



PRODUCT DESIGN BRIEF

Management of New Product Development

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Synopsis

The company is currently exploring the manufacture and release of a new product line – a device that can detect viral presence on a person in real time. It has not yet been determined whether this device can/should/will detect the level of viral load or the presence of more than one virus; likewise, the mechanism for detection has not been determined fully yet, although the most likely mechanism at present is via a saliva sampling port. The product design brief is critical for defining critical product capabilities and features such as these.

The company has a level of existing experience in the manufacture of diagnostic tools given its history producing, amongst other lines, electronic breathalyser systems. The potential to expand to an adjacent market has been recognised and so this project is underway.

Given the impact of the recent (and ongoing) Covid-19 global pandemic, it's necessary (and prudent) for the company to release this product to market as rapidly as possible, hence this design brief must consider the relevance of time scales at every stage of the process, from initial design through to build and eventual sale, and the impact upon, for example costs, safety and reputation, of fast-tracking certain stages where possible.

This design brief outlines all aspects of the planning, design, production and operation processes related to this new product and evaluates all and any considerations required relating to these phases. Specifically, it is a vehicle by which the NPD team and all related parties can review and assess the requirements for the successful launch of this product, and provide a platform from which to further/better develop the product with these considerations in mind. The interested parties will include, but are not limited to:

- The executive and non-executive board teams
- Shareholders and stakeholders
- Component and materials suppliers
- Third-party manufacturing, distribution and sales partners
- Third-party R&D partners
- Retained legal advisors working on behalf of the company
- Internal teams
 - ❖ Finance
 - ❖ Engineering
 - ❖ Branding/Marketing
 - ❖ Operations
 - ❖ Health & Safety
 - ❖ Compliance
 - ❖ Production
 - ❖ R&D
 - ❖ Sales
 - ❖ Admin

NB: this is a controlled document. Reviews and amendments must be tracked and approved by the NPD lead – no unauthorised amendments are to be accepted or progressed by any individual or department. Printed and/or offline copies are uncontrolled.

Limitations of this design brief:

This document provides an outline consideration of all aspects of this product but product dimensions/layout/design features for production should be read from the approved manufacturing drawings only.

Identification of the new market potential for this product:

The product will sit within the rapid, non-invasive clinical detection market. In terms of market positioning, the retail price (including the retail price of ongoing consumables e.g. saliva test consumables) will need to be pitched at a level such that ordinary individuals are able to afford, and prioritise, the purchase of this product. As such, all contributors to this design brief will need to keep the impacts of design/manufacture etc decisions upon costs prominent in their minds during the whole process. There are a range of potential new markets for this product as outlined below:

Clinical Settings

1. Hospital admissions – patients can be assessed prior to admission (if scheduled in/out patients) or in triage (for urgent car admissions) to control and prevent further viral spread to staff and vulnerable patients
2. GP surgeries – rapid confirmation of viral presence/absence in patients presenting with key, 'hallmark' symptoms to free up GPs time, improve service levels and help to reduce unnecessary prescribing of antibiotics
3. Nursing homes/hospices – real time 'on the spot' checking of patients and visitors to identify and control viral spread

Personal/Domestic Settings

1. Travellers – immediate testing prior to travel to prevent a) viral spreading and b) potential issues around entry requirements to other countries (provides peace of mind for travellers)
2. Schools/day-care settings – rapid confirmation of presence/absence of virus to allow teaching staff/childcare providers to make an informed decision on whether to accept/deny children who present with symptoms
3. Individuals displaying symptoms - allows individuals to self-diagnose (at a very basic level – presence or absence) and therefore make an informed judgement on their need to access further medical care (self-treat at home vs pharmacy vs GP vs urgent care), easing pressure on GP services and reducing unnecessary GP/urgent care visits

Specific considerations relating to this market potential:

- a. Consideration of skill/intellect/comprehension levels of end users
- b. Ethical considerations surrounding the use of at-home diagnostic testing on newborns/infants/children
- c. It is important to note that such at-home diagnostic tools are not a substitute for advice/clinical judgement from a licensed doctor (insurance implications/duty of care/acknowledgement of limitations)
- d. Legal statements/mitigations to safeguard the company against legal action in the event of misdiagnosis

Private Sector Corporate Settings

1. Stadiums/Arenas – rapid testing on entry for ticket holders if required by Coronavirus (2019) regulations or similar
2. Airports/Airlines – qualitative testing of passengers prior to boarding in order to prevent/minimise viral spread
3. Oil rigs/offshore/contained environments – real time testing for the prevention of viral spread between closely contained staff members/contractors

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1.0 Aesthetics | Branding | Size | Weight | Ergonomics

- **Colour**
 - Matching brand identity/image
 - Matching to other products within the same range
 - Durability of colour coatings/features
 - Method of colour coating – spray, dip, wrap etc
 - Future recyclability of product with this colour coating
 - Similarity of colours to competitors
 - One product available vs the same product available in several colours/designs
- **Logos**
 - Placement of logo (if logo is present) and product name etc.
 - Trademarking/IP considerations of logo use
 - Size and position of logo – prominence on product
- **Fonts**
 - Should be on-brand
 - Should be appropriately sized, spaced clearly and easy to read
 - Colour of fonts – easy to read and discernible against background colours
 - Compatibility with visual disabilities
- **Associated packing aesthetics**
 - Colour and visual design of accompanying packaging
 - Size
 - Textures
 - Print techniques – embossing, debossing etc.
 - Print capabilities – ink types
 - Packaging substrate and accompanying materials e.g. padding
 - Fit within initial/secondary packaging
 - Requirement for storage bag/case (further design brief consideration is required for this)
- **Product differentiation**
 - Similarity of colours/design/layout etc to competitors' products
 - Shelf appeal
 - On-packaging descriptors/imagery etc.
- **Shape & Weight**
 - Compatibility with hand/arm/muscle disabilities/physical limitations e.g. arthritis
 - Should facilitate easy storage
 - Suitably weighted for both male and female grip/handspans
- **Ergonomics**
 - Suitable for use one-handed
 - Tactile/ridged/clearly defined area (by touch alone) to indicate correct positioning within hand without visual assistance
 - Lightweight enough to be held in one hand, including by weakened/vulnerable adults/those with arthritis etc
 - Smooth, rounded shape with slight weighting to one end to facilitate easier positioning in the cradle between thumb and rest of hand for comfortable use
 - Sized appropriately to fit both male and female hands
 - Sampling port (if present) must be accessible without any other part of the product obstructing view/being distracting/risk of contact with eyes etc

- **Size**
 - Handheld device – should be sized appropriately for both male and female handspans
 - Minimum and maximum size to be considered alongside:
 - Cost implications of sizing options
 - Packaging options for sizing options (primary, secondary and tertiary)
 - Optimum size for visual preference
 - End use – does it need to fit in a handbag/briefcase etc.?
 - Pricing implications based on size
- **Display**
 - Basic colour indicators vs digital display
 - Contents/detail of display
 - Length of display/auto power off after defined period of inactivity
 - Buttons vs touchscreen – size/location/single use or multi-menu function
- **Alerts**
 - Audible alerts to verify positive/negative outcome, incorrect use etc
 - Visual alerts to verify positive/negative outcome, incorrect use etc. (flashing lights)
 - Impact of flashing lights etc. on disabilities/medical conditions e.g epilepsy
 - Digital display of outcome, ready signal etc.
 - Length of alert
- Accessories – charging port vs. battery compartment and location/shape/prominence of these
- Detection mechanism – single use breathalyser-style tubes/sanitize-able sensors/non-contact etc.
- Finish – smooth to facilitate sanitising vs any ridges required to indicate correct placement in hand etc.

Cross Reference Considerations With:

Social | Cultural

Materials

Environment

Manufacturing Facilities | Processes

Testing | Prototypes | Standards | Specification | Quality

Performance

Life In Service

Product Cost

Packaging | Shipping | Size | Weight

Timescales

Competition

Intellectual Property | Legal

2.0 Social | Cultural

- Language
 - Communications during NPD/internal processes
 - Communications with third party suppliers/manufacturers etc to ensure nothing is lost in translation/misinterpreted
 - Range of languages within product instruction manual/warranty booklet/packaging etc and how these will be verified for accuracy
- Technical Language – depending on the end user, the level of technical language utilised will need to be reviewed. For clinical consumers, a technical level is appropriate but this should be softened if the end user is more likely to be a domestic consumer ('layman's terms')
- Cultural Awareness
 - Checks to ensure that no product names, imagery, logos, product shapes etc have negative/inappropriate connotations in other cultures and countries
 - Review of colour schemes to ensure that colours used are not perceived as unlucky/inappropriate etc in other countries and cultures
 - Varying date/time formats by country
 - Varying number formatting and units of measurement
 - Cost/benefit analysis of including e.g. Cyrillic alphabet if required
 - Intuitive visual display of positive/negative result
 - USA, Japan, UK etc – red = negative result/failure, green = positive result/pass
 - Taiwan, Korea – red = positive result/pass, green = negative result/failure
- Demand
 - Review of culture towards personal responsibility for healthcare/viral detection/isolation requirements/adherence to public health regulations across a range of cultures and countries to determine whether there is likely to be strong demand from one country or culture, or very low demand (e.g. China's response to the Covid-19 pandemic – a high level of personal responsibility for illness prevention/prevention of spreading, mask wearing etc suggests that this product would be likely to be successful if launched within the domestic Chinese market – therefore, greater emphasis could be placed upon appropriate branding/Chinese language prominence within this product)
- Accessibility
 - Consideration required as to how end users will obtain and use the product depending upon their location and the surrounding infrastructure;
 - A battery powered option (either single use or rechargeable) is most appropriate for developing countries/disaster zones/rural/off-grid settings as this would allow immediate and constant access

Cross Reference Considerations With:

Aesthetics | Branding | Size | Weight | Ergonomics

Environment

Testing | Prototypes | Standards | Specification | Quality

Competition

Intellectual Property | Legal

3.0 Materials

- Costs
 - Minimum order quantities, bulk purchase discounts
 - Impact of varying colour/casing/materials/packaging/displays etc upon cost
- Availability and sourcing
 - Availability of materials in colour/size/substrate outlined in specification
 - Continuity/security of supply on an ongoing basis for a number of years
 - Location of primary manufacturing sites for all components/materials; impact of this upon costs/lead times/supply chain resilience
- Sustainability/circularity
 - Use of recycled/recyclable materials within product manufacture and within packaging and subsequent logistical operations
 - Presence of single use/disposable sensors/detector sticks etc
- Durability
 - Toughened materials
 - Rubberised protective secondary casing
 - Wipe-clean, non-porous initial casing
 - Replaceable materials – non-permanent bonding between parts to allow for replacements
 - Impact of interfacing of component parts, pressure points, material constraints
- Pre-assembled vs loose componentry
 - Potential for cost savings if loose componentry used BUT
 - Impact upon storage methods/space requirements, labour costs/requirements and potential for issues when assembling componentry
 - Methods/materials for adherence – glue, snap-fit, screw-fit, complete moulding
- Power source - mains vs battery (single use) vs battery (rechargeable)
 - Impact upon sustainability/circularity
 - Cost implications (both in manufacturing and to the end user)
 - Reliability – battery-powered (both single use and rechargeable) can be used anywhere regardless of facilities/infrastructure – potential for use in developing countries/disaster zones etc as well as more standard fields
- Capability of existing materials vs requirement to develop innovative new materials – is what is desired/required already in existence, or is innovation required?
- Use of universal/common materials with existing products within company to maximise cost savings/minimise stock-holding (impacting cashflow)/providing the ability to switch between manufacturing of different products at short notice
- Batteries (if present) – it would be preferable/more convenient to domestic/personal consumers to use common type batteries e.g., AA/AAA rather than specialist batteries

Cross Reference Considerations With:

Aesthetics | Branding | Size | Weight | Ergonomics

Environment

Manufacturing Facilities | Processes

Testing | Prototypes | Standards | Specification | Quality

Performance

Life In Service

Product Cost

Packaging | Shipping | Size | Weight

Timescales

Company Constraints

4.0 Environment

- Should be operable in, and unaffected by, areas of high and low humidity (e.g. labs)
- Must be water resistant at the very least - if not waterproof - to reasonable depth (to permit adequate and full cleaning)
- Casing/all externally facing components must be unaffected by the use of alcohol sanitisers/abrasive cleansers (to facilitate proper cleaning to prevent/minimise viral spread)
- For operating potential across the widest number of markets globally, the unit should be operable within reasonable minimum and maximum temperatures e.g. -10°C - 45°C (cost/benefit analysis of establishing this is strongly recommended)
- Casings should be either a) one single casing or b) the minimum required number of casings with minimum interfaces between them to minimise 'dead spots' where dust/dirt/residues gather (during manufacture, storage and use)
- If the power source is via battery (either single use or rechargeable), mitigations should be in place to minimise the risk of battery corrosion/battery acid leaks in the event of local temperature extremes/impact/low utilisation for a prolonged period
- Display should contain anti-glare/low reflection screen to allow optimum visibility/readability in all environments (including both artificial and natural lighting, sunlight glare etc)
- Mitigations should be in place to prevent damage by shock or vibration, particularly during transport or handling (drops). This may be in the form of protective casing, or secondary/tertiary packaging e.g., bubble wrap

Cross Reference Considerations With:

Materials

Manufacturing Facilities | Processes

Testing | Prototypes | Standards | Specification | Quality

Performance

Life In Service

Product Cost

Intellectual Property | Legal

5.0 Manufacturing Facilities | Installation | Processes

- Cost/benefit analysis to assess internal/in-house manufacturing/packaging/dispatch vs third-party
- If internal/in-house;
 - Is there adequate scope and capacity in existing production operations to introduce this new product line and on what schedule?
 - Is there then the capability to upscale for year 2 production levels?
 - Is the infrastructure sufficient or does it require upgrading/entirely new production lines?
 - What are the minimum and maximum run/unit rates? Do these match the production volumes anticipated?
 - Requirement for manufacturing facilities to obtain UKAS/BS/ISO etc standards
 - Timescales
 - Costs (and methods of funding e.g subsidies, grants, and then ROCE/ROI)
 - Resources
 - Investment into technology/systems/infrastructure
 - Methods of financing for labour/material costs/infrastructure (e.g. new production line) costs
 - Is there adequate storage?
- If third-party;
 - Sourcing of appropriate facility and agreement of partnership
 - Agreement that production volumes, dispatch rates, quality etc are to agreed standard
 - Potential for upscale for year 2 production requirements
 - Requirement for ongoing audits of third-party manufacturing facilities
 - Agreed costings/financial deal and payment terms for this agreement
 - Assessment of continuity of supply
 - Fallbacks in the event of failure to supply, breach of quality standards etc
- Processes – requirement for full specifications, work instructions, safe working procedures, risk assessments, conformance testing, product testing
- Define order of assembly for all componentry
- Installation – timescales for infrastructure to be installed, setup times, initial component lead times etc

Cross Reference Considerations With:

Materials

Environment

Testing | Prototypes | Standards | Specification | Quality

Packaging | Shipping | Size | Weight

Timescales

Company Constraints

Market Constraints

6.0 Testing | Prototypes | Standards | Specification | Quality

- Defined idea of how product should look and operate
- Initial drawings/specifications outlining a) product size/dimensions and b) size and relative position of secondary features on/within the product e.g. location of charging port/battery compartment/digital display/buttons/casing etc as appropriate
- Agreed aims and testing parameters for each stage
- Agreed verification strategies to clearly define pass or fail at each stage
 - Internal
 - External/independent
- Prototyping costs and ability to prototype to specific/close degree of final product to match real conditions as far as possible – R&D skill levels/R&D infrastructure
- Anticipated number of prototypes and specific angles/purposes for which they are required
- Testing requirements
 - Internal
 - Legal minimum standards (domestic and global)
 - Minimum standards of conformity (domestic and global)
- Repeatability of results in both lab and ‘in the field’ testing scenarios
- Defined and measurable quality level/standards and quality assurance procedures – BS EN ISO 13485, BS EN 62366
- Ongoing quality management systems – ISO 13485
- This device will fall under Medical Devices Class I – Low Risk
- Defined system for the management of units that do not meet the defined quality standards
- Wastage policies
- Testing/reviews of performance under repeated and high-frequency usage/cyclical loading
- Defined sampling rates and frequencies
- Defined upper and lower detection limits
- Scope of viral detection – detection of specific virus type, or broader range
- Qualitative vs quantitative detection
 - Impact upon cost
 - Impact upon reliability
 - Range of potential end users

Cross Reference Considerations With:

Materials

Performance

Life In Service

Packaging | Shipping | Size | Weight

Company Constraints

Intellectual Property | Legal

7.0 Performance

- Required vs achievable input and output levels
- Duty required
- Stresses
 - Environmental
 - User activity
 - Physical stresses (during manufacture/storage/transport/use)
 - ideal performance vs achievable performance (critical functions vs added value/idealistic functions)
- Definition of 3 possible unit states:
 - Dormant (device is turned off, no digital displays, no functionality)
 - Passive (device is using power, but is not actively obtaining/reporting data – awaiting further user activity)
 - Active (device is monitoring/interpreting/reporting data – i.e. detecting the presence or absence of a virus)
- The device needs to be portable and safe in all 3 states
- Suitable for staccato use albeit potentially on a high-frequency basis (staccato as the unit will require either sanitising or changeout of detection components between users but potentially on a high-frequency basis in settings such as arenas/airports etc where visitors may be tested in entry queues)
- Outline of product operating mechanism:
 - The unit will contain a port to load a saliva sample
 - How is sample security/prevention of contamination managed?
 - The user will load the saliva sample by swabbing
 - How easy is the product to use for normal consumers/unskilled users/the elderly/disabled users?
 - The unit will then determine whether a viral load is present or absent
 - What mechanism will the unit use to detect? (assay/electric current/antibody binding etc and clinical evaluations of each)
 - How accurate is this mechanism? What are the detection limits?
 - Next the unit will interpret this detection outcome and convert it to a reportable outcome before reporting it (green or red lights/+ or – text/quantification of load level etc)
- Definition of time taken to test, and time taken to achieve results
- Expectation, and verification of, repeatability of results (see also ‘Testing’)
- Obtainable vs ideals - is the reporting outcome qualitative or quantitative?
 - A quantitative result would result in a far wider potential market reach and would likely appeal to more users in bulk clinical settings, but would inevitably require far heavier investment in terms of money, time and R&D
 - Given the time scale within which this product is expected to be ready for market, a qualitative diagnostic tool is more obtainable at this stage
- Accessibility of the battery compartment (if present) – this must be secured appropriately to ensure that babies and children are not able to access the battery directly for safety reasons

Cross Reference Considerations With:

Materials

Environment

Manufacturing Facilities | Processes

Testing | Prototypes | Standards | Specification | Quality

Life In Service

Product Cost

Intellectual Property | Legal

8.0 Documents

- Records of conformance/accreditations
 - Calibration certification
 - UKAS certification
 - British Standard certification
 - ISO certification
 - Certificate of conformance
- Testing records – to permit verification/proving of marketing claims, performance claims etc
- Requirement for an instruction manual – paper vs digital vs video link
- Requirement for warranty record/information (if warranty is agreed to be necessary by NPD team)
- Range of languages required for warranty information and instruction manual and resultant impact upon costs
- Technical drawings
 - Sign off procedures and records for technical drawings issue and approval
 - IP/patent/trademarking management of technical info/drawings
 - Storage of data/documents and subsequent reviews
 - Electronic sign offs/document issues/amendments vs manual
 - Establishment of an approved update/sharing/approval process for the NPD team to ensure no updates are missed/lost/misconstrued

Cross Reference Considerations With:

Social | Cultural

Manufacturing Facilities | Processes

Testing | Prototypes | Standards | Specification | Quality

Performance

Life In Service

Market Constraints

Intellectual Property | Legal

9.0 Life in Service

Product Life Span | Maintenance & Repair

- Minimum and maximum expected life in service
 - Definition of 'reasonable use'
 - Frequency of use
- Contingency if minimum life in service not met
 - Warranty
 - Optional product insurance
- Mitigations to prolong life in service
 - Toughened materials
 - Rubberised casing
 - Facilities for servicing and repair (and recommended frequencies)
- Availability and cost of replacement components (including single use components)
- Level of user modifications permitted – can users repair the product; full repair/limited (e.g., battery changes) or no user repairs?
- Purchase methods – outright purchase/hire/loan

Circular Economy | Sustainability

- Impact of colour/materials/power source on recyclability of product
- Cost implications of opting for a more sustainable/circular product (full or compromise)
- Impact of sustainable materials on product durability and lifespan
- Potential for internal repair/refresh to create a secondary market for pre-used/'pre-loved' products
- Use of recycled materials within product manufacture (including single use components to be used as part of this product)
- Impact of power source on circular economy and sustainability
 - Battery (single use) vs battery (rechargeable) vs mains power source
- Construction of product
 - Adherence of components to each other – permanent bonding (potentially limiting the re-useability/recycling of product) vs screwed/tension/slotted components
 - Use of minimum number of different materials to make recycling 'as a whole' more likely/easier
- Packaging components
 - Single use vs recyclable/recycled
 - Minimum tertiary packaging to ensure product integrity and protection while minimising shipping footprint/weight and disposable wraps
- Transport and logistics
 - Minimum shipping volumes
 - Carbon footprint offsetting
 - Minimising total product weight by stripping weight from each component ('lightweighting')
 - Sharing logistics
 - Use of EV in transport where possible
- Management of manufacturing waste related to this product

- Operating methods and sustainability culture of 3rd party manufacturing sites (both component and whole product) including emissions, VOCs etc

Cross Reference Considerations With:

Materials

Environment

Manufacturing Facilities | Processes

Testing | Prototypes | Standards | Specification | Quality

Performance

Documents

Product Cost

10.0 Product Cost

- RRP/wholesale/bulk product costs
- Impact of import/export taxes (both at component stage and final sale stage)
- Consumer perception of product value vs RRP
- Benchmarking against competitor products
- Evaluation of acceptable profit margins
- Buffering against price increases in the near future (< 18 months) and exchange rate fluctuations
- Purchasing methods – outright purchase vs commercial lease/subscription service
- Servicing/calibration/repair costs (if required)

Cross Reference Considerations With:

Aesthetics | Branding | Size | Weight | Ergonomics

Materials

Manufacturing Facilities | Processes

Testing | Prototypes | Standards | Specification | Quality

Performance

Life In Service

Company Constraints

Competition

11.0 Packaging | Shipping | Size | Weight

- Availability of packaging components to match stock holding methods of company e.g JIT
- Packaging aesthetics (considerations as per section 1.0)
- Minimum/maximum packaging volumes at secondary and tertiary level
 - To maximise shipping carton/pallet/shipping container space (minimising shipping fees and maximising shipping volumes)
 - To comply with shipping/logistics weight/loading requirements
 - To hold/move appropriate stock volumes for a reasonable order-to-sale time window
- Likewise, minimum/maximum packing dimensions/weights for the same purposes
- Packaging configurations for primary, secondary and tertiary levels (to include shipping cartons, pallets and shipping containers) to maximise available space in storage and on dispatches
- Strength of packaging materials – maximum load testing for single units, plus secondary/tertiary packs
- Stacking limits for complete packages (single and bulk units, and for prolonged periods)
- Requirement for additional inserts for bulk shipping cartons (requires further NPD brief scope if it is agreed that such inserts are rewired)
- Requirements for barcodes/unique product identifiers to support stock-holding, identification and sale
- Sustainability of packaging
- Cost of packaging to required design/specification
- Packaging considerations across global markets
 - One version of primary, secondary and tertiary packaging for all markets (more cost effective, but requires either a) all potential languages for relevant markets on one label/accompanying document or b) and overlay sticker with the relevant information in relevant languages for each market OR
 - Different packaging at primary/secondary/tertiary stage for each market, specific to the relevant language for that market
 - Impact on cost and stock-holding capabilities for option 2 vs option 1
- Requirement for additional inner packaging/protection substrate e.g., bubble wrap, tissue, sealed bags/sanitised wrapping
- Requirement for any components to have sterile packaging e.g., sensor tubes
- Domestic and global legal requirements for packaging including for customs use

Cross Reference Considerations With:

Aesthetics | Branding | Size | Weight | Ergonomics

Materials

Manufacturing Facilities | Processes

Testing | Prototypes | Standards | Specification | Quality

Performance

Documents

12.0 Timescales

- Establish reasonable and obtainable sales targets for years 1 – 5 (continuously reviewed) in order to work back to establish required componentry lead times, financial outlay scheduling, shipping timescales, and manufacturing rates and timescales.
- Outline the critical stop/go points within this NPD process
 - Implement a 'critical path' plan to establish this
- Outline the milestones that need to be hit by specific dates to allow for a successful 'on track' launch
- Determine which activities can run concurrently and which require triggering from other specific outcomes
 - Implement and maintain a shared Gantt chart
- Establish the existence of any flex points (i.e. where the timings of some processes can slip slightly without impacting the follow on points drastically), where they sit and the degree of flex

Cross Reference Considerations With:

Aesthetics | Branding | Size | Weight | Ergonomics

Materials

Manufacturing Facilities | Processes

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Performance

Product Cost

Company Constraints

13.0 Company Constraints

- Financial
 - Affordability – short and long term
 - Infrastructure, machinery, modifications to production lines etc
 - Labour costs (production line, R&D, design, engineering, sales etc)
 - Components and tooling, setup fees etc
 - IP, patenting, licensing fees etc.
 - Marketing costs
 - Return on investment/return on capital employed – payback
 - Funding options – internal vs/+ external funding, government grants, subsidies etc
 - Potential for joint venture(s)
- R&D
 - Availability and skill level of R&D facilities/team
 - Acceptance of this product as an R&D focus
 - Affordability/allocation of company funds
 - Timescale – length of time to plan, implement and evaluate the R&D strategy
- Manufacturing Capabilities/Facilities
 - Available time (labour and machine time) to produce prototypes/test processes
 - Minimum/maximum production run levels
 - Required unit production rate
 - Level of automation available/necessary
 - Outline of automated processes vs manual processes and impact upon production schedules and labour costs
 - Capacity within existing manufacturing systems/operating schedules to insert production of this item
- Knowledge & Skills
 - Internal skill levels
 - Potential for upskilling existing staff
 - Requirement to recruit additionally skilled staff
 - Potential for outsourcing
 - Cost/benefit analysis associated with recruitment/upskilling/outsourcing
- Culture – culture of innovation, company/executive team approach to risk
- Buy-in
 - Employees
 - Executive team
 - Shareholders
 - Stakeholders

Cross Reference Considerations With:

Materials

Manufacturing Facilities | Processes

Testing | Prototypes | Standards | Specification | Quality

Performance

Product Cost

Timescales

Intellectual Property | Legal

14.0 Market Constraints

- State of existing market
 - Market sensing
 - Management Information Systems (MIS)
 - Marketing Research
 - Marketing Intelligence (MI)
 - Cross Disciplinary Tools (MI+)
 - Market saturation
 - Market dominance by competitors
 - Existing product/market perception
 - Existing brand perception
 - Current demand for similar products and consumer willingness to pay appropriately
 - Price ceilings in existing market for similar products/technology
 - Stability/resilience of market – market history/future prospects/market trends
 - Market model – traditional vs digital vs direct – open market vs closed market
- Proposed product compatibility with existing market/product/ancillary accessories – potential for integrated systems
- Small/fragmented market results in greater risk as the potential for ROCE/ROI is limited
- Economic conditions specific to this product market (both domestic and global)
- Presence of market for this product – does one exist or can it be created? Is it/will it be sufficient?
- Specific constraints to local markets
 - Accreditation/conformance to clinical/legal regulations
 - Import restrictions, trade barriers etc
 - Minimum/maximum unit pricing
 - Restrictions on marketing direct to domestic consumers (vs healthcare professionals for example)
 - Language and cultural obstacles

Cross Reference Considerations With:

Social | Cultural

Testing | Prototypes | Standards | Specification | Quality

Performance

Product Cost

Competition

Intellectual Property | Legal

15.0 Competition

- Similarity to competitor's product
 - IP management
- Product differentiation
 - Branding/colour schemes/designs/style
 - Marketing approach
 - Use/performance/adaptability
- Performance against competitor's product
 - Performance testing and benchmarking
 - Performance claims – verification and marketing claims
- Pricing model – position within the market vs competitors (luxury version vs budget version vs 'everyday' version)
- Reasonable projected market share (product viability)
- Market sensing
- Identification of competitors/competitors' products

Cross Reference Considerations With:

Aesthetics | Branding | Size | Weight | Ergonomics

Performance

Market Constraints

Intellectual Property | Legal

16.0 Intellectual Property | Legal

- Patents already existing for this/similar products
- Assertion of ownership strategy
 - Trademarking
 - Patenting
 - IP etc
- Ownership rights of the new product (especially if outsourcing/joint venturing)
- Domestic and global IP management
- Copywriting and data security of technical drawings etc
- IP management/patenting process – timescales, costs, verifications
- Verification of marketing claims
- Strategic partnerships/knowledge transfer with competitors/manufacturers/skill providers to develop new, innovative technology
- Ability of competitors to reverse engineer a similar product
- Likelihood/desirability of competitors wishing to reverse engineer a similar product
- Future additional revenue stream opportunities in licensing any patents

A legal team will be consulted on all matters relating to potential legal challenges, IP queries etc.

Cross Reference Considerations With:

Aesthetics | Branding | Size | Weight | Ergonomics

Testing | Prototypes | Standards | Specification | Quality

Performance

Documents

Intellectual Property | Legal

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