

MedTech BEST

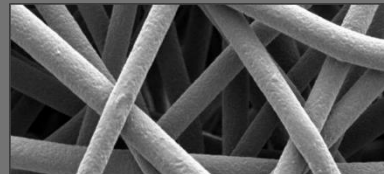
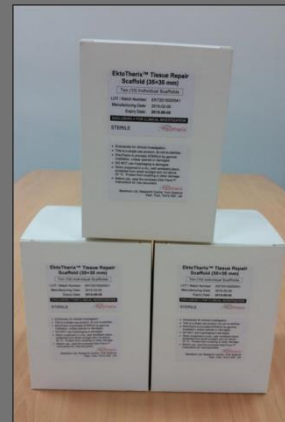
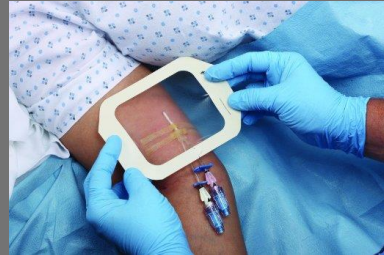
Launch meeting 6 December 2017

Business and Entrepreneurial Skills Training

Innovation and New Product
Development – Early Stages

Mike Raxworthy

- BSc Applied Biology, Lanchester Polytechnic, Coventry
- PhD Biochemical Pharmacology, University of Leeds
- MBA, Warwick Business School
- Industry:
 - Pfizer (3 years)
 - 3M Health Care (6 years)
 - Smith & Nephew (11 years)
 - Neotherix (10 years)
- Academia:
 - PDRA, Leeds (5 years)
 - Regener8 (8 years)



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Module Objectives

- Training in business skills needed for translation of MedTech research into the clinic and market
- Learn about how to put a business plan together and how to make a pitch
- Learn about what makes a good (successful) product
- Learn about the barriers to translation of MedTech
- Compete with other teams
- Have fun!

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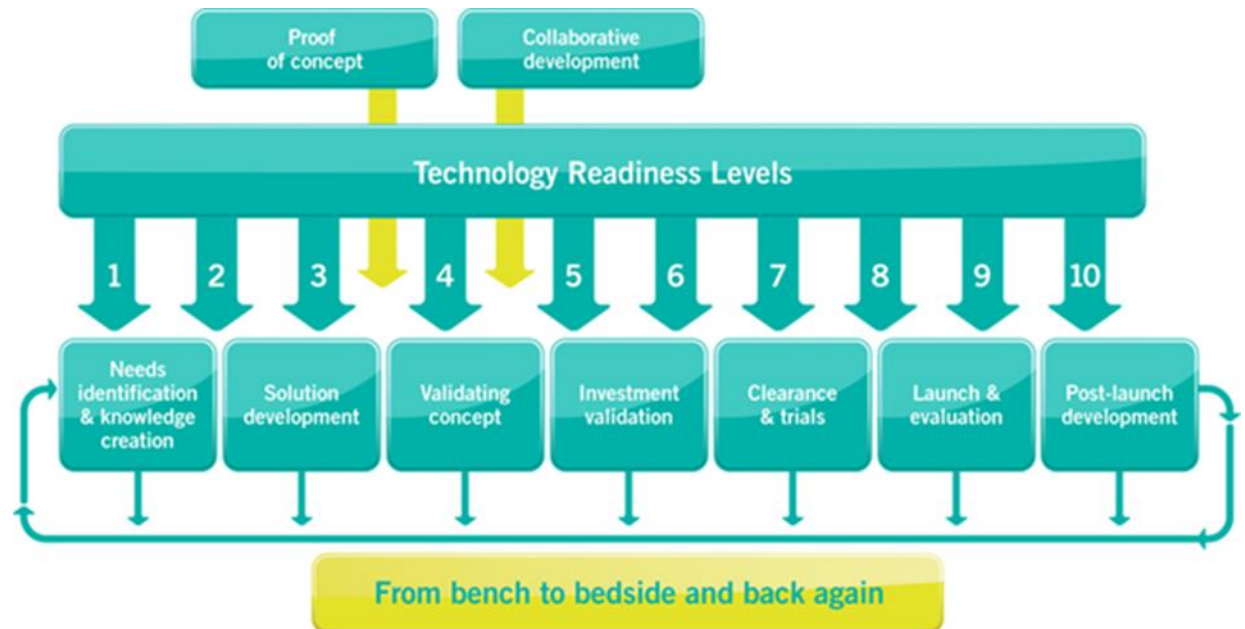
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Today

- New product development process
- Innovation funnel
- Idea Generation

Product Development

- How will you translate your **idea** to the market?
- **Product** essential features and benefits – competitive advantage
- IP – protects **investment**



“Nothing is accomplished in the real world unless it is adopted by industry.

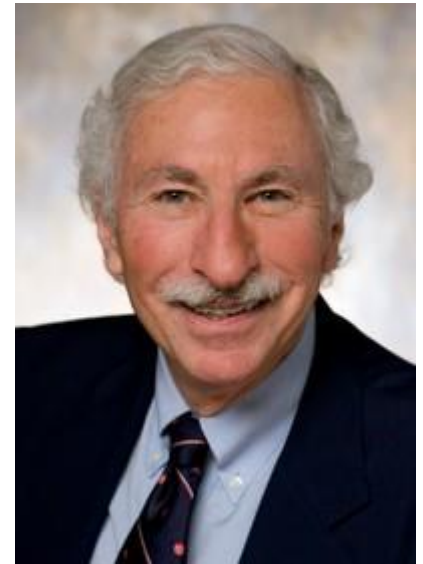
Academic scientists do not manufacture devices.

A paper in Science cannot save lives.

How to repay the taxpayers supporting academic research?”

Buddy Ratner

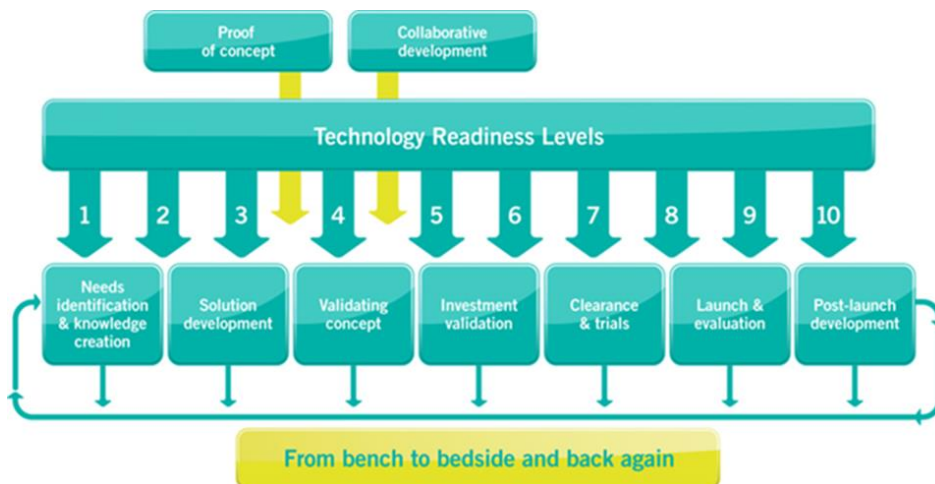
Biomaterials Scientist & Entrepreneur



See David Farrar talk on NPD on MedTech BEST site (Sector Specialist Presentations, January 2017)

Product Development - Stage Gate Process

- Development process broken into key phases
- Project reviewed by management team at end of each phase – Gate Review
- Project must successfully pass through Gate before it can proceed to next phase
- Stops projects running out of control
- Focuses team on what information/results are required

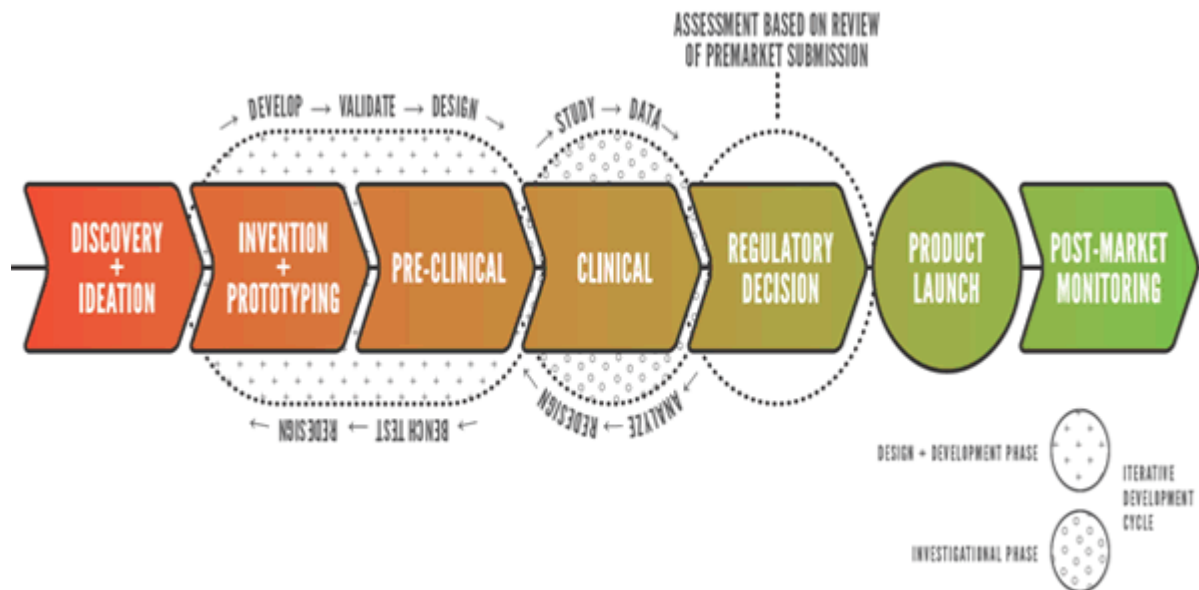


New Product Development



Product Development - Stage Gate Process

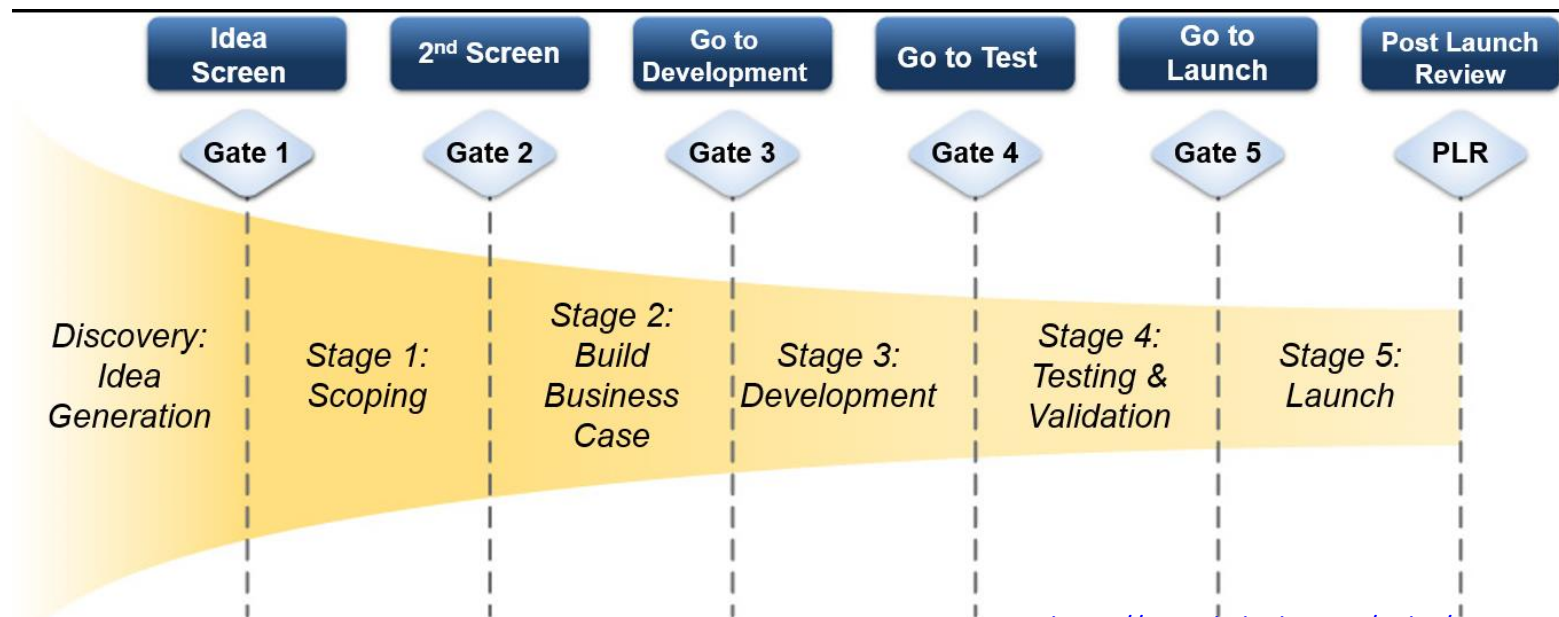
- Development process broken into key phases



The medical device development pathway from discovery and ideation to product launch and post market monitoring. The regulatory process affects a significant portion of the device development pathway and should accommodate the iterative, cyclical nature of device design and development. (Source: FDA (CDRH))

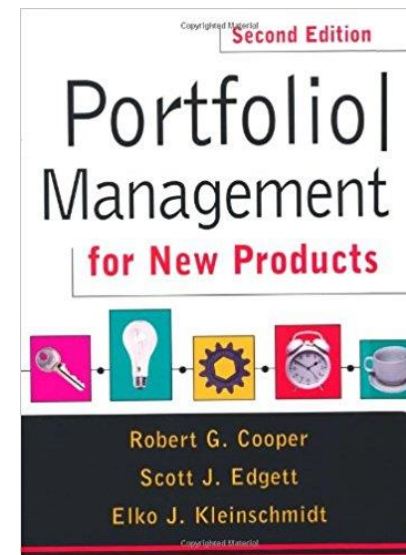
Product Development - Stage Gate Process

- Development process broken into key phases
- Project reviewed by management team at end of each phase – Gate Review
- **Project must successfully pass through Gate before it can proceed to next phase – minimises risk & allows portfolio approach**
- Stops projects running out of control
- Focuses team on what information/results are required



Product Development - Stage Gate Process

- NASA used a phased review process in 1960s - considered a first generation process because it did not take into consideration the analysis of external markets in new product development
- A variation of the phase-gate process, known as the *stage-gate process*, arose from the work of Robert G. Cooper in 1986
- Refined over next 20 years
- Gates allow an assessment of the quality of an idea to be undertaken. It includes three main issues:
 - Quality of execution: Checks whether the previous step is executed in a quality fashion.
 - Business rationale: Does the project continue to look like an attractive idea from an economic and business perspective?
 - Action plan: Are the proposed action plan and the requested resources reasonable and sound?

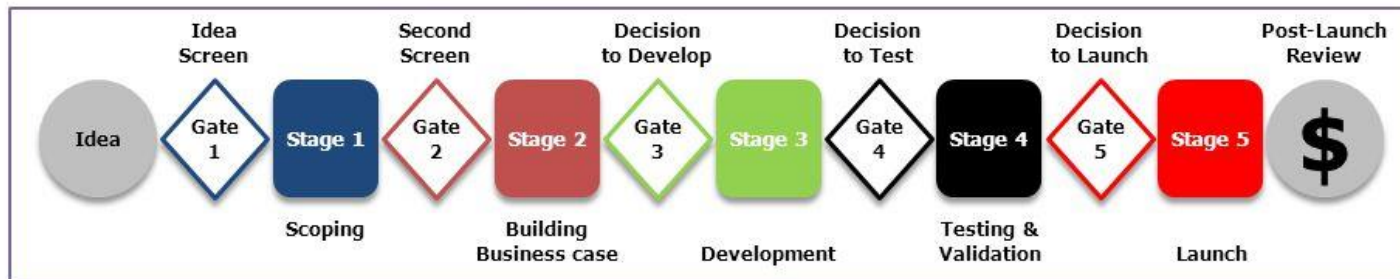


Product Development - Stage Gate Process

Stage-Gate Process (1/4)

- Stage-Gate Process
 - Introduced by Robert G. Copper in 1990
 - Conceptual and operational road map for moving a new-product project from idea to launch
 - Blueprint for managing the new-product process to improve effectiveness and efficiency

- Generic flow of the Stage-Gate Process



- Stages
 - Stages are where cross-functional action occurs: There is no R&D or marketing stage
 - Each stage consists of a set of parallel activities undertaken by people from different functional areas in the firm, working together as a team and led by a project team leader
- Gates
 - At the entrance to each stage is a gate, which serves as the quality control and Go/Kill check point in the process

Development Process

Stage	Description/Activities	
0: Idea creation/gathering	<ul style="list-style-type: none"> Brainstorming Internal R&D Technology scouting 	<ul style="list-style-type: none"> Literature review Companies/Universities
1: Initiation/Feasibility	<ul style="list-style-type: none"> Initial proposal & business case 	<ul style="list-style-type: none"> Initial proof-of-concept and prototypes
2: Concept/Definition	<ul style="list-style-type: none"> Full business case & project plan Research Customer Requirements Market evaluation IP Review 	<ul style="list-style-type: none"> Initial regulatory plan Manufacturing plan Further develop/test prototypes
3: Design & Development	<ul style="list-style-type: none"> Define design inputs Verification & Validation Plan Further testing/development Risk assessment Develop/review manufacturing process 	<ul style="list-style-type: none"> Develop/test final prototype Design packaging/labelling Update market, IP, regulatory reviews etc.
4: Transfer to Manufacturing	<ul style="list-style-type: none"> Establish and validate process Approve suppliers 	<ul style="list-style-type: none"> Document procedure Train operators
5: Regulatory	<ul style="list-style-type: none"> Prepare Technical File Regulatory submission 	<ul style="list-style-type: none"> Obtain regulatory approval
6: Post Launch	<ul style="list-style-type: none"> Surgeon training Product/Process improvements 	<ul style="list-style-type: none"> Complaints Post-market surveillance

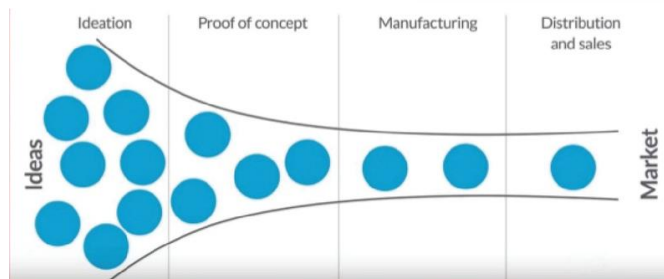
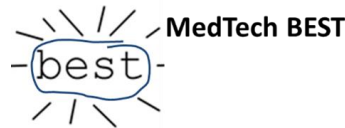
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- Competition
- Working in teams of 4 or 5 to....
- Develop a **MedTech product** concept – to solve a verified clinical need. **Hypothetical but plausible** and grounded in real science to address a real market
- Each team member to take on a role
- Sessions led by industry and sector specialists
- Mentors assigned to teams
- Concluded with pitch for “investment” – best business case and pitch will win!



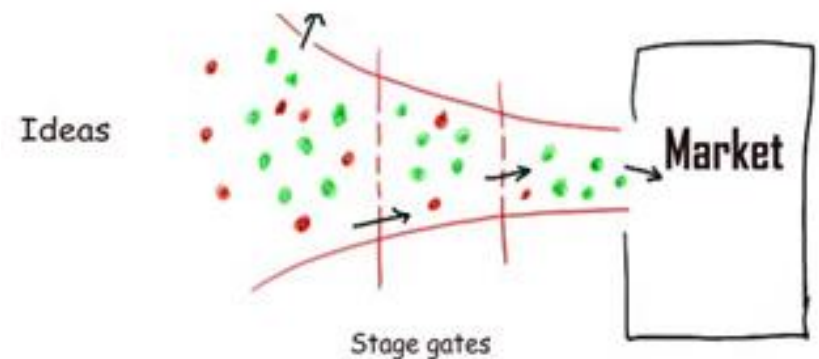
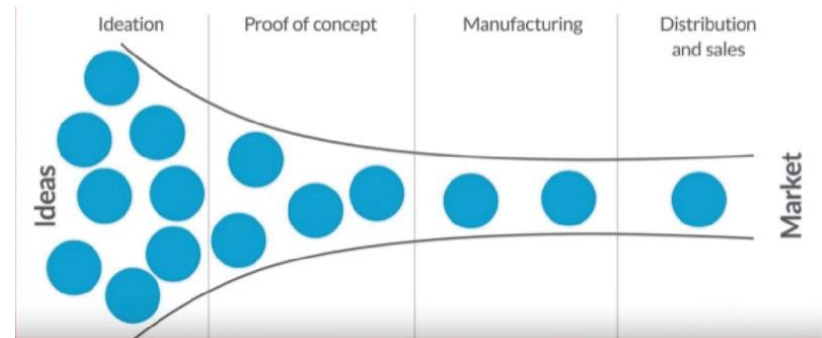
Lessons from Falling Over - Innovation

- Graduates need to be “innovation-ready”
- Dialogue needed to understand needs of industry (especially SMEs) for work force-ready graduates and post-graduates
- Opportunities:
 - MedTech BEST
 - Innovation Thinking and Practice
 - Translate Secondment
 - Other modules



Innovation Funnel

- Innovation process viewed as a funnel: lots of **ideas** come in the wide end on the left, and a few **finished innovations** come to market at the right.
- You may want to use the funnel to first select your **clinical need/target**
- Inside the funnel apply:
 - Strategic thinking: will the outputs be aligned with your strategic intent/overall goal?
 - Consider how the innovation is going to add value to your strategic intent



The ultimate definition of innovation

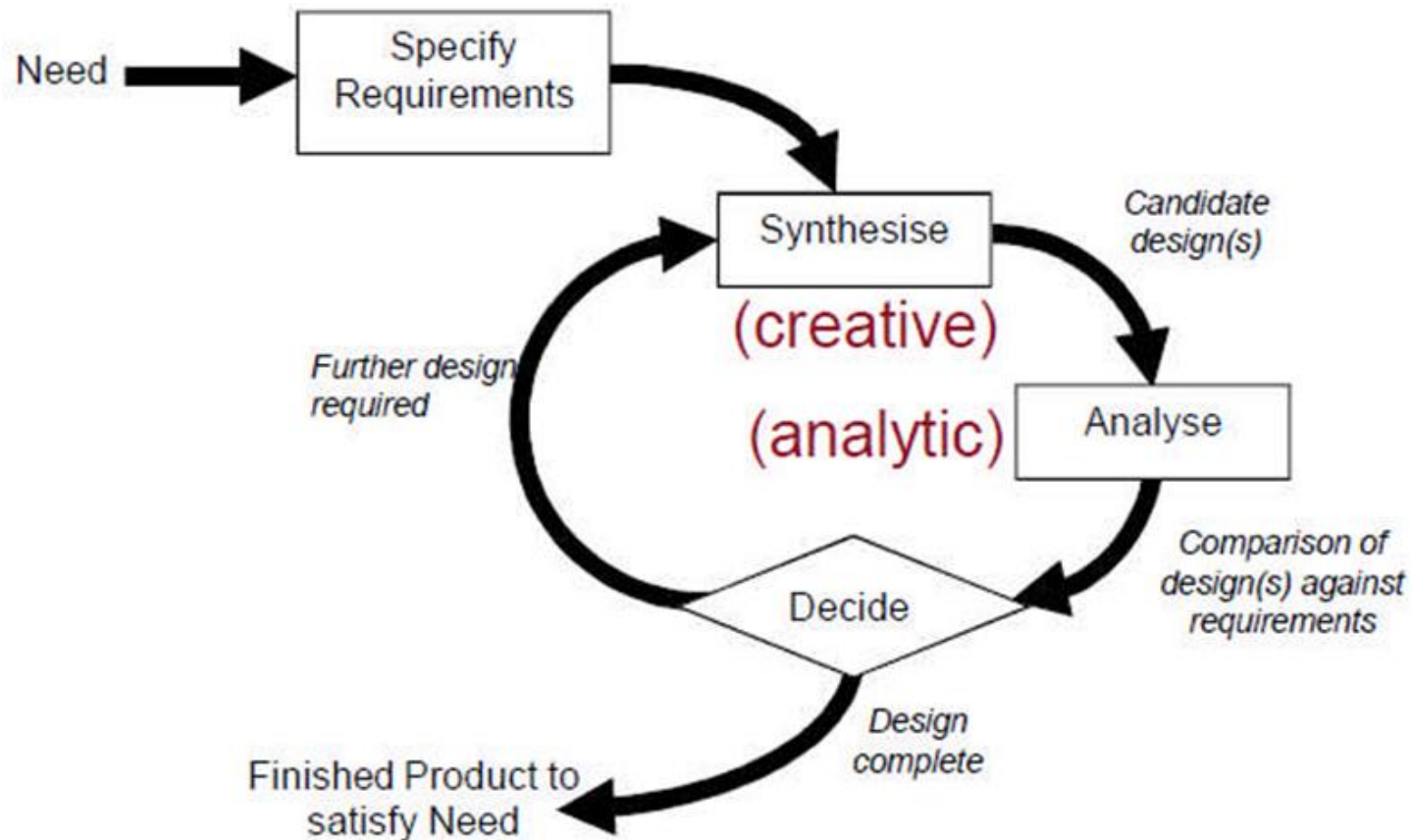
Executing an idea which addresses a
specific challenge and achieves value for
both the company and customer

Idea Generation and Selection – Now for your BIG IDEA!

- You are going to BRAINSTORM potential ideas
- DEVELOP the most promising ideas
- SELECT the best idea(s)
- Form into small teams



Idea Generation and Selection – Now for your BIG IDEA!





Idea Generation and Selection – BRAINSTORMING

- As many ideas as possible - even if they seem ridiculous!
- No such thing as a silly idea - record all ideas
- Impractical ideas OK!
- No criticism
- No judgements
- “Yes and”....not “Yes but” – build on ideas; combine and improve
- Stay focused!



Idea Generation and Selection – IDEA DEVELOPMENT

- Cluster related ideas – can a better idea be distilled from joining these up?
- Ask questions among your team to **clarify** an idea or group – re-write/re-word the idea if needed; screen out those ideas (even though they may be good) that don't fit the **brief**.
- Each team member to cast 3 votes to choose best ideas – can place all 3 votes on the same idea if desired!



Idea Generation and Selection – IDEA SELECTION

- Take top idea(s) and discuss “what I like” and “what needs improving” amongst your team
- Reach consensus on the idea you will go with – hold a vote only as a last resort!
- **You have your big idea!**
 - Give it a name and identity – this will be a product name
 - Create an identity/name for the company you will form to commercialise this idea.

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Ways of Working

- Work in teams of ~5
- Each team member to take on a role
- Mentors assigned
- Industry and sector specialists will be contributing to future sessions
- Competition (with prizes)!



Next Session

23 January 2018

- You will need to have your innovation/technology/product/service identified and the concept outlined
- There will be time to work with your mentors



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