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SCOTLAND

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08

SCALING MANUFACTURING AND MANAGING SUPPLY CHAINS

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ABOUT US

With a long tradition of innovation, entrepreneurship and commercialisation, the product design sector is one of Scotland's key industries. Through advances in technology, designers are providing innovative products across a number of global markets, including healthcare, energy, communications and mobility. Integration of these technologies into viable, efficient and commercially attractive products is key, and the partnership between technology and product design is becoming ever more important.

Product Design Scotland, managed by Technology Scotland, the representative body for Scotland's Enabling Technologies Sector, has been established to support the product and industrial design sector in Scotland. The network aims to be the focal point for the community, raising awareness of the critical importance of design to future growth and competitiveness and creating a thriving, collaborative network to drive innovation.

By working with companies and organisations across Scotland, we support the sector through:

- Promoting the value of strategic design to government and industry
- Raising the profile of Scotland's product/ industrial design sector
- Increasing visibility of those operating within relevant supply chains
- Improving competitiveness through collaboration and knowledge exchange
- Creating new networks to shape the future of design in Scotland.

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TOPIC INTRODUCTION

INTRODUCTION

The transition from product design and development into volume manufacturing can be a tricky, slow and expensive journey to navigate. Get it wrong and the product can be late to the market; late changes to the product or manufacturing problems can cause a large amount of scrap or rework or even product recalls; tooling and component costs for volume start up can be expensive, involve long lead-times and often require pre-payment so the funding and cash flow is an important consideration.

To get it right requires early planning and early selection of suppliers, a structured implementation process for all components and assemblies, careful management of the supply chain and careful management of costs. The scale up plan needs to meet the volume, quality, performance and cost requirements but still be flexible enough to adapt to changes in the plan.

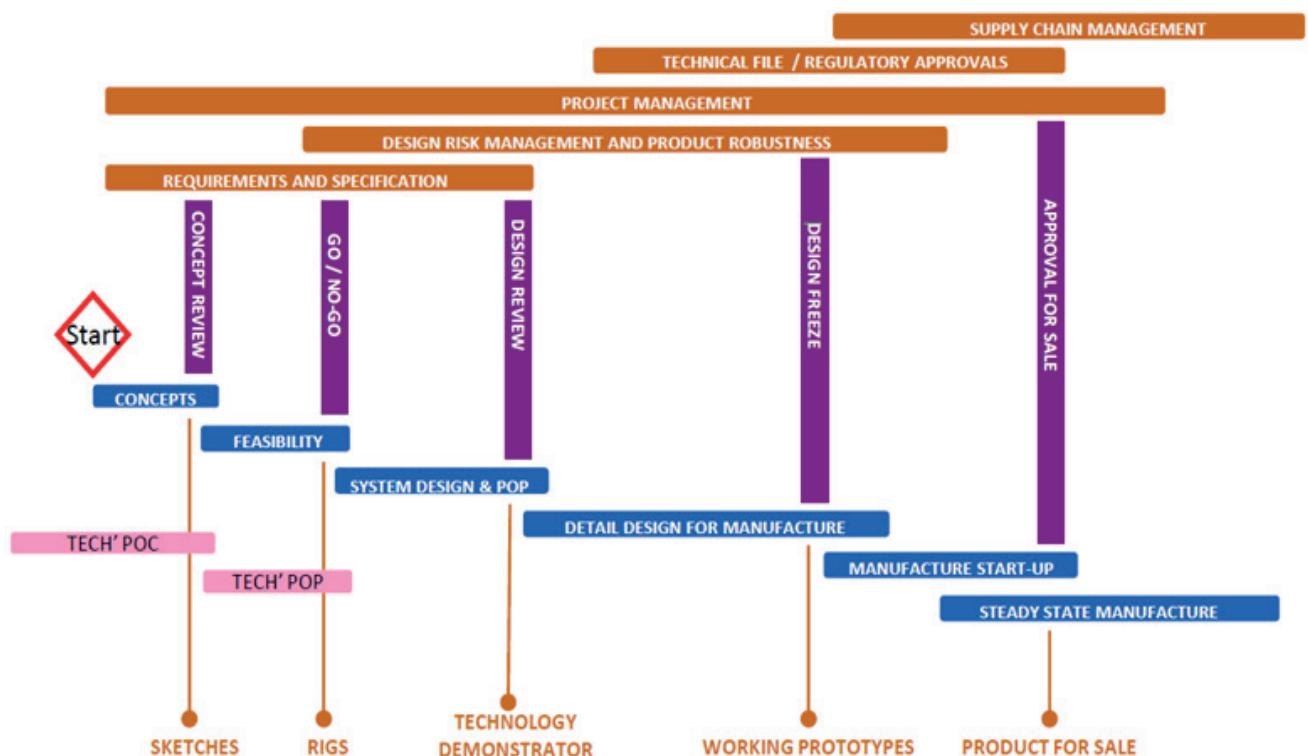


KEY STEPS IN SCALING MANUFACTURING AND MANAGING SUPPLY CHAINS

MANUFACTURING SCALE UP PROCESS TOOLS

Every new product designed and developed is different to previous products so require slightly different approach. There are some useful general principles in the TRL / MRL scales and the full product development process which help describe the steps and considerations at each stage.

Wideblue's standard Product Development Process is described as

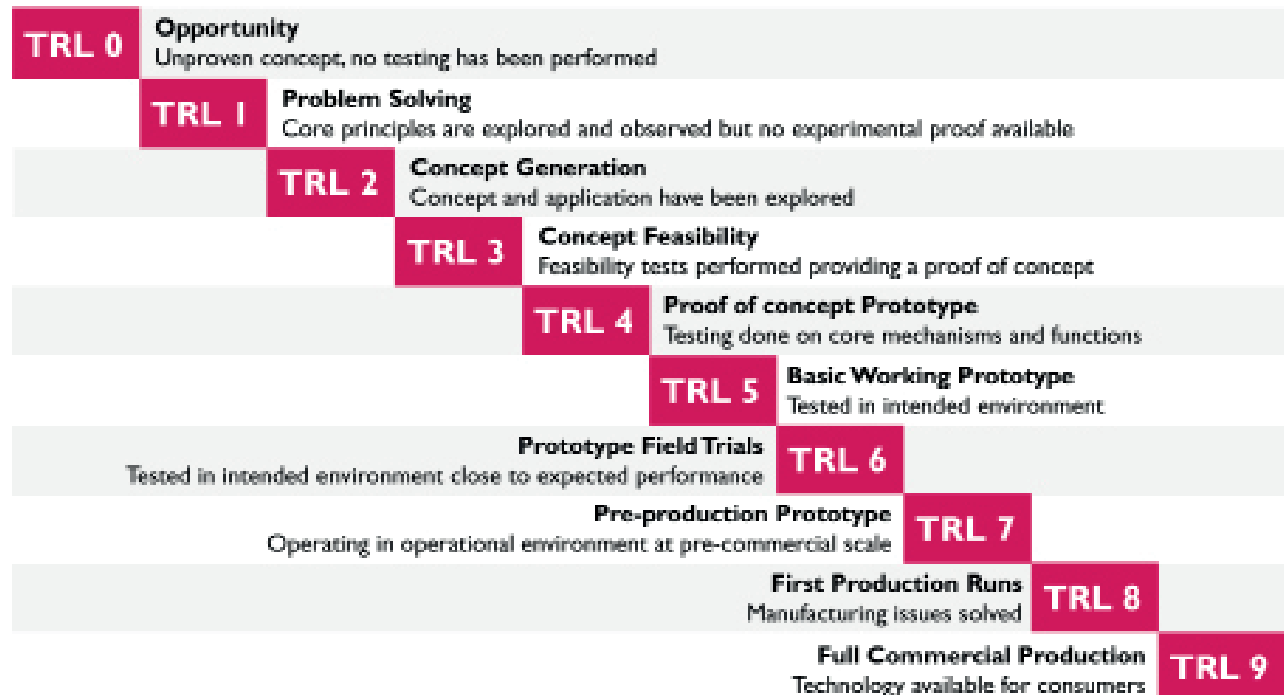


Development is managed through a series of stage gate reviews with key later manufacturing involvement at Feasibility Go/No Go, Design Review, Design Freeze, Design for Manufacture, Manufacturing start up, Approval for sale.

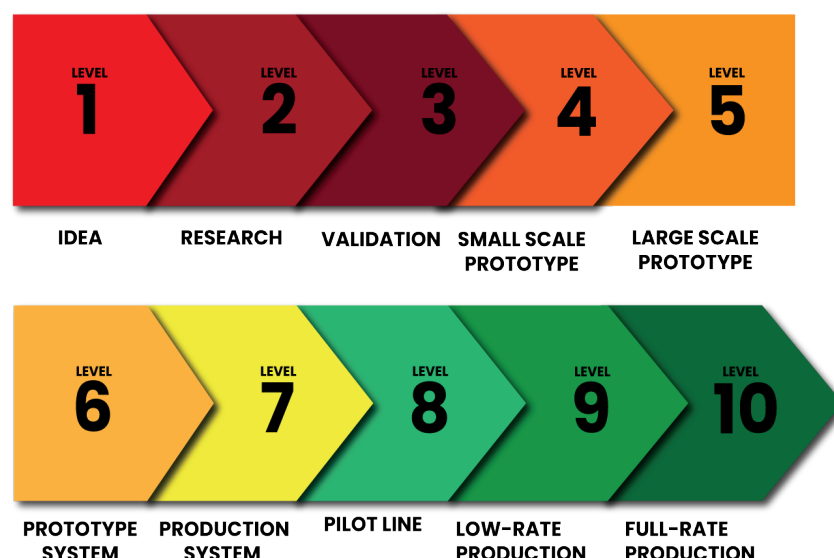
Many companies assume that by making one technology demonstrator they are close to manufacture. In practice they are still at a very early stage of commercialisation. Making one successful prototype is just a first step in the journey to get ready for manufacturing. The design team often have the most technical knowledge about the new product so are a very useful resource in helping to establish the production process. To help with the understanding of product maturity many companies use the TRL scale. NASA developed the Technology Readiness Level (TRL) scale to assess and describe the maturity of different technologies.

It describes the activities, performance, testing and reliability of new technologies and new products at various stages of development. It is a very useful, widely used tool to use in new product design and development (especially for technology products)

Technology Readiness Level



Similarly, there is a Manufacturing Readiness Level (MRL) scale describing the manufacturing activities as a new product goes from idea through to full production. The MRL scale is a very useful reference to help guide decisions, testing and considerations at the various levels of scale up.



The early stages of the MRL scale (Levels 1,2 and 3) are largely carried out with only high level consideration to manufacturing requirements and process.

Some of the key manufacturing stages during scale up start at MRL4 and beyond:

MRL 4

Small scale prototype to the final aesthetic design – likely a mix of custom parts (3D prints, PCBAs) and COTs parts. Suitable for early stage in-house demonstration but also allows understanding of manufacturing challenges, candidate suppliers and manufacturing cost drivers.



Example of a hand built advanced prototype

MRL 5

Larger Scale Prototyping – Prototype products of suitable quality for Alpha trials. Leads to the development of a manufacturing strategy for the range of expected volumes to be produced (make/buy decisions, low / high volume costed BOM estimates, identify critical components, critical processes required eg automation, clean rooms, alignment of parts etc., decide on suppliers including single/dual source for critical components). Alpha prototypes are generally used with “tame” customers (who are not sensitive to early life failures) to get early feedback on the proposed product.



(Hand assembly of multiple units for clinical trials with production quality electronics)

MRL 6

Final prototypes being manufactured for Beta trials in small production like facility with materials and packaging representative of final product quality – Feedback and quality requirements from Alpha trials incorporated into the design. Detailed design updates for manufacture and tooling. Test strategy and design of product production testers. Supplier negotiations and quality agreements (if required). Beta prototypes are usually near market ready and are used with a wider variety of users.



(Specialist clean room for small volume prototype medical device assembly)

MRL 7

Manufacturing systems to be put in place. Detailed materials specifications, in-process and finished goods quality targets, assembly work instructions and test instructions, update costs and volumes, final development of custom parts and test equipment (eg T1 / T2 injection mold parts), training of operators, device history records / job cards, commissioning specialist test equipment, programming of automation (if required), incoming goods assessment of parts



(commissioning of specialist manufacturing equipment)

MRL 8

Pilot production Process. Build of a large batch of the product (typically 200-1000 units) to test all production and quality processes. Products typically 100% tested, burn-in and used for final regulatory testing. Performance of production evaluated on quality / yield / rework, expected cost in high volumes, performance of the product. Validation and verification of production processes, materials and equipment. Products used for photo shoots, sales training, trade shows, early adopters, soft launch in limited market.



(Burn-in and testing of pilot production quantity)

MRL 9

Low production process – Continuous output (multi shift) production at a single site with performance monitoring. Controlled with six sigma process to minimise waste and rework. Continuous improvement system in place for materials and production process.



(small low volume production line with paper based QC system)

MRL 10

Full rate steady state production. Multiple lines, multiple shifts, multiple competing locations. Minimal design or engineering changes. Full six sigma control. Changes mainly for improvement of cost or quality.

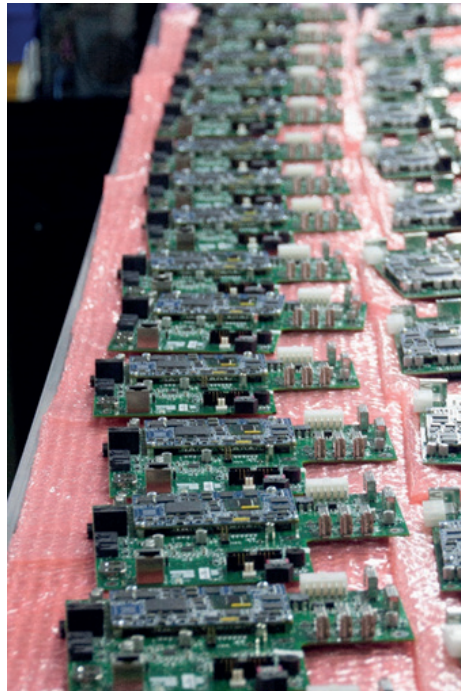


(high volume multiple production line with automated QC system)

SUPPLY CHAIN MANAGEMENT

Every new product has a different set of requirements and challenges with the proprieties changing during the design and scale of the new product.

Early stage supply chain challenges are usually about the performance of the product and the development time. Where possible use commercial off the shelf components as they will have the best cost, availability and reliability. For new PCBAs best to invest early in surface mount assembly (even for low volumes) rather than hand placement of components to achieve best quality and minimum errors. Identify and order long lead time components early to speed up the prototyping process.



(low volume PCBs are often better quality using an automated process which also aids with scale up)

Choose the right process for your custom parts as the volumes increase. Custom parts (optics, castings, injection moldings, sensors) can be expensive in medium volumes but the temptation is always to commit to high volume tooling early to get the best price and quality. This often prevents you from making the changes required as you get feedback from the various prototypes. Generally better to prototype often with 3D printing, CNC machining or vac casting than invest in tooling.

However, if production quality materials are required for strength or biocompatibility reasons in medium volumes then often a development tool is cheaper than machined or cast parts. Generally only move to single cavity tooling when the product is proven and certified. Generally only move to multi cavity tooling when there is clear demand for the product in volume. Make sure you own the tooling and have it stamped and on your asset register so you can move it to another supplier if required.

Identify the critical parameters requiring supply chain management early. Split the components into Class 1 - specialist custom or specialist manufacturer (sensor with IP, supplier with specialist equipment), Class 2 - commercial off the shelf or standard custom processes (injection mold or PCBA) and Class 3 – generic Components (eg screws, packaging etc). Where possible multi source for suppliers to get best pricing and availability. Class 1 suppliers are often more difficult to multi source. Class 1 suppliers might be for a critical sensor, a specialist manufacturing process, a critical dimension, a rare or specialised material. Focus your supplier development on Class 1 for quality and Class 2 for cost.



(Large aspheric mirror manufacturer – Class 1 supplier)

Put a supply chain and quality agreement for critical suppliers at the right time. Often done too early so the supplier loses interest or too late and the supplier already “has you over a barrel”. You will know the right time for this.

Finally – don’t be reliant on one supply location. Ideally split high volume production over multiple locations. This keeps each supplier keen and local production helps with shipping, freight and duty costs. If you don’t have the volume to split production over multiple suppliers then choose a supplier with multiple locations so they can at least move production in the event of a major incident or change in business.

MANAGING OF PRIORITIES

There are often competing requirements which have to be carefully managed usually within your company. Different functions or personnel can have different expectations on cost, timeline, quality. Best to discuss these items internally to achieve alignment and incorporate the agreed strategy into the business plan, NRE costs (development, tooling, materials, testing), product costs, pre-payments, contingency (costs and time) and their impact on the business cashflow or ROI.

Areas where priorities often clash include:

- Selection of key component manufacturers well in advance but usually before volume commitments can be made
- Time to market / launch date commitments vs maturity of product
- Unpredictable sales volumes but very different low volume and high volume product costs
- Tooling strategy – when to invest in high volume high cost tooling
- Test strategy – Need to ensure quality and reliability but higher costs for 100% testing. Going too early with regulatory testing often requires a repeat test – better to do some initial pre-compliance testing before committing to the full testing
- A realistic set of worst case scenario planning for delayed entry, higher costs, lower sales, competitor product etc

OTHER CONSIDERATIONS

Packaging and Instruction manuals are often designed late in the product development process so remember to allow time for artwork design; layout, graphics, text and translation of instruction manuals; single box design / multiple shipper size / pallet layout; think about accessories, kitting, spares.

It is useful to have the design team start the service and repair manual and also be involved with an early returns analysis activity. They have experience of the intended design and operation, the selection of suppliers, the initial prototyping and pilot production line, they are involved with the product testing and regulatory approvals so know the intended use and operation of the product. The design team can usually quickly establish the root cause of any non-conformances or returns. Once the service and repair team get up to speed then they will typically add to the initial service and repair manual.

It is very useful to have a Quality Management System in place during development and scale up as well as steady state production. This is mandatory for most medical device manufacturing but it is still very beneficial for non-medical product scale up. Having the discipline of documenting the various stages of scale up, specifications, device history records / job cards, change control will save you from many unexpected problems, help you solve problems more easily and will help reduce your product and professional liability insurance costs!



WIDEBLUE PROFILE

Formed in 2006 as a management-buy-out from Polaroid Corporation Wideblue is a full-service, multi-disciplinary product design, product development and design for manufacturing company. Our design studios, development labs and production facilities are located in The West of Scotland Science Park in Glasgow, Scotland. An in-house manufacturing start-up facility and links to many international suppliers and manufacturing locations helps clients to bridge the gap between product development and full-scale manufacture.

Many of the projects and products in our portfolio are the first of their kind, based on novel technology or intellectual property. Our strength is developing integrated systems which are commercially viable products. Wideblue cover industries including Consumer, Commercial, Renewables, Medical Devices, Quantum Technology, Aerospace and Wideblue specialise in photonics products, IoT products and Medical Devices. Wideblue work with many large multi-national companies, small and medium enterprises (SMEs), start up companies and University spin-outs and also participate in collaborative R+D projects.

Designing technology-based products requires a multi-disciplinary technical team that can work together to create system based solutions and develop them into commercial products. Wideblue's 24 person team of industrial and ergonomic designers, product designers, mechanical, medical device, electronic and software engineers, physicists and optical designers all have many years' experience designing products through to successful manufacture and commercialization.

In 2018 Wideblue joined the Pivot International group of companies. This gives Wideblue access to a larger network of engineering design skills, testing equipment, suppliers and manufacturing locations including USA, Philippines, China, Mexico, UK, Taiwan. In 2019 Wideblue were joined within the Pivot International group by A2E in Livingston to extend their skills in Electronics design, Firmware and Software design and IoT products and projects.

Wideblue and Pivot International are accredited to ISO9001 and ISO13485 (medical devices) and are involved at all stages of the product lifecycle.



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