MANAGING NEW PRODUCT DEVELOPMENT

Creating the Product Design Brief

Session IX March 2023

Alan Mumby

The purpose of Product design ?

It’s a strategic business initiative that can differentiate companies in competitive markets,

a method/ process by which a company develops new products to meet the wants and needs of its existing or new customers.....

……brought to life by well considered and managed innovation strategy.

purpose

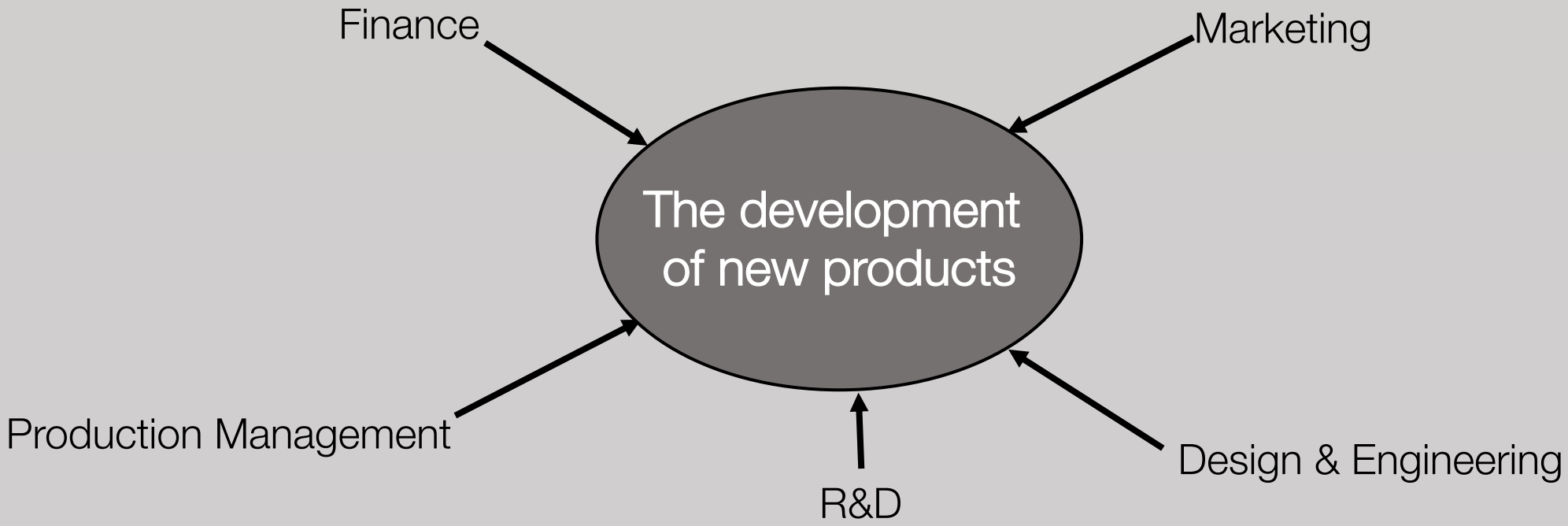
A product design brief is a document employed during NPD serving as a central meeting place for the various requirements of an NPD project, such as product development objectives, descriptions of the target market, current industry trends,

.....competing firms and offerings, relevant technical or technological specifications, timelines, production objectives, budget and success metrics, along with product design and attribute details-e.g. shape, branding, dimensions, materials, personality, and so on..

(Phillips, 2004; Bruce and Daly, 2007).

Previously.... in Innovation Management & NPD we discussed

product design brief



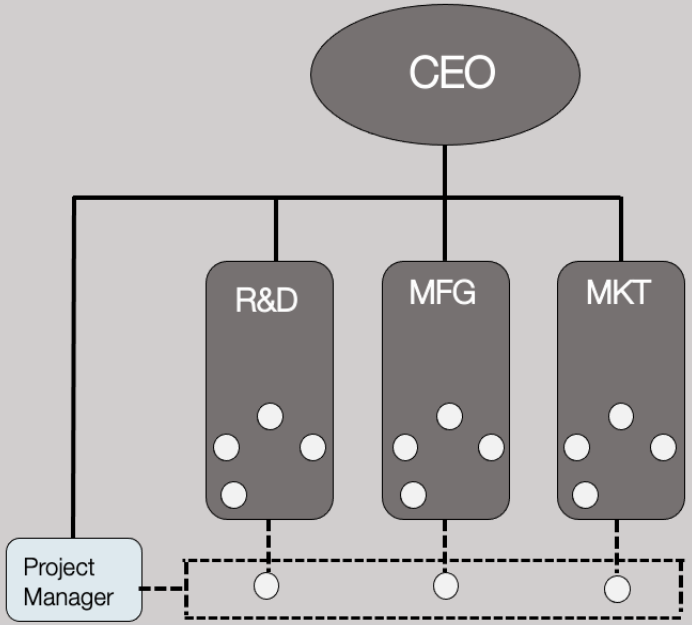
The variety of views presented on the subject is not a weakness. Indeed, it should be viewed as a strength, for these different perspectives all bring something to the table.

product design….complex ?

product design brief

The product design process can be a complex one, involving cross-functional teams from within your own organisation working together, or possibly with help from designers (and other contributors) from outside of the company.

Regardless of whether you are developing a product entirely in-house or using an external product designer…..



A clear **product design brief is essential** if you want to be rewarded with a smooth-running project and a worthwhile outcome.

Usually starting with the <u>awareness</u> of customer and their changing needs……

product design….complex ?

product design brief

Marketing Sensing and Learning – processes that define, create and deliver value

2. Sources of market knowledge

2.1. Internal records CRM data Databases → Management information Systems (MIS)

2.2. Market tests Surveys/Polls Observation → Marketing Research (MR)

2.3. Scanning Trends and Clues → Marketing Intelligence (MI)

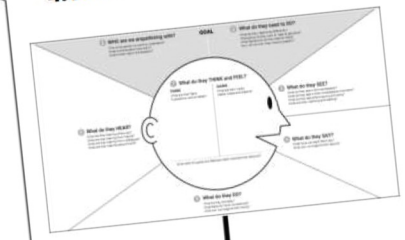
2.4. Ethnography Scenarios Future forecasting etc → Cross-disciplinary Tools (MI+)

3. Processes of management understanding

Interpretation

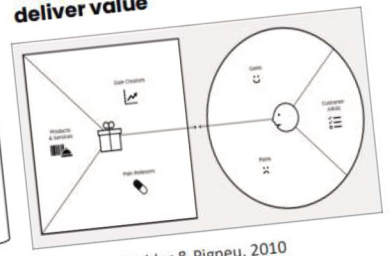
Market-sensing capabilities → Market understanding

4. Processes that define value



For the target customer persona

5. Processes that create and deliver value



Adapted from Piercy, 2017, Osterwelder & Pigneu, 2010

© 2023 Jackie Harris

Prifysgol Cymru
Y Drindod Dewi Sant
University of Wales
Trinity Saint David

ld a footer

customer need

Successful new products should be based on what your research-based insights are telling you the customer could need and want in the future.

WHAT THEY THINK THEY WANT ……MIGHT NOT BE WHAT THEY NEED!

This can be found from a range of sources including focus group research, customer advisory panels, analysis of your competitor products, trend information etc.

The key here is to identify what insights you have gained that might help differentiate your new product from others on the market.

the market for the product

Information in this section is critical to understanding the risk and financial return involved with new product development. It should include:-

- Potential market size and growth trends
- Anticipated market share
- Pricing range
- Competitive products or services
- Research of existing patents to identify any conflicts
- Other influencing factors on the market
- Research whether or not legal and or industrial standards or accreditation is required…..COMPLIANCE

product design brief

A brief should clearly explain:-

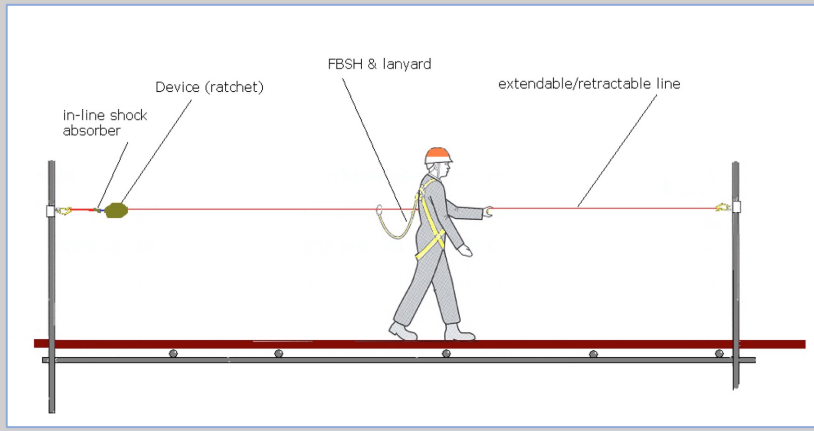
Purpose

- Where and what the product is used for?
- Fully understand the environment and context for use and how it may be used in connection with other products or processes.

a synopsis is usually a good idea…..

defining the NPD

product design brief



Defining the NPD – **getting the words right is really important**

"The product is a horizontal safety line device (with 'inline' shock absorber), which once attached to two fixed anchor points, is then tensioned by means of an integral ratchet.

A worker with a Full Body Safety Harnesses is then able to attach himself to this line by means of the carabiner fixed at the end of the FBSH lanyard, this allow the worker to operate safely within his now extended (2 – 8 meters) work space."

product design brief..
product design specification
(PDS)
?

product design brief

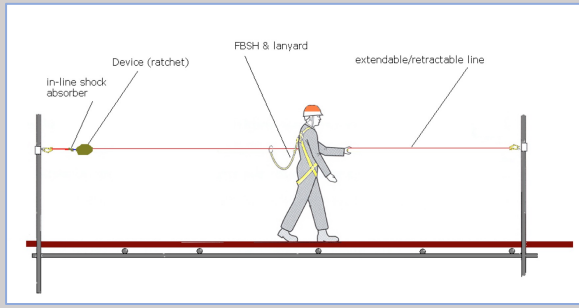
From Product Design Brief to…..Product Design Specification (PDS)

The PDS evolves from the PRODUCT DESIGN BRIEF.

- The design brief outlines the design goal and any major constraints and considerations that need to be addressed
- The PDS goes further to determine the precise limits for the full set of requirements in the product being designed.
- For the Product Design Brief - it's not all about engineering, or whether it can it be manufactured…..

performance & features

Performance



What does the product have to do? Explain what the primary operating characteristics are, i.e. this product must be designed to work in wet conditions, be assembled for use in less than 30 seconds or can integrate with other similar products or component parts.

Features

- What additional things must it have?
- Apart from doing its job, what else will make it more appealing, useful and user-friendly?
- Does it need a non-slip handle, a child-proof cap, a non-graffiti surface?
- Will recyclability of all the components be required?

aesthetics, colour shape form and finish….

product design brief

prototype ?

is it required?

how much will it cost?

prototype ?

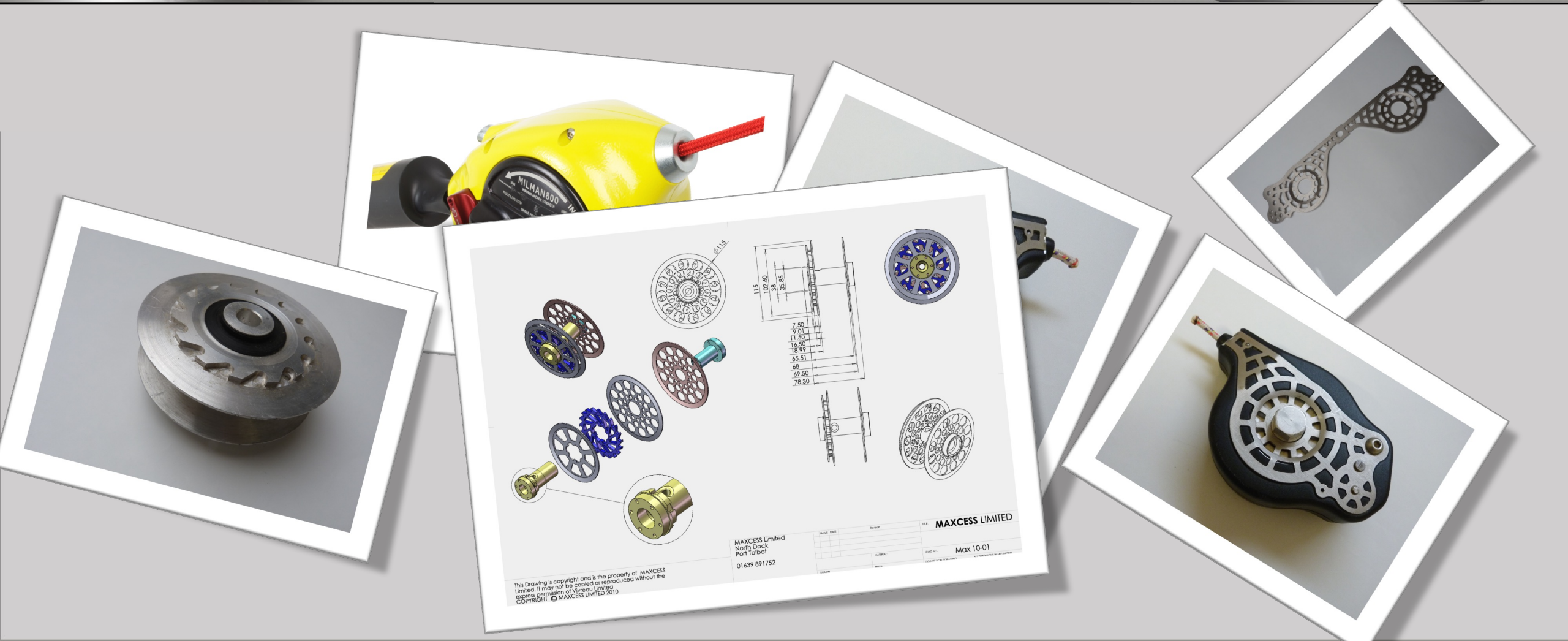
product design brief

aesthetics, colour shape form

prototype ?

form and
function, as well
as aesthetics

product design brief



Elements of a Product Design Brief ?

Elements are questions we need to first pose, understand our findings…

…….and them consider their relevance or importance

So, what are the elements we consider when developing a product or service

elements of a product design brief

aesthetics
branding
company constraints
competition
customer
circular economy
documentation
environment
ergonomics
installation
intellectual property
legal
life in service
materials
manufacturing facilities
market constraints
maintenance & repair
packaging
performance
politics
processes
prototyping
product cost
product life span
quality
quantity
reliability
safety
size
shelf life and storage
shipping
social & cultural
standards & specifications
testing
time scale
weight

Performance…

In discussing the preparations of a product design brief, most technicians and scientists think primarily in terms of performance, since performance achievement forms a major part of their design activity.

so let's start there

performance…

The performance demanded or likely to be demanded should be fully defined:-

how fast

how slow

how often in use - continuous or staccato

loadings likely

electrical or pneumatic

tolerance of speed rate of work etc.

performance…

Is the performance demanded attainable in an economic manner? A common failing in specifying performance is to ask for the ultimate, rather than that which is obtainable.

Successful NPD teams pay great attention to establishing objectives that can be attained.

It is extremely easy to tighten up a performance specification to such an extent that if one designed to meet that performance, the customer would not be willing or able to afford it.

environment…

All aspects of the product's likely environment should be considered:

- Temperature range
- Pressure range (altitude)
- Humidity
- Shock loading (gravity forces)
- Dirty or dusty - how dirty? - how clean? How wet? How cold? How hot?.....

environment… cont'd

- Corrosion from fluids - type of fluid or chemical
- Noise levels
- Insects
- Vibration
- Type of labour or persons who will use the equipment- likely degree of abuse?
- Any unforeseen hazards to customer, user or environment - for example, inclusion of CFC's?

environment… cont'd

All manufactured items experience a number of these environmental changes in any or all the areas before being called on to function for the user. These may occur at the following stages:

- During manufacture - exposure to cutting fluids, solvents, fluxes (flow soldering), acids (plating and cleaning), etc.
- During storage - in the plant
- During assembly - assembly forces, contamination from sweating hands?

environment… cont'd

All manufactured items experience a number of these environmental changes in any or all the areas before being called on to function for the user. These may occur at the following stages:

- During packaging
- During transportation
- During storage - at a wholesaler's warehouse
- During display
- During use

Should service life be short or long and against which criteria should this be applied? Against which part of the Brief is (or should) the product life be assessed? One year on full performance, 24 hours a day, seven days a week, or what?

Reliability

What is the expectation for the product life?

Have sustainability issues been considered?

Ease of repair

Is it designed for self-repair or does it need to be taken to an expert? Is a spare part included with the initial product? What is the estimated repair time?

Is regular maintenance available or desirable?

Will designing for maintenance-free operation prejudice the design to such an extent that the product will become too expensive to buy in the first place?

Does the company, or indeed the market into which the product will ultimately go, have a definite maintenance policy?

Are end-user companies able to maintain equipment once it is purchased?

target cost

Target production **costs should be established from the outset** and checked against existing products. Invariably, all target costs are on the low side, and in many cases they are unattainable within the constraints of the Brief.

Care should be taken at this stage to ascertain whether the **target cost is compatible with competitors'** products and, most importantly, with the manufacturing facility available to make the product. Cost patterns should be established and studied in detail before setting the target cost.

Consider....

You will need to consider **the selling price expectations of the retailer** and identify if there is enough margin between your cost price and selling price to make a good profit and cope with any fluctuations in material costs, exchange rates etc.

cost – what are your expectations

- Development costs
- Prototyping and pilot/testing costs
- IP protection costs such as patents, design registrations, trademarks
- Capital costs such as tooling, additional plant and machinery
- Manufacturing costs
- Distribution costs such as warehousing, freight, import or export taxes

competition

A thorough analysis of competition must be carried out, including a comprehensive literature search, patents and product literature search relating not only to the proposed product area, but also to adjacent product areas.

These must be analysed.

The nature and extent of existing and likely competition is probably the most important aspect of the Brief - at least from a comparative viewpoint.

packing

Depending on the type of product being designed, some form of packaging may be necessary for transport, storage, etc.

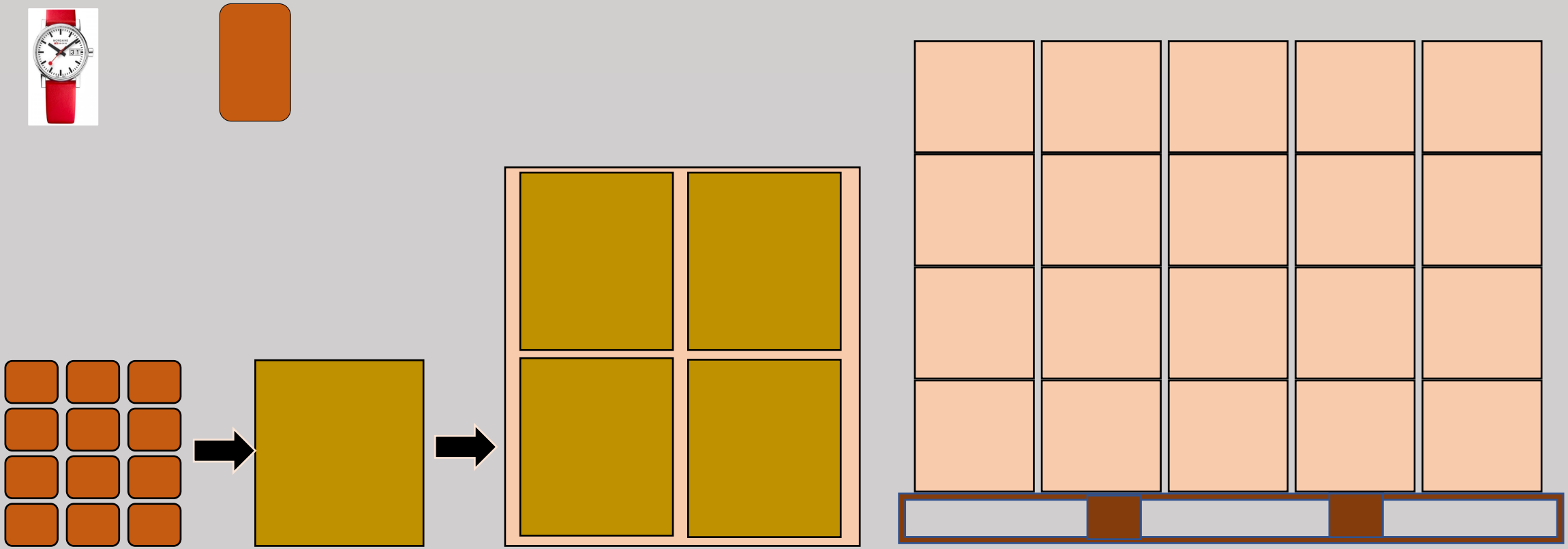
The cost of packing will add to the product cost and volume. Should the packaging protect against the environmental effects of shipping such as salt water, corrosion, shock-loading, etc?

packing

Depending on the type of product being designed, some form of packaging may be necessary for transport, storage, etc.

- What are the requirements for packing in regard to labelling and handling?
- Does it need to fit in a standard-size shipping container pallet or box?
- Is sustainability a factor in purchase and does the packaging need to be recyclable?

establishing the footprint



it is necessary to determine how the product is to be delivered:

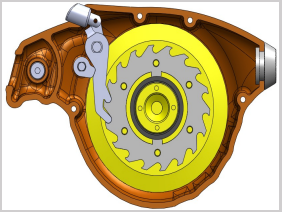
- Home or overseas; what type and size of truck, pallet container (ISO) is used for the type of product under consideration.

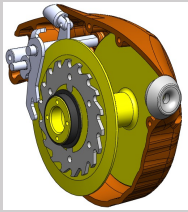
- A product may be competitive in the UK but by the time it is shipped overseas it may have become too expensive.

quantity

Likely numbers to be run off - the size of the run - will affect all aspects of a product's design.

Moderate numbers may require cheap temporary tooling, while large numbers may require permanent, expensive tooling.





This has a considerable effect on the supportive investment required and the plant already existing in-house.

manufacturing facility

Are we designing to fill an existing plant.. or is the plant and machinery involved a constraint to our design?

What are the plans for any new plant and/or machinery?

It is no good designing for a one-plant set-up to find a new one in existence by the time the production phase arrives.

Make-in or buy-out policy: is the product constrained to techniques with which the company is familiar?

Is our proposed flexible manufacturing system the ultimate in inflexibility?

More and more companies are resorting to subcontract manufacture which will make them less capital intensive and reduce their fixed costs.

Scale and type of production

How much of this product are you aiming to produce yourself?

How is production going being managed?

What are the production constraints that need to be taken into account?

size

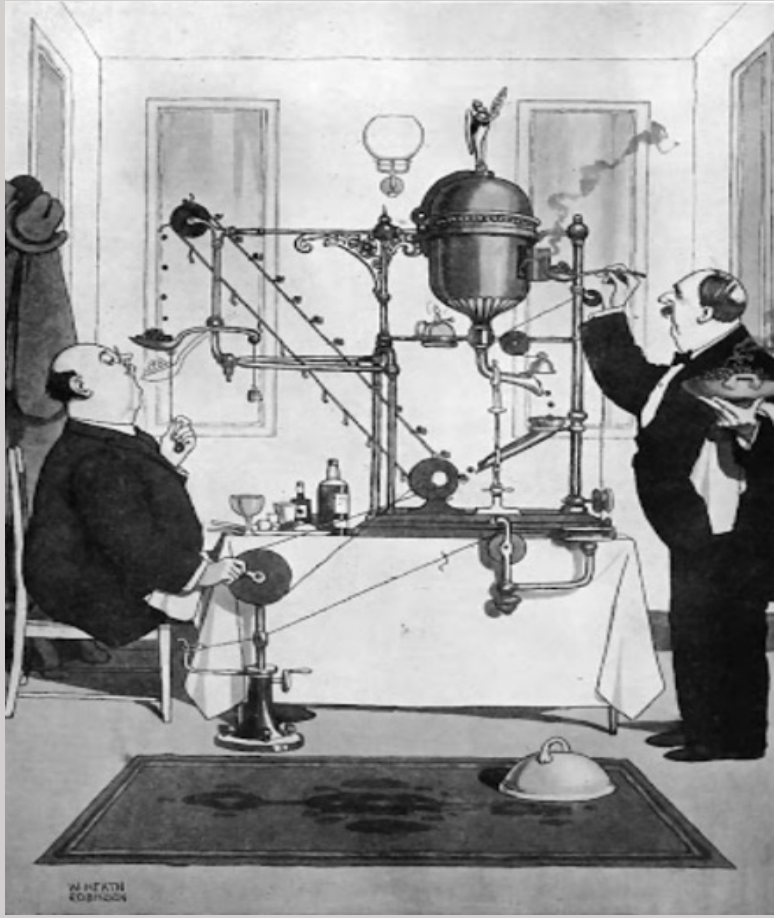
Are there any restrictions on the size of the product?

Does the product size and shape make it difficult to handle?

Size constraints should be specified initially.

many designs seem to ‘grow’ - with the result that the equipment will not fit into the space provided !

and even if it does, access for maintenance could be difficult.



An elegant solution for conveying peas to the mouth

weight

What is the desirable weight? (Remember that, for a given technology, weight is frequently directly related to cost.)

Allied to size, weight is important when it comes to handling the product on the shop floor during manufacture, in transit, during installation or in the user situation with the customer.

weight

It also has an impact on possible ergonomic or anthropological considerations – is it too heavy to hold in one hand for too long?

Should the design be modular to assist in the size/weight area?

For heavy products - should lifting points be provided?

Aesthetics, appearance and finish

- What about the look and feel for the user?
- How important is the ergonomics in relation to appearance and finish of the product?
- Is there a product colour range that it needs to match?
- What brand values need to be reflected in the look and feel?
- How will it sit against the competitor's range of products?

Aesthetics, appearance and finish

The appearance of a product is a difficult thing to specify and therefore, in many instances, it is left to the designer: the complaints come afterwards.

Colour, shape, form and texture, should always be considered from the outset. Advice and opinion should always be sought either from within the company or without.

Sales, marketing, production and others will always criticise a design once it exists?!

Therefore, efforts should be made to obtain these opinions before the design commences, and certainly as it progresses.

Aesthetics, appearance and finish

Everybody's a design critic, accomplished or otherwise.

So often the final appearance of a product 'just happens' and then strenuous efforts are made to make it look better, which usually prejudices the design in all aspects.

Never forget, whatever the product, that the customer sees it first, before he buys it - the physical performance comes later. The visual performance is always first.

Ergonomics
User interface

All products have to some degree a user interface, certainly during manufacture and most definitely in this case during usage/operation and also maintenance. it is therefore necessary to make clear the likely nature of the interaction with the product.

Ergonomics
User interface

All products have to some degree a user interface, certainly during manufacture and most definitely in this case during usage/operation and also maintenance. it is therefore necessary to make clear the likely nature of the interaction with the product.

Ergonomics
User interface

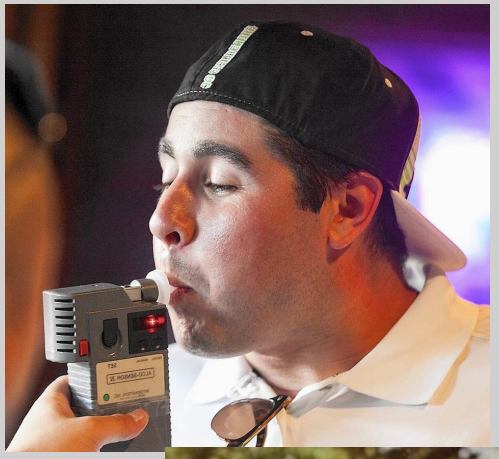
All products have to some degree a user interface, certainly during manufacture and most definitely in this case during usage/operation and also maintenance. it is therefore necessary to make clear the likely nature of the interaction with the product.

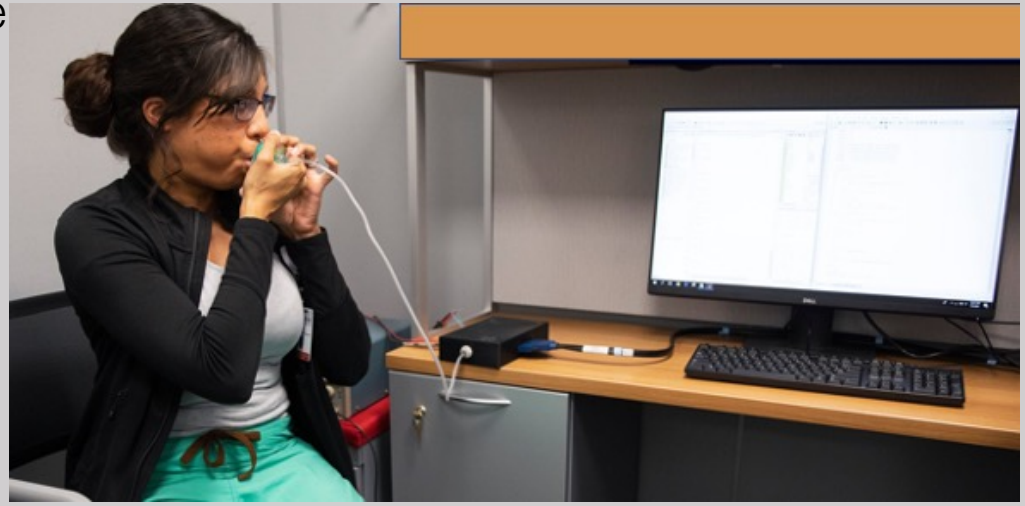
Ergonomics
User interface

All products have to some degree a user interface, certainly during manufacture and most definitely in this case during usage/operation and also maintenance. it is therefore necessary to make clear the likely nature of the interaction with the product.

Ergonomics
User interface

All products have to some degree a user interface, certainly during manufacture and most definitely in this case during usage/operation and also maintenance. it is therefore necessary to make clear the likely nature of the interaction with the product.





Ergonomics
User interface

All products have to some degree a user interface, certainly during manufacture and most definitely in this case during usage/operation and also maintenance. it is therefore necessary to make clear the likely nature of the interaction with the product.

Ergonomics
User interface

All products have to some degree a user interface, certainly during manufacture and most definitely in this case during usage/operation and also maintenance. it is therefore necessary to make clear the likely nature of the interaction with the product.

- what height
- what reach
- what hand room is available around the controls
- what operating torques are acceptable to the user during usage/operation and also maintenance.
- what is visibility like for the user during usage/operation and also maintenance etc.

materials

what materials are required to produce the product (or parts)? are appropriate standards be quoted - for example an encasement or cover may be needed, is it to be injection moulded ? if so what type of thermoplastic is required, what specification of material and to what standards ASTM, DIN, BS, ISO?

- Quality & Reliability
- Legal
- industrial standards
- Industrial Standards & Specifications
- Manufacturing facilities

Some indication of the life of a product as a marketable entity should be sought.

Is likely to remain in production for two years or 20 years?

The answer is crucial as it can affect the design approach and interacts with the market and competition, tooling policy, manufacturing facility and the like.

standards & specifications

Is the product to be designed to current international and/or British standards? If so, then these should be specified and copies obtained.

Cross-correlation of such standards should be carried out prior to commencement of the design. It is difficult, costly, time consuming and inefficient to attempt retrospective matching of designs already finalised to such standards.

Cross-correlation of such standards, e.g. BS, EN, AFNOR, DIN, ASTM, ISO etc

standards & specifications...cont'd

" It is essential that the device complies fully with all standards that are requisite within country of purchase....."

standards & specifications...cont'd

“ The product will conform to all industrial standards (BS;EN) for personal protection equipment / prevention of fall from height BS;EN 795 Class C, including

BS:EN 354 [lanyards]

BS:EN 362 [line connectors]

BS:EN 365 [generation of instructions and maintenance documentation for safety equipment]

BS:EN 355 [energy absorbers]

BS:EN 355 [anchorage system] “

The laying down of levels of quality and reliability necessary to ensure product success and acceptability in a particular market is a cause for increasing concern. They are the most difficult aspects to quantify in absolute terms.....

shelf life – storage

A factor often overlooked in specifications is that of ‘shelf life’.

With respect to products, shelf life must be specified at the outset and the means to combat decay considered (see ‘Environment’), otherwise rusty gearboxes, perished components, seized bearings, defective linings, corrosion and general decay will occur.

If special processes are to be used during manufacture, they should be defined.

e.g - plating specifications, wiring specifications etc.

Alternatively, the relevant standards - British, foreign, in-house, client's etc. - could be called upon.

time-scales

What is the time-scale for the project as a whole, in parts or phases?

Is there need to fit in with the time-scales of others concerned with the project?

time-scales

Lead times allowed for design activity are frequently inadequate, but they determine the time-scale for the whole project up to manufacture and product launch.

There are a number of milestones and ‘go’ or ‘no go’ points in product development. Any timescale needs to take account of the development process being used, the complexity of the development and the number of parties who are involved in the development process.

time-scales

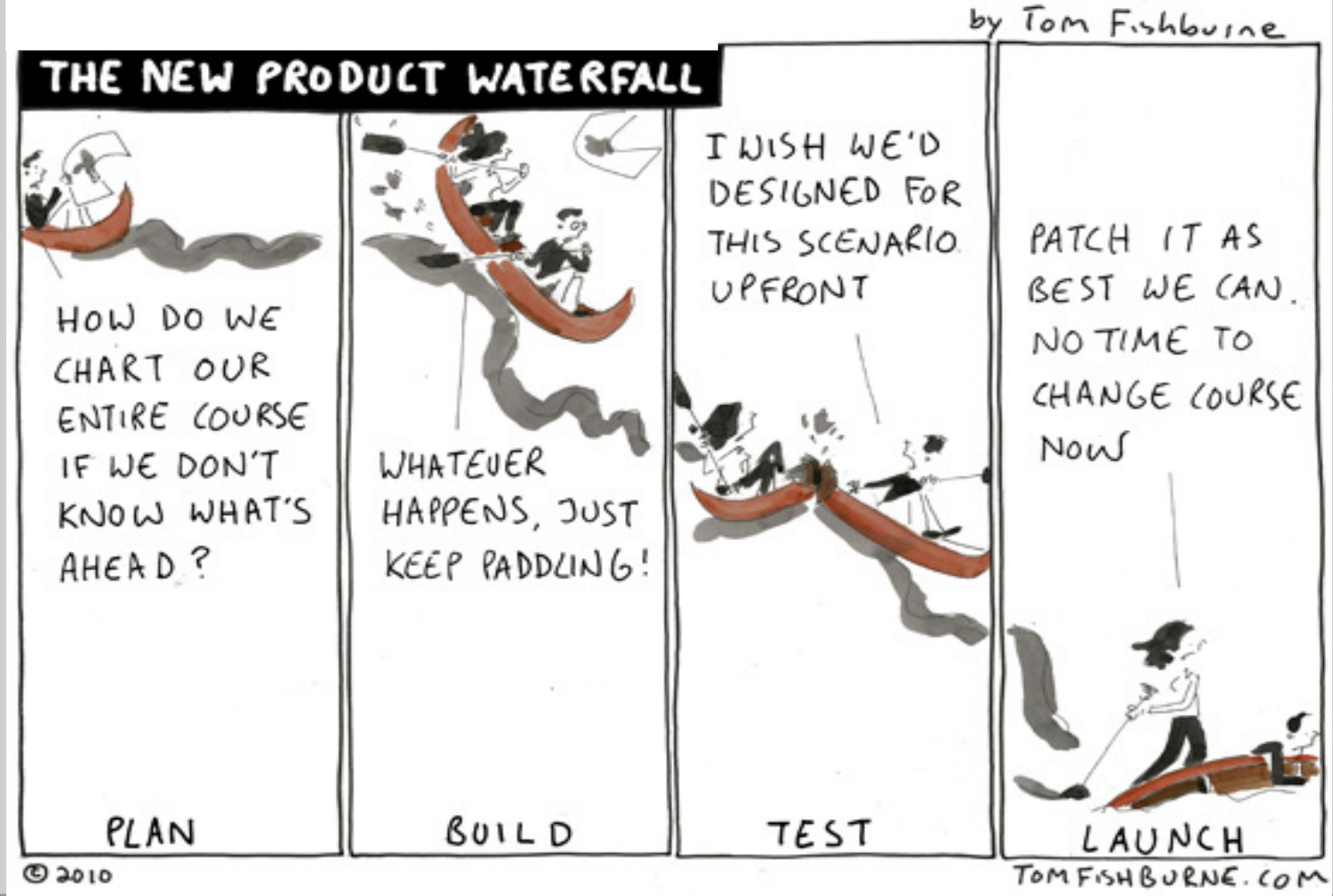
Design time must be adequate to ensure that the product is designed effectively and efficiently - in other words, professionally.

Lack of adequate time spent at the beginning of a design project will lead to other people's time-scales being effected due to defective products, market mismatches, overwhelming competition and the likes.

There is no alternative to adequate design time.

time-scales

product design brief



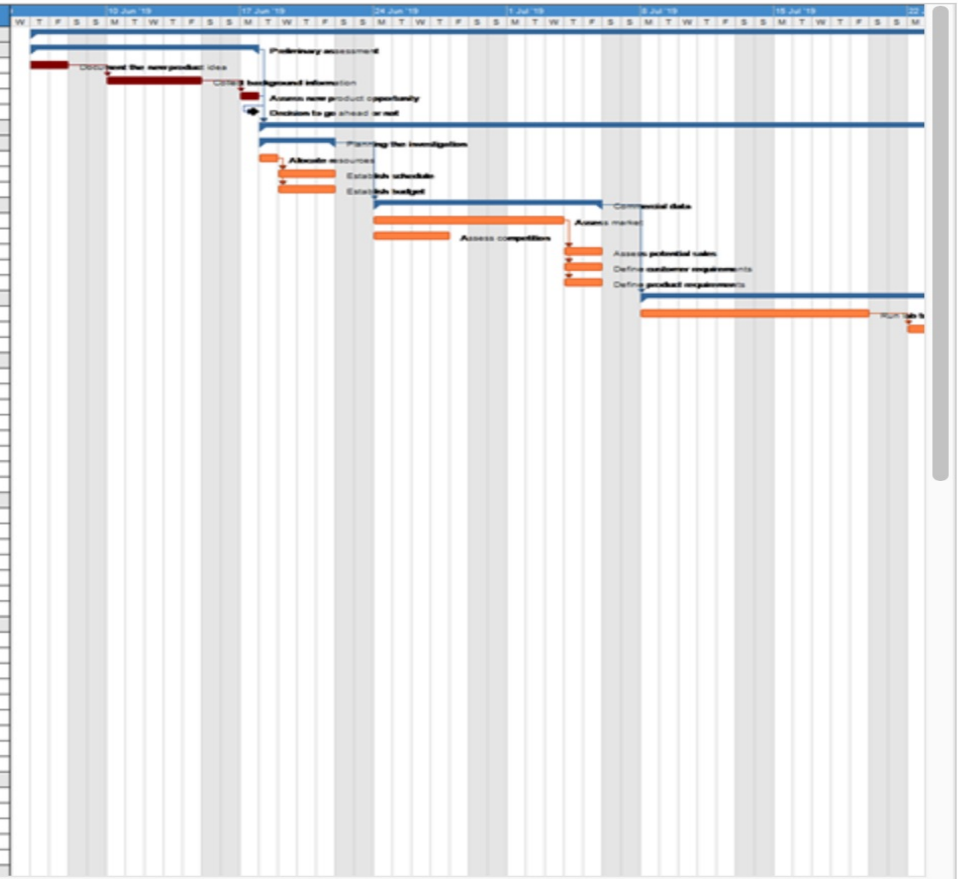
time-scales

product design brief

Developing a New Product - Gantt Chart

Open in MindView

			Task Name	Duration	Start	End	Predecessors	Completion	Priority	Resources	Work	Cost
1			**Developing a Ne...**	**250 days**	**06/06/2019**	**20/05/2020**		**0%**	**500**		**0 hrs**	**$0,00**
2			**Preliminary a...**	**8 days**	**06/06/2019**	**17/06/2019**		**0%**	**500**		**0 hrs**	**$0,00**
3			Document th...	2 days	06/06/2019	07/06/2019		0%	500		0 hrs	$0,00
4			Collect backg...	5 days	10/06/2019	14/06/2019	3	0%	500		0 hrs	$0,00
5			Assess new...	1 day	17/06/2019	17/06/2019	4	0%	500		0 hrs	$0,00
6			Decision to g...	0 days	17/06/2019	17/06/2019	5	0%	500		0 hrs	$0,00
7			**Investigation**	**44 days**	**18/06/2019**	**16/08/2019**	**2**	**0%**	**500**		**0 hrs**	**$0,00**
8			**Planning th...**	**4 days**	**18/06/2019**	**21/06/2019**		**0%**	**500**		**0 hrs**	**$0,00**
9			Allocate re...	1 day	18/06/2019	18/06/2019		0%	500		0 hrs	$0,00
10			Establish s...	3 days	19/06/2019	21/06/2019	9	0%	500		0 hrs	$0,00
11			Establish b...	3 days	19/06/2019	21/06/2019	9	0%	500		0 hrs	$0,00
12			**Commercia...**	**10 days**	**24/06/2019**	**05/07/2019**	**8**	**0%**	**500**		**0 hrs**	**$0,00**
13			Assess m...	8 days	24/06/2019	03/07/2019		0%	500		0 hrs	$0,00
14			Assess c...	4 days	24/06/2019	27/06/2019		0%	500		0 hrs	$0,00
15			Assess p...	2 days	04/07/2019	05/07/2019	13	0%	500		0 hrs	$0,00
16			Define cus...	2 days	04/07/2019	05/07/2019	13	0%	500		0 hrs	$0,00
17			Define pro...	2 days	04/07/2019	05/07/2019	13	0%	500		0 hrs	$0,00
18			**Technical f...**	**15 days**	**08/07/2019**	**26/07/2019**	**12**	**0%**	**500**		**0 hrs**	**$0,00**
19			Run lab te...	10 days	08/07/2019	19/07/2019		0%	500		0 hrs	$0,00
20			Establish p...	4 days	22/07/2019	25/07/2019	19	0%	500		0 hrs	$0,00
21			Overall as...	1 day	26/07/2019	26/07/2019	20	0%	500		0 hrs	$0,00
22			**Define requ...**	**5 days**	**29/07/2019**	**02/08/2019**	**18**	**0%**	**500**		**0 hrs**	**$0,00**
23			Developm...	5 days	29/07/2019	02/08/2019		0%	500		0 hrs	$0,00
24			Manufactu...	5 days	29/07/2019	02/08/2019		0%	500		0 hrs	$0,00
25			Resource...	5 days	29/07/2019	02/08/2019		0%	500		0 hrs	$0,00
26			Resource...	5 days	29/07/2019	02/08/2019		0%	500		0 hrs	$0,00
27			Systems	5 days	29/07/2019	02/08/2019		0%	500		0 hrs	$0,00
28			Operations	5 days	29/07/2019	02/08/2019		0%	500		0 hrs	$0,00
29			Maintenance	5 days	29/07/2019	02/08/2019		0%	500		0 hrs	$0,00
30			Service	5 days	29/07/2019	02/08/2019		0%	500		0 hrs	$0,00
31			**Other asse...**	**9 days**	**05/08/2019**	**15/08/2019**	**22**	**0%**	**500**		**0 hrs**	**$0,00**
32			Financial	5 days	05/08/2019	09/08/2019		0%	500		0 hrs	$0,00
33			Safety	5 days	05/08/2019	09/08/2019		0%	500		0 hrs	$0,00
34			Environme...	5 days	05/08/2019	09/08/2019		0%	500		0 hrs	$0,00
35			Legal and ...	5 days	05/08/2019	09/08/2019		0%	500		0 hrs	$0,00
36			Risk analy...	4 days	12/08/2019	15/08/2019	35;34;33;32	0%	500		0 hrs	$0,00
37			Assess inve...	1 day	16/08/2019	16/08/2019	36	0%	500		0 hrs	$0,00
38			Decision to g...	0 days	16/08/2019	16/08/2019	37	0%	500		0 hrs	$0,00
39			**Planning**	**11 days**	**19/08/2019**	**02/09/2019**	**7**	**0%**	**500**		**0 hrs**	**$0,00**
40			Product spec...	10 days	19/08/2019	30/08/2019		0%	500		0 hrs	$0,00
41			Financial plan	10 days	19/08/2019	30/08/2019		0%	500		0 hrs	$0,00
42			Schedule	10 days	19/08/2019	30/08/2019		0%	500		0 hrs	$0,00
43			Development...	10 days	19/08/2019	30/08/2019		0%	500		0 hrs	$0,00
44			Production pl...	10 days	19/08/2019	30/08/2019		0%	500		0 hrs	$0,00
45			Advanced n...	2 days	29/08/2019	30/08/2019	44FF	0%	500		0 hrs	$0,00
46			Launch plan	10 days	19/08/2019	30/08/2019		0%	500		0 hrs	$0,00
47			Assess plan...	1 day	02/09/2019	02/09/2019	46	0%	500		0 hrs	$0,00
48			Decision to g...	0 days	02/09/2019	02/09/2019	47	0%	500		0 hrs	$0,00
49			**Development**	**117 days**	**03/09/2019**	**12/02/2020**	**39**	**0%**	**500**		**0 hrs**	**$0,00**
50			Assign reso...	1 day	03/09/2019	03/09/2019		0%	500		0 hrs	$0,00
51			Establish use...	10 days	04/09/2019	17/09/2019	50	0%	500		0 hrs	$0,00
52			Review com...	2 days	04/09/2019	05/09/2019	50	0%	500		0 hrs	$0,00
53			Develop proc...	10 days	06/09/2019	19/09/2019	52	0%	500		0 hrs	$0,00
54			Produce first...	25 days	20/09/2019	24/10/2019	53	0%	500		0 hrs	$0,00
55			**Review pro...**	**25 days**	**25/10/2019**	**28/11/2019**	**54**	**0%**	**500**		**0 hrs**	**$0,00**



Most products require some form of testing after manufacture, either in the factory, on site or both. Products for the consumer or engineering markets usually require a factory test to verify the quality of the product and its eventual compliance with the PDS.

Curiously, this usually relates to the performance aspects which, although essential, represent a narrow view of the whole question of product evaluation.

Do we sample test one in ten, one in a hundred, or what?

Data collection and product history are needed to answer these questions. An initial test specification should be written at this stage. It is too late after the design has been completed!

regulations or directives which may be applicable to your product:-

- Active Implantable Medical Devices Directive
- ATEX Directive (Electrical and Mechanical equipment for use in explosive atmospheres)
- Energy Labelling Directive
- Energy Using Products Directive (EUP)
- Gas Appliances Directive
- General Product Safety Directive
- Hot Water Boilers Energy Efficiency Directive
- In-vitro Diagnostic Medical Devices
- Lift Safety Directive
- Low Voltage Directive
- Medical Devices Directive
- Measuring Instruments Directive
- Noise Emission of Outdoor Equipment Directive
- Non-automatic Weighing Equipment Directive
- Non-Road Mobile Machinery Exhaust Emissions Directive
- Personal Protective Equipment Directive
- Pressure Equipment Directive
- Radio and Telecommunications Terminal Equipment Directive
- Recreational Craft Directive
- Restriction of Hazardous Substances (RoHS) Directive
- The Batteries Directive
- Cableway Installations for Passengers Directive
- The CE Marking Directive

compliance

Compliance is ensuring that the requirements of legislation, guidelines or specifications are met.

Therefore have an understanding what regulations may be applicable that could influence this developmental process.

For example as a minimum requirement all non-food consumer products must conform to the General Product Safety Regulations.

compliance

Aspects that need to be considered include:-

- What function does your product/service have?
- Does it have a safety feature?
- Does it have any electrical components?
- Will it be sold In the UK?
- Will it be sold overseas?
- Is your product subject to specific regulations or are there tests or conformances which you as the supplier feel it would be appropriate to apply?

Example directive information: Medical Devices Directive and associated directives the **In Vitro Diagnostic Device Directive** and the **Active Implantable Medical Device Directive.**

Medical devices fall into one of four classifications: -

Class I	Low risk	(e.g. Temperature monitor)
Class IIa	Medium risk	
Class IIb	Medium risk	
Class III	High risk	(e.g. Stent)

There are a large number of rules (currently 18) to determine into which classification a medical device may fall, for example: -

“Rule 1 All non-invasive devices are in Class I, unless one of the rules set out herein-after applies....

There are a large number of rules (currently 18) to determine into which classification a medical device may fall, for example: -

" Rule 2 All non-invasive devices intended for channelling or storing blood, body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in Class IIa:

- if they may be connected to an active medical device in Class IIa or a higher class,
- if they are intended for use for storing or channelling blood or other body liquids or for storing organs, parts of organs or body tissues, in all other cases they are in Class I."

company constraints

The constraints of current company practice should be highlighted and discussed.

Possible manufacturing facility constraints, financial and investment constraints etc

Are there adequate in-house facilities for research, design, development, testing etc., including quality of personnel.

political, social and cultural... - implications

The likely effect of the product on the political and social structure of the market or country for which it is to be designed and manufactured should be considered. Typical factors include the effect of consumer movements, the stability of the market, and the avoidance of product features that can create social unrest and upset.

political, social and cultural... market constraints - implications

Feedback from the market intel' should be considered.

e.g. The first rough terrain telescopic handler was designed to utilise a range of Ford engines. At that point in time Ford products were unacceptable in the Middle East. So the design was changed to accommodate Perkins engines, as well as ford engines.

political, social and cultural... market constraints

product design brief

political, social and cultural... - implications

Knowledge of local conditions, particularly overseas, combined with a full knowledge of the market must be incorporated in the Design Brief and the PDS at the beginning of the project and as the design evolves.

Otherwise, if during the course of the project the market disappears, the whole activity may have proved to be a waste of time.

Patents, literature and product data

All areas of likely useful information should be investigated and researched, and in particular possible patent clashing should be known about as soon as possible.

It’s pointless designing something for sale in ignorance of someone else’s patent.

refence Sarah Whittle lecture session.

With the adoption by the EEC of product liability legislation (*still valid*), based in part on US experience, it is essential to consider the legal aspects of a design at both the product design brief and then again at the PDS stage.

Such legislation considers ‘product defect’ as its primary basis. Many defects are designed into a product through lack of adequate consideration of all the constraints at the outset.

It is suggested that ‘defect of specification’ may account for many ‘defects of design’ and even for subsequent ‘defects of manufacture’.

installation

Many products must interface with other products or be assembled into larger products or become structurally part of a building.

Installation therefore must be considered. This will include fixing holes and lugs, access, the volume available for the product, system compatibility, power compatibility and the like.

Circular Economy
(reference Eoin Bailey lecture session)

Disposal has been included as a primary element as the effects of man's design of products impinge more and more on our environment.

With many products, it is now not possible to 'forget' about the item after ownership has passed to the customer.

If the product contains hazardous or toxic parts, or indeed parts worth reclaiming, these should be considered at the PDS stage. Should we, for instance, design for disassembly.

Non-biodegradable plastic packaging and items made from plastic present a problem of increasing magnitude - in fact the whole problem of waste disposal and recycling looms large indeed.

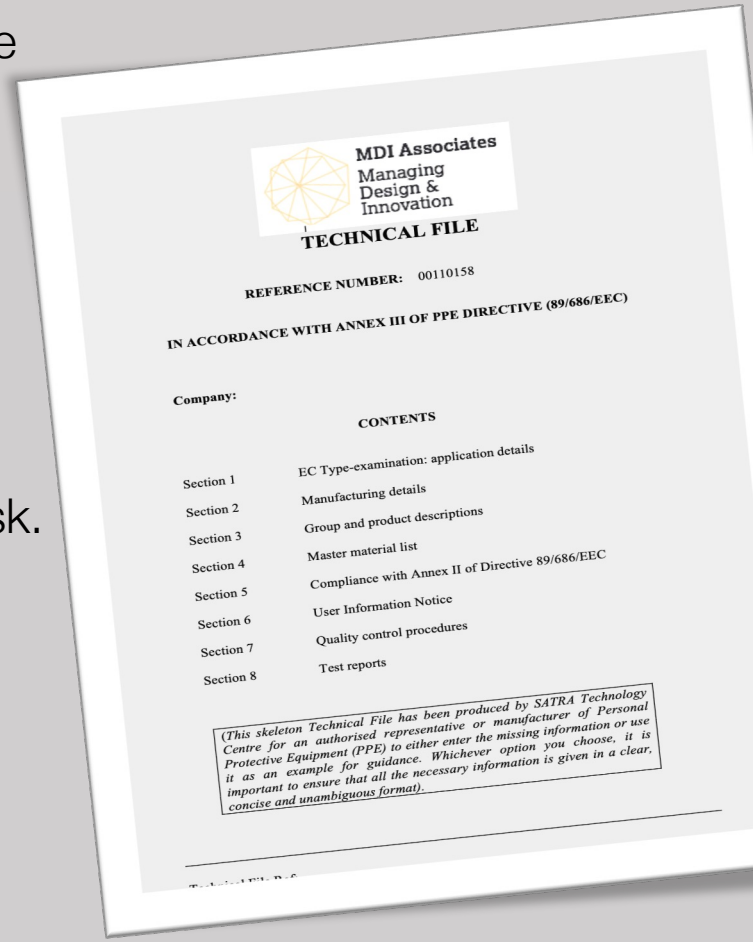
documentation

Product documentation is always important in terms of instructions to the user, the maintainer or others.

Even with consumer products, it is an important and vital task that must not be shirked (see ‘Safety’ and ‘Legal’ elements). With large turnkey projects, the associated documentation can become a substantial part of the overall design task.

In the light of previous comments re legal requirements, it is imperative that full documentation is prepared for all projects –

this should be done formally, not informally.



MDI Associates
Managing Design & Innovation

TECHNICAL FILE

REFERENCE NUMBER: 00110158

IN ACCORDANCE WITH ANNEX III OF PPE DIRECTIVE (89/686/EEC)

Company:

CONTENTS

Section 1	EC Type-examination: application details
Section 2	Manufacturing details
Section 3	Group and product descriptions
Section 4	Master material list
Section 5	Compliance with Annex II of Directive 89/686/EEC
Section 6	User Information Notice
Section 7	Quality control procedures
Section 8	Test reports

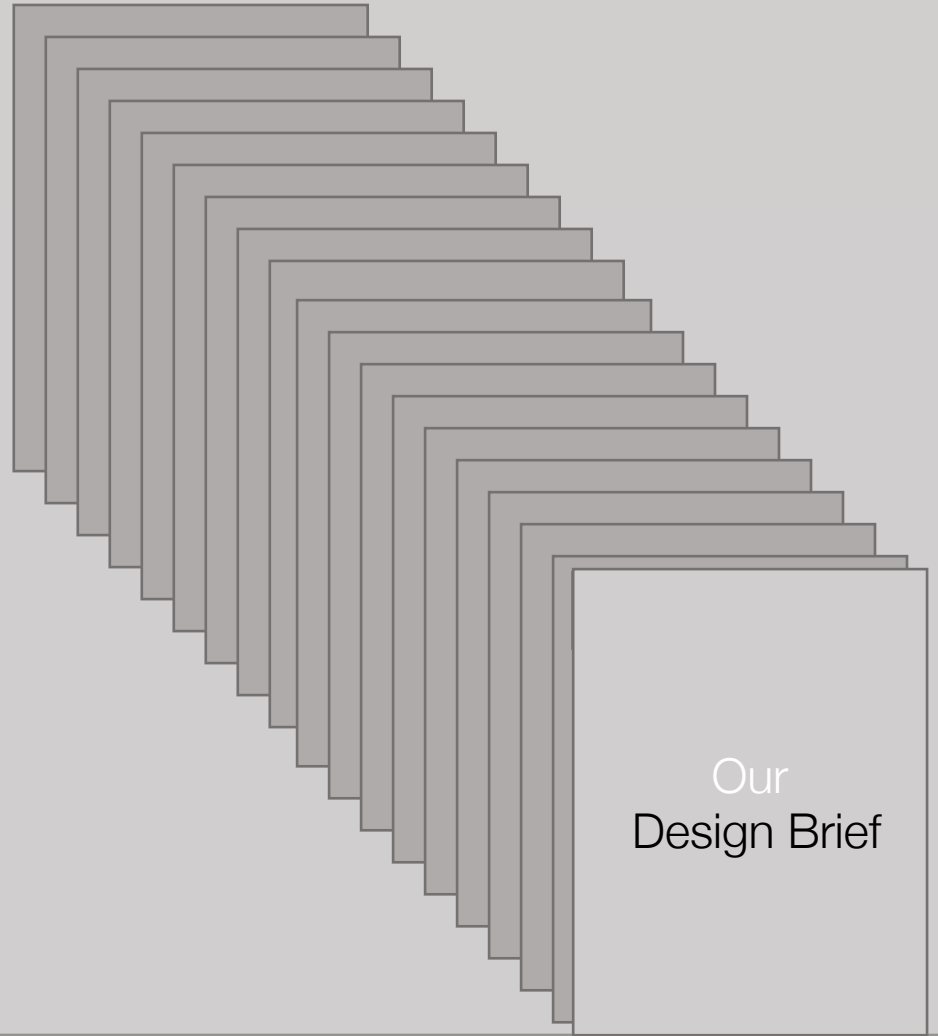
(This skeleton Technical File has been produced by SATRA Technology Centre for an authorised representative or manufacturer of Personal Protective Equipment (PPE) to either enter the missing information or use it as an example for guidance. Whichever option you choose, it is important to ensure that all the necessary information is given in a clear, concise and unambiguous format).

documentation

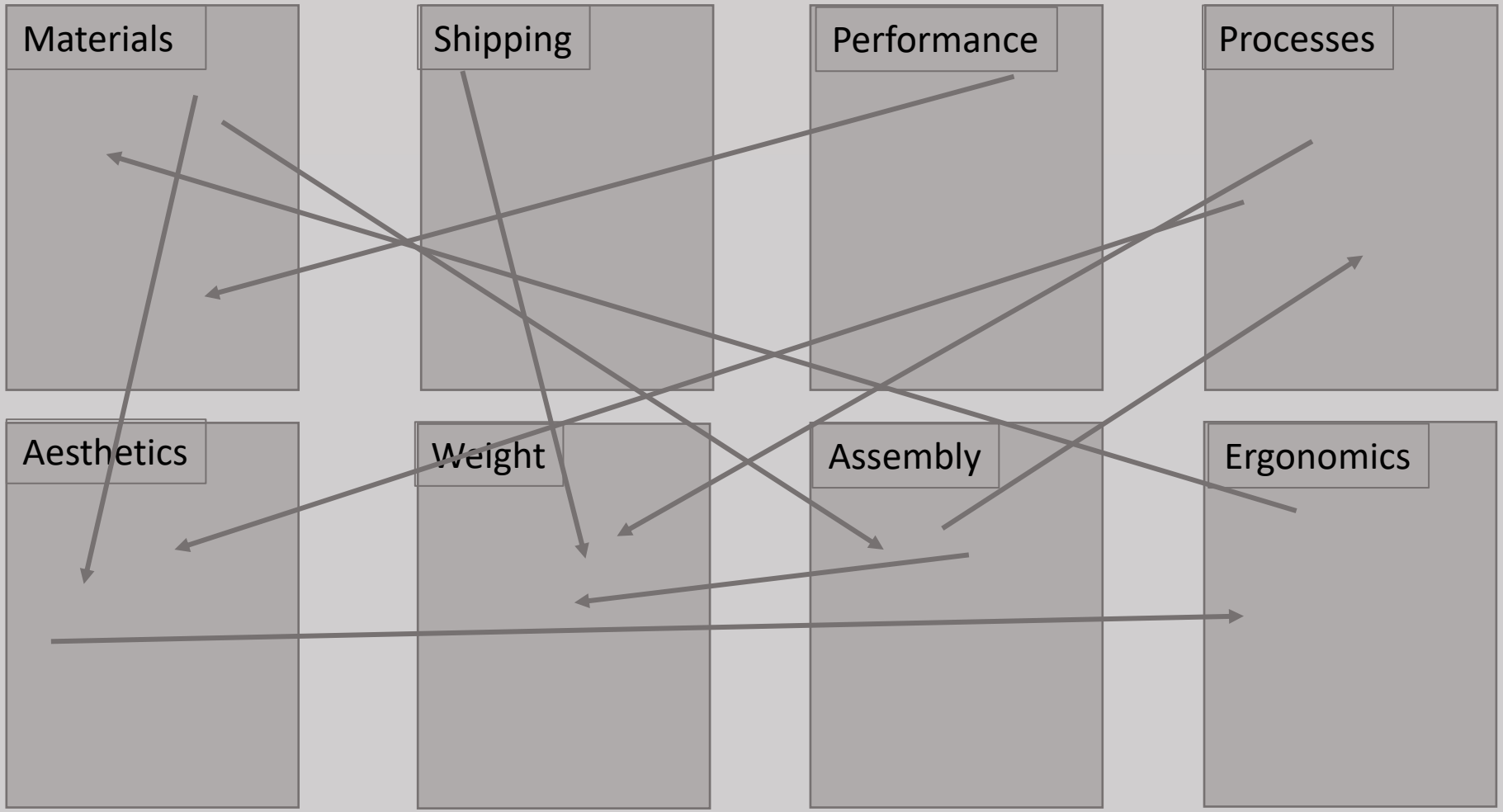
product design brief

Materials	Shipping	Performance	Processes
Aesthetics	Weight	Assembly	Ergonomics

the relationship
between the elements



the relationship
between the elements



the relationship between the elements

so be careful how you view your product design brief

INTRO TO ASSESSMENT B

background

- You are NPD and Innovations Manager of a Welshpool -based SME which currently specialises in the manufacture of electronic breathalyser systems

(Consider the website of Lion Laboratories as an example company of this type ONLY)

A new product development project

In light of the recent Coronavirus pandemic, the Company see great potential in developing a product that can meet both clinical and personal requirements for such virus detection and are therefore anxious to bring the new product to market as soon as possible.

Task One

The Brief will require and therefore preceded by a synopsis of the device – and its potential as a new product development.

Task Two

The development of an NPD control document –The Product Design Brief

Tasks

Examples of the elements to be considered may well be, but not exclusively;

aesthetics	installation	performance	safety
branding	intellectual property	politics	size
company constraints	legal	processes	shelf life and storage
competition	life in service	prototyping	shipping
customer	materials	product cost	social & cultural
circular economy	manufacturing facilities	product life span	standards & specifications
documentation	market constraints	quality	testing
environment	maintenance & repair	quantity	time scale
ergonomics	packaging	reliability	weight

Task Two

The development of an NPD control document –The Product Design Brief

- As the NPD and Innovation Manager you're required to produce a Product Design Brief that will provide a touch point for all the company's managers; design & engineering, manufacture, finance, marketing logistics etc.
- The brief will focus on the what needs to be considered to bring the product into existence - and will used to inform the various mangers within the company of the elements of the Product Design Brief that will need to be appreciated and deliberated.
- The projected manufacturing volumes in the first year is likely to be no more than 750,000, potentially 3million per annum afterwards.

Tasks

Word count: 4,500 words

Hand in date: noon 26th May 2023