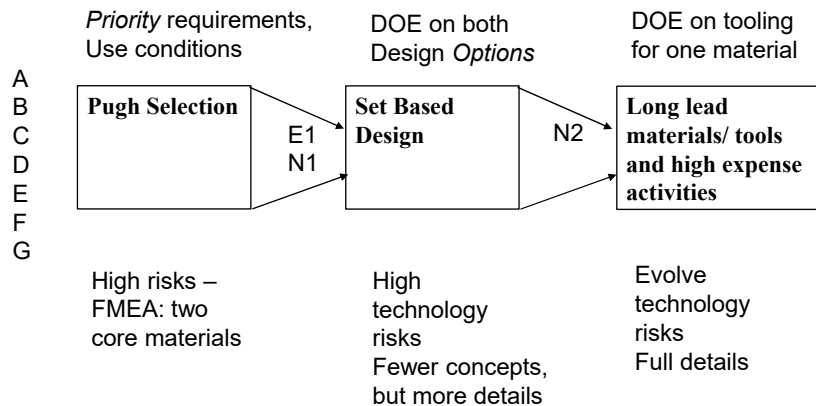
## Medical Device Project Situation

- **Competitive, medical device required a fast New Product Development turn around.**
- **A typical 18 month device project was requested in 10 months.**
  - Direct management supported 12 months as a possible stretch if we leveraged an existing design.
  - Leverage assumption ended up not being true!
  - Included design, manufacturing, tooling and reliability test functions
- **Risks related to materials and tooling**

## Medical Device Project Solution

- **Requirements focus**
- **Carry parallel concepts**
- **Understand and develop regulatory approach**
- **DOE for:**
  - Design (7 variables and 32 tests, versus potential of 2187 combinations using 3 conditions and all combinations)
  - Tooling (5 variables and 16 tests versus potential of 243)

## Convergent/ Divergent in Action



## Medical Device Project Results

- **Delivered project in 11 months, with a 3 week FDA approval.**
  - Yes, three weeks with the FDA is unheard of.
  - Beat competition to approval.
- **The rationale for the potential schedule reduction to 12 months was inaccurate. The typical 18 month duration was more appropriate**
  - Many design and manufacturing issues on previous design. Long lead tooling could not be reused.
  - We also fixed the previous design and tools in this period of time.

Completed project in 60% of standard schedule

## The NPD Solution Framework

- Understand what is important for your business and for your market
- Vision of the end state
- Understanding the right customers
- Risk management/ contingencies
- *Decision* making
- Increase the speed... of learning!
- Smart prototypes, maximize the learning from each *option*

Requirements, planning and execution  
Parendo, 2011, MQC, <https://bit.ly/14aLnwH>

# Thank you!

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## QUESTIONS?

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