


**THE INNOVATION
CHALLENGE**

Powered by  TBAT
Innovation

Welcome The Innovation Challenge

Product Development & Protection Workshop – How to design and protect your innovation



| Innovation

Headline Sponsor



Workshop Sponsor



Before we begin...

Housekeeping



- Please keep your microphone muted for the duration of the workshop
- Please use the chat function for any questions throughout
- We will have a 10 minute comfort break at 1:55pm and 3:15pm
- There will be a Q&A opportunity and we will finish with a panel discussion

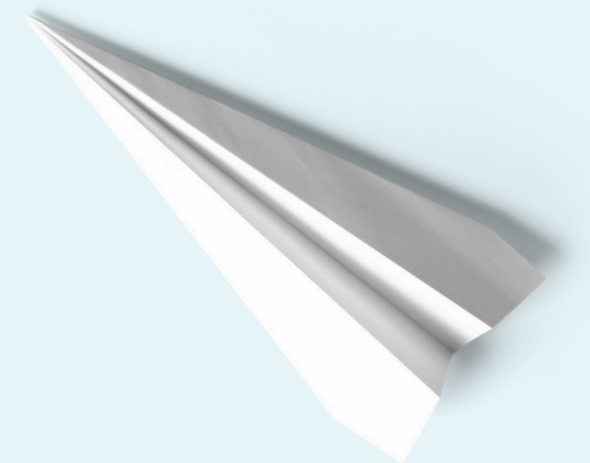
Full Application Stage

Now open - closes 31st July 2023

Submit your business plan and further information, for a chance to be selected to pitch at the final showcase on 11th October and have a chance to win the prize package.

Prize Package includes:

- £5000 cash
- Support from selected partners based on the winner's requirements
- 2 runners up will also receive support from partners



Why run a Product Development & Protection workshop?

“As we know, there are known knowns; there are things we know we know. We also know there are known unknowns; that is to say we know there are some things we do not know. But there are also unknown unknowns—the ones we don’t know we don’t know.”

Donald Rumsfeld 2002

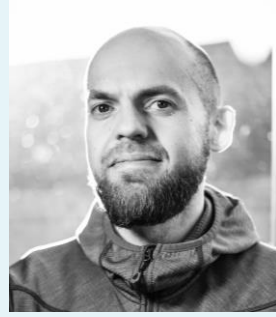
Speakers

THE INNOVATION CHALLENGE

Powered by TBAT Innovation



Sam Stephens
TBAT Innovation



Andy Last
Oxford Product Design



Lee Garton
Bulb Studios



Neil Carter
Ignys



Ed Wright
Shakespeare Martineau



Al Mills
IMed Consultancy



Tim Bubb
IMed Consultancy



Chris Wordley
Conformance



Dr Jagvir Purewal
Forresters IP



Greg Smith
Forresters IP



**OXFORD
PRODUCT
DESIGN**

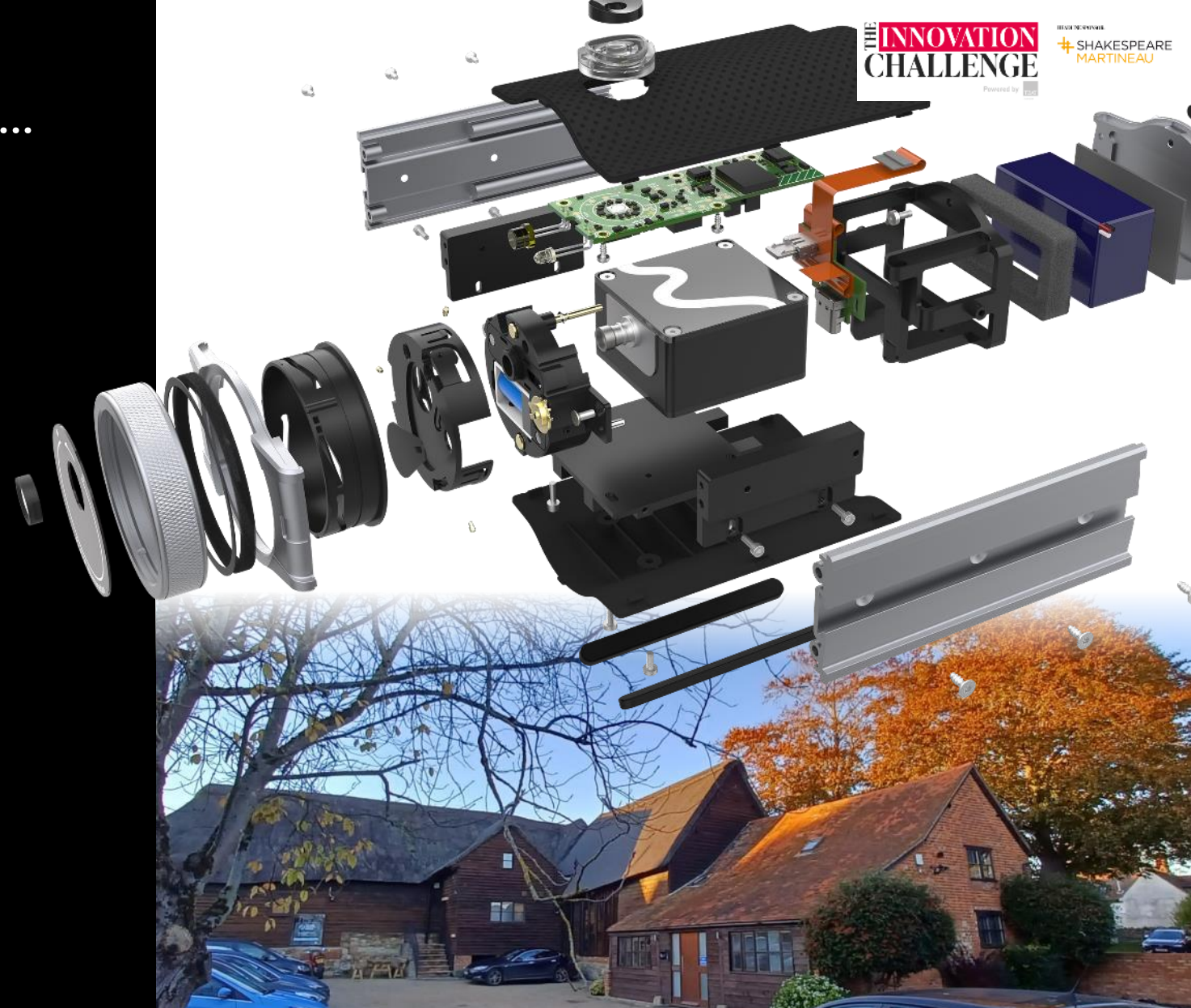
ANDY LAST

Lead Industrial Designer
al@opd.uk.com

THE DESIGN PROCESS

ABOUT OXFORD PRODUCT DESIGN...

- Founded in 2013
- Design team of 25 staff
- Located in Harwell, Oxfordshire
- State of the art, in-house prototyping and workshop facilities.
- We can manage any scale of design challenge
- OPD are independently audited to ISO9001:2015
- Quality, creativity and speed underpin our approach
- We love what we do



THE INNOVATION CHALLENGE
Powered by

RESEARCH POWER
SHAKESPEARE MARTINEAU



OUR CLIENTS...



ADLENS®



Cadent
Your Gas Network

CASELLA



DERWENT

EIC
Together we innovate

elvie

equivital



FUEL3D™



inamo

iotaSciences
shaping fluids



Keeler
Focused on you



MADSON BLACK
FINE BESPOKE LIGHTING



metric



NATIVE UNION



OSLER



OX SIGHT



Prepd

ReXel®

Shark NINJA

Streamlines

STREETDRONE
DELIVERING AUTONOMY



THRUVISION
PEOPLE-SCREENING

UWE Bristol
University of the West of England

VeriVin
INSTRUMENTS



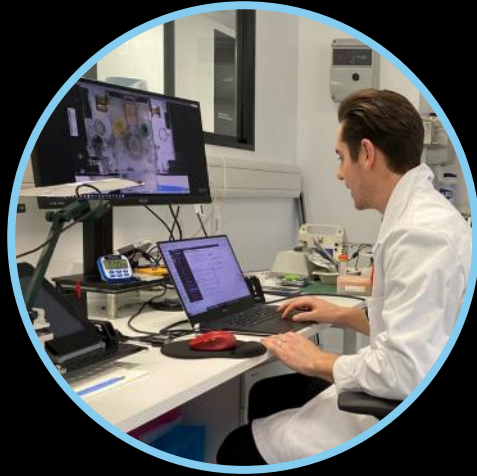
WHAT IS PRODUCT DESIGN?



The creative process of developing products that solve specific user needs.



THREE TYPES OF DESIGN CHALLENGE



INNOVATE

Technology Development
 Novel New Ideas
 New Solutions
 Generate Core IP
 New, Unique, Difficult...



OPTIMISE

Detail Development
 Solution Refinement
 Cost reduction
 Product Iteration
 Testing + Simulation



DIVERSIFY

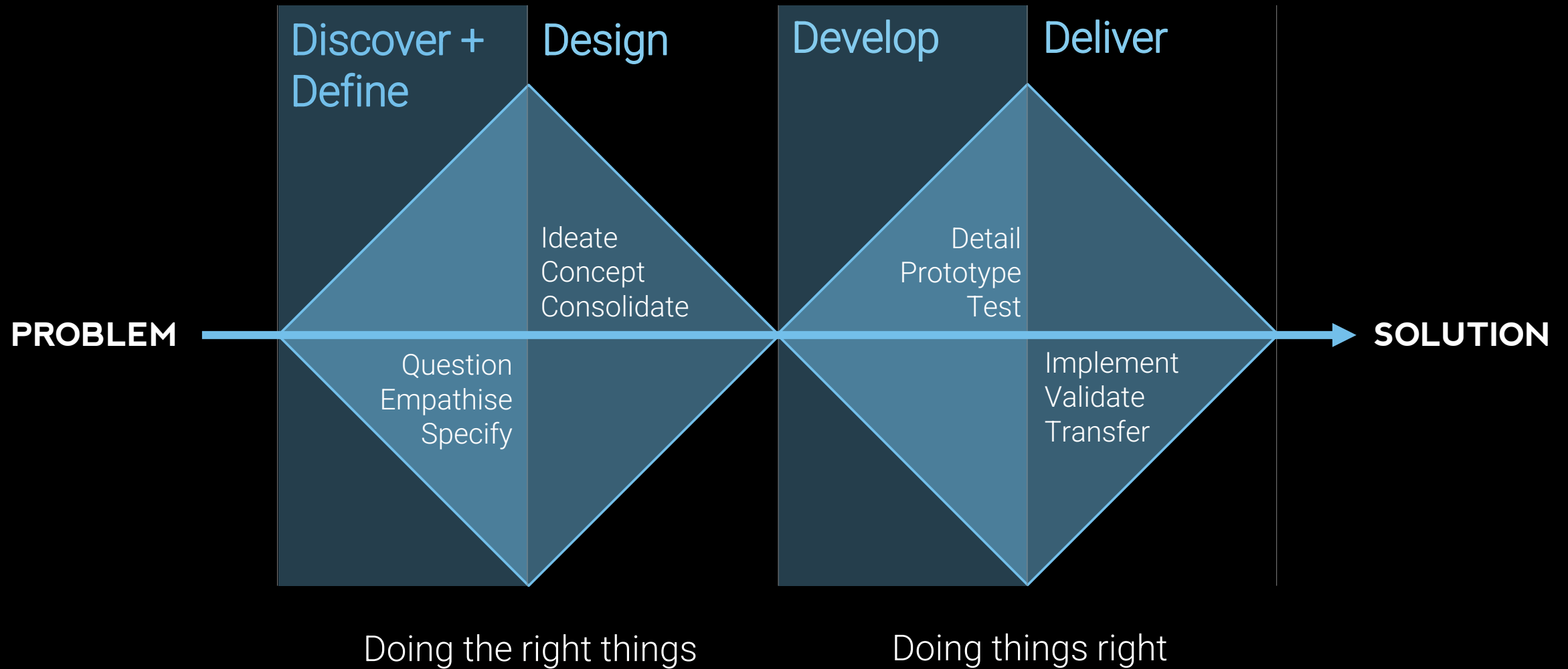
Repurposing Technology
 New Applications
 Parallel Products
 Road Mapping
 Feature development



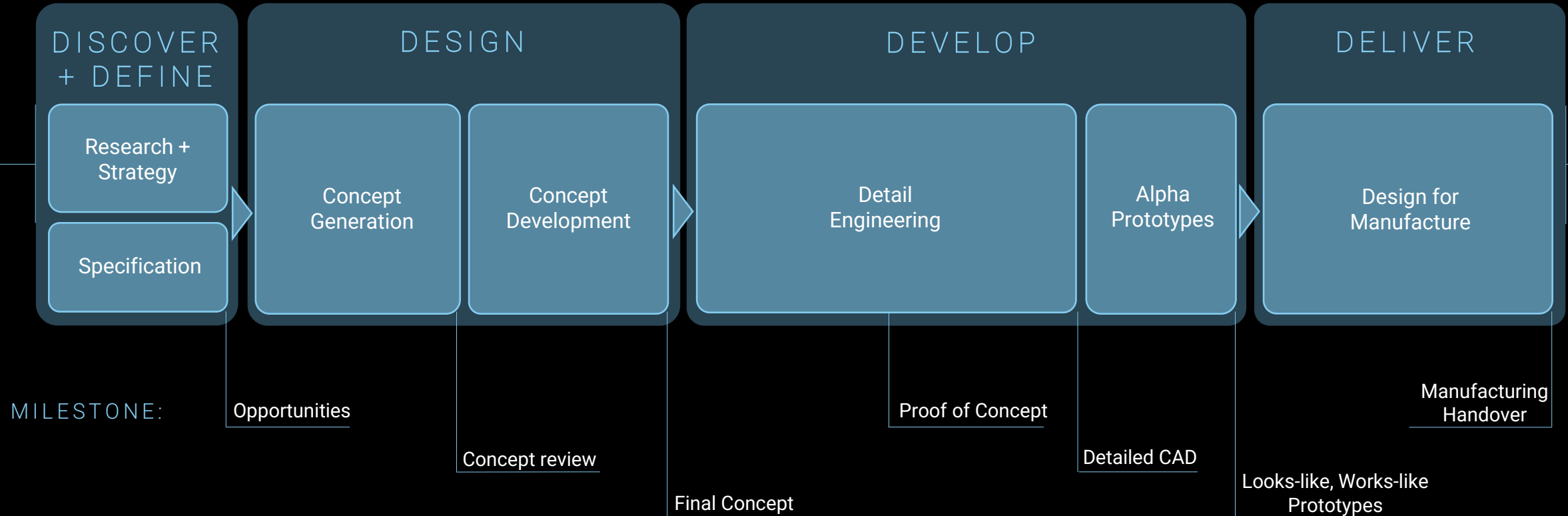
THE DESIGN PROCESS.



A TYPICAL APPROACH TO PRODUCT DESIGN...



A TYPICAL APPROACH TO PRODUCT DESIGN...



DEFINING THE REQUIREMENTS

GOALS

- Lay the foundations
- Identify key needs
- Identify Opportunities for Innovation

TYPICAL ACTIVITIES

- Primary user research
- User-centred workshops
- Design thinking
- Competitor analysis



CONCEPT GENERATION

GOALS

- Explore a wide range of ideas and solutions
- Ideate around functionality, aesthetics, usability

TYPICAL ACTIVITIES

- Brainstorming
- Concept sketching
- Ergonomics
- Human Factors
- Model making



CONCEPT DEVELOPMENT

GOALS

- Narrow the ideas down
- Agree a final concept vision

TYPICAL ACTIVITIES

- Architecture
- A-Surface capture
- CAD – Computer Aided Design
- 3D Renderings
- Colour, Material, Finish
- Model making



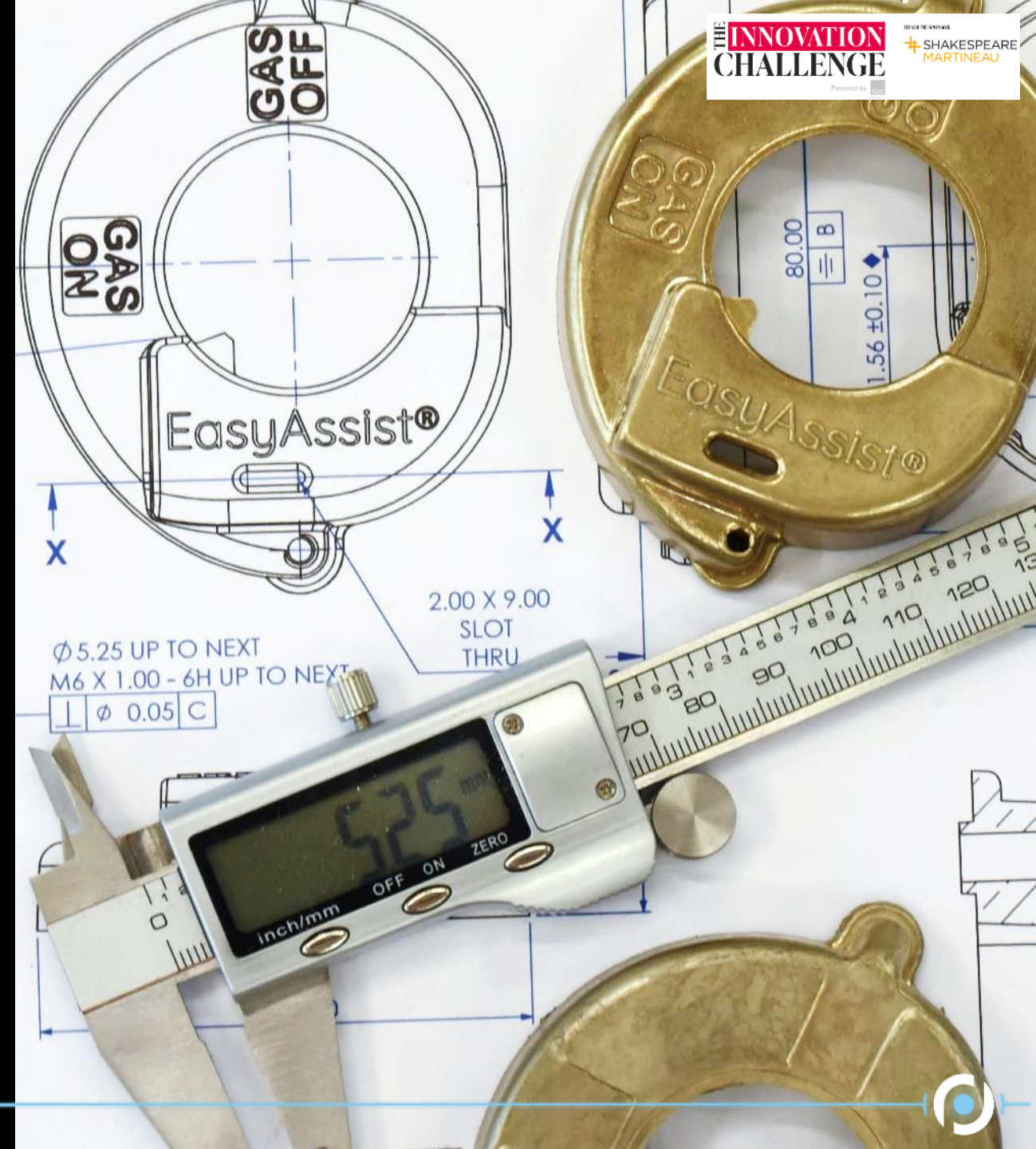
DETAIL ENGINEERING

GOALS

- Prove the concept
- Detail design
- Functional design

TYPICAL ACTIVITIES

- Mechanical engineering
- Prototyping – 3D printing
- 2D Drawings
- Hardware/Firmware



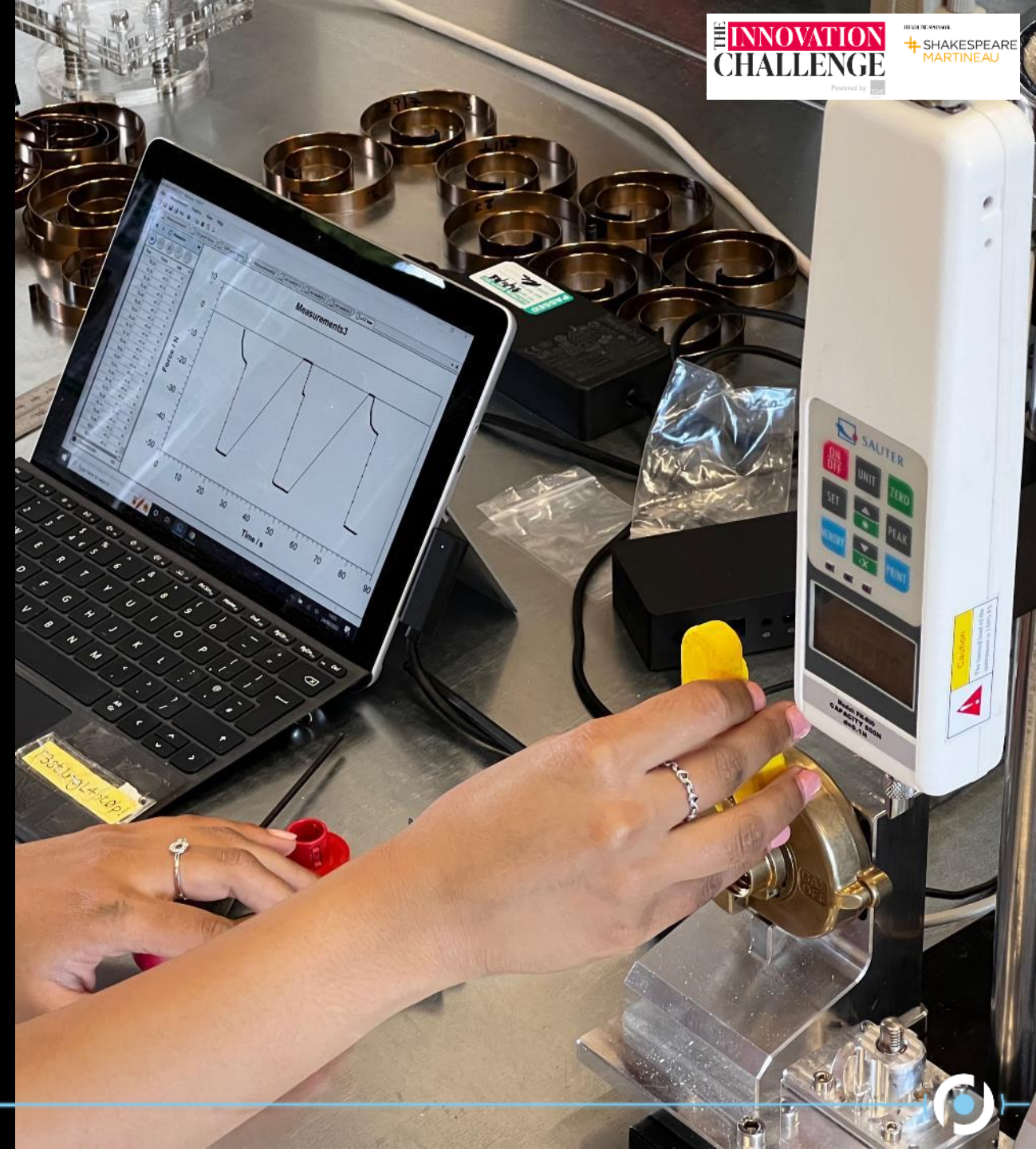
ALPHA PROTOTYPING

GOALS

- Build 'looks-like, works like' prototype
- Evaluate the design

TYPICAL ACTIVITIES

- Prototyping
- Sourcing
- Testing
- Verification
- Hardware/Firmware



DESIGN FOR MANUFACTURE

GOALS

- Implement feedback
- Final design details
- Handover to manufacturer

TYPICAL ACTIVITIES

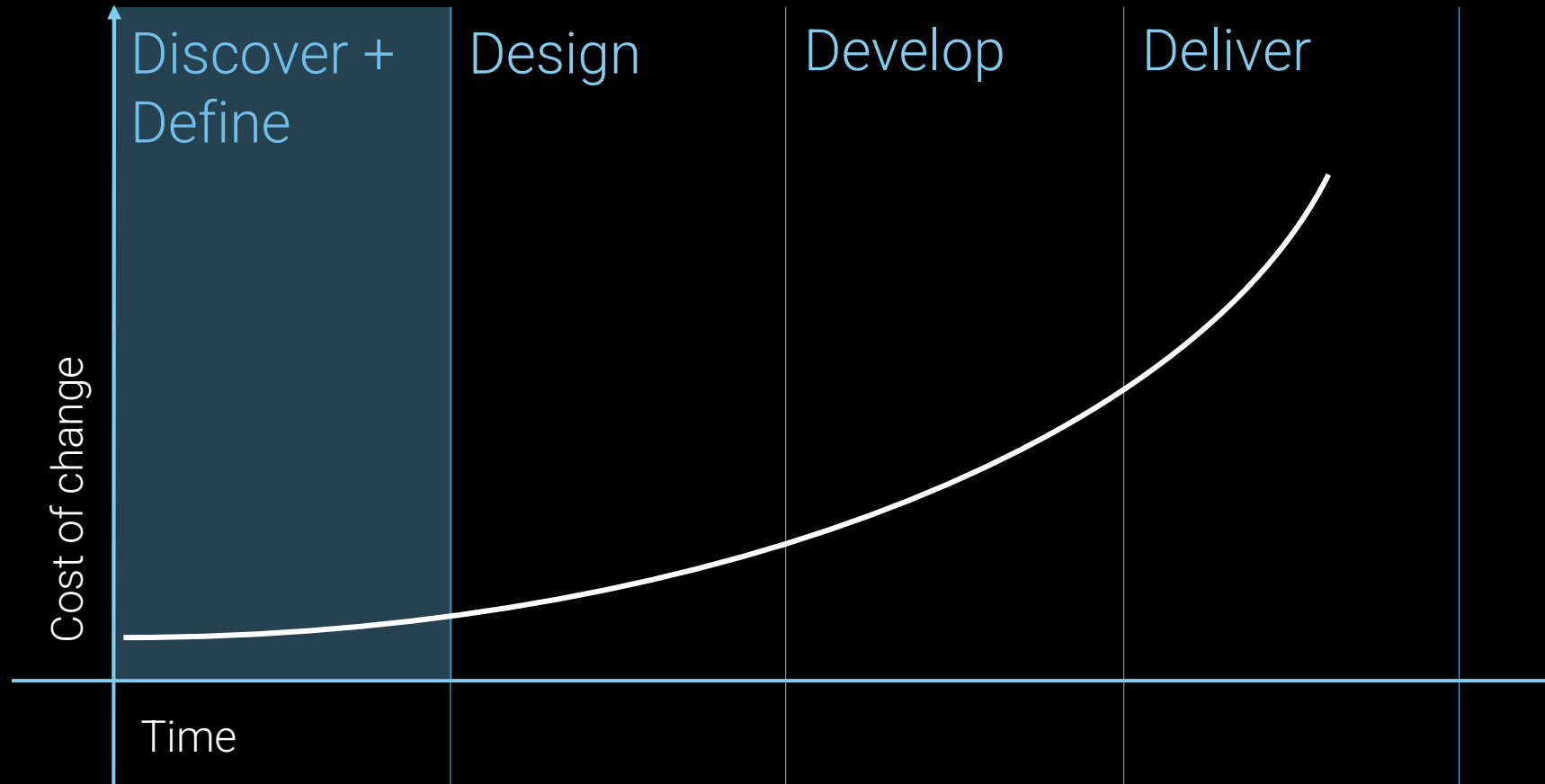
- Factory liaison
- Engineering drawings
- Design documentation
- Beta production
- Verification & Validation



WHAT ARE THE CHALLENGES?



COST OF CHANGE



COMMON CHALLENGES

- Sustainability
- Time
- Cost
- IP Landscape
- User focus
- Manufacturing
- Legislation



SECTORS AND THEIR CHALLENGES

MEDICAL



- Highly Regulated
- High Risk
- High Investment
- High quality requirements
- Long development timelines
- Traceability

CONSUMER



- High volume
- Rapid turnover
- Demanding Consumers
- Brand Embodiment
- Tight Margins
- Highly competitive

INDUSTRIAL + SCIENTIFIC



- Low Volume, High Spec
- Challenging requirements
- Approval Standards
- Safety Critical
- Cost sensitive
- Brand choice



ENGAGING WITH DESIGNERS.



“A problem well-stated is a problem half-solved”

CHARLES KETTERING



UNDERSTAND YOUR CONSUMER

CONSUMER

WHO? ...is the user?
...is the product aimed at?

WHY? ...do users want this?
...choose this over the competition?

WHAT? ...is the innovation?
...is the need being met?

HOW? ...does this make the user feel?
...does it meet their needs?



UNDERSTAND YOUR PRODUCT

PRODUCT

WHY? ...is it needed?
...is it useful?

WHAT? ...do users want from it?
...is it's USP?

WHEN? ...is it used?
...is it needed / not needed?

WHERE? ...is it used?
...is it sold / advertised?



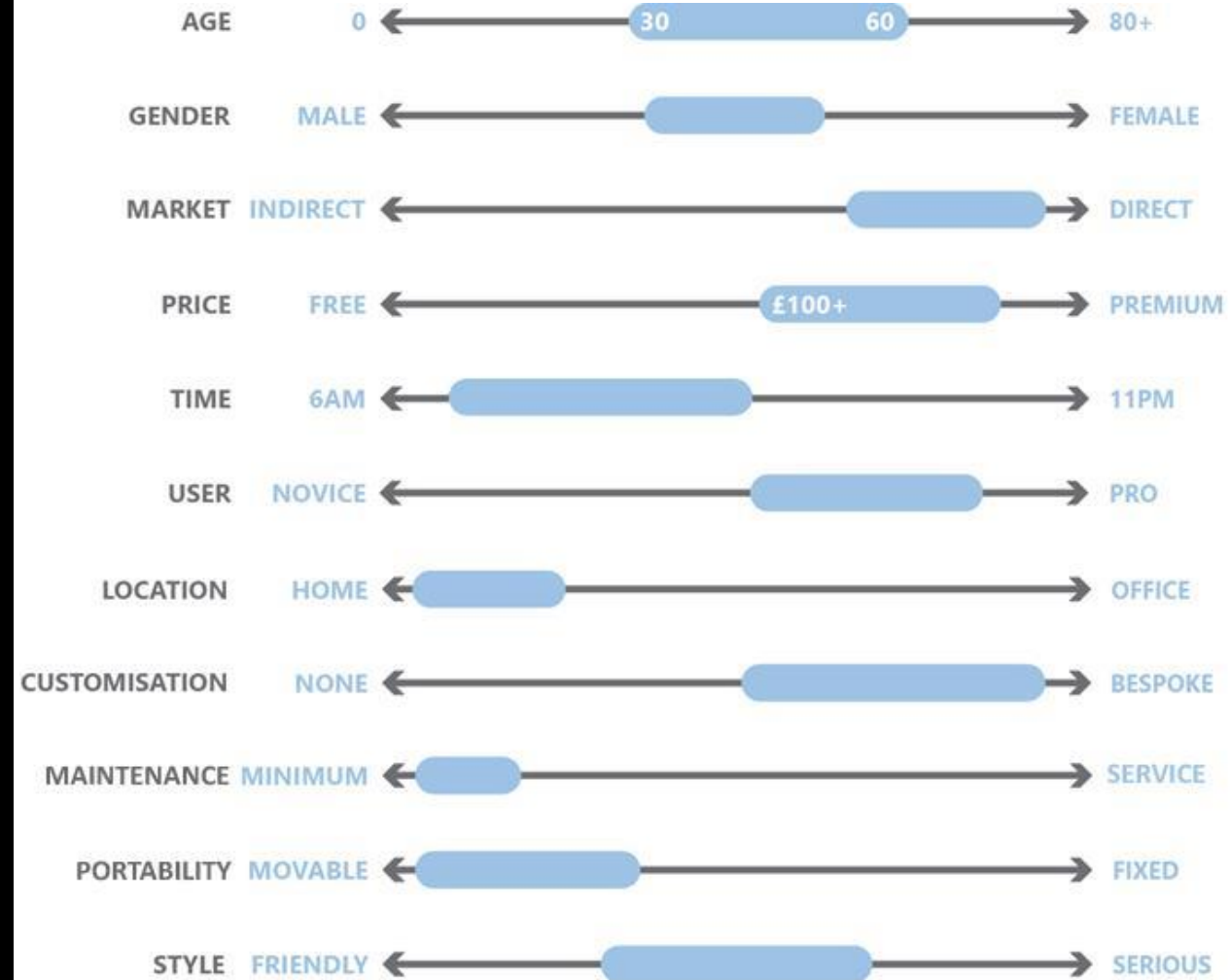
DEFINE YOUR SPECIFICATION

WHY HAVE A SPEC?

- Provide prioritised goals
- Keeps the design process focused
- Metrics of success

WHAT GOES IN A SPEC?

- Physical requirements
- Usability requirements
- Performance requirements
- Technical requirements
- Environmental requirements
- Regulatory standards



DOING YOUR HOMEWORK

- Be realistic
- Collaborate
- Time-bound milestones
- Consider budget
- Prioritise critical path elements
- Don't expect things to work first time
- Fail fast and iterate
- Manage risk



BENEFITS OF A USER-CENTRED DESIGN APPROACH.



BENEFITS OF A USER-CENTRIC APPROACH

- Understanding your Stakeholders
- Empathy for your Consumer
- Verify your assumptions
- Define the needs early
- Identify “Opportunities for Innovation”



BENEFITS OF A USER-CENTRIC APPROACH

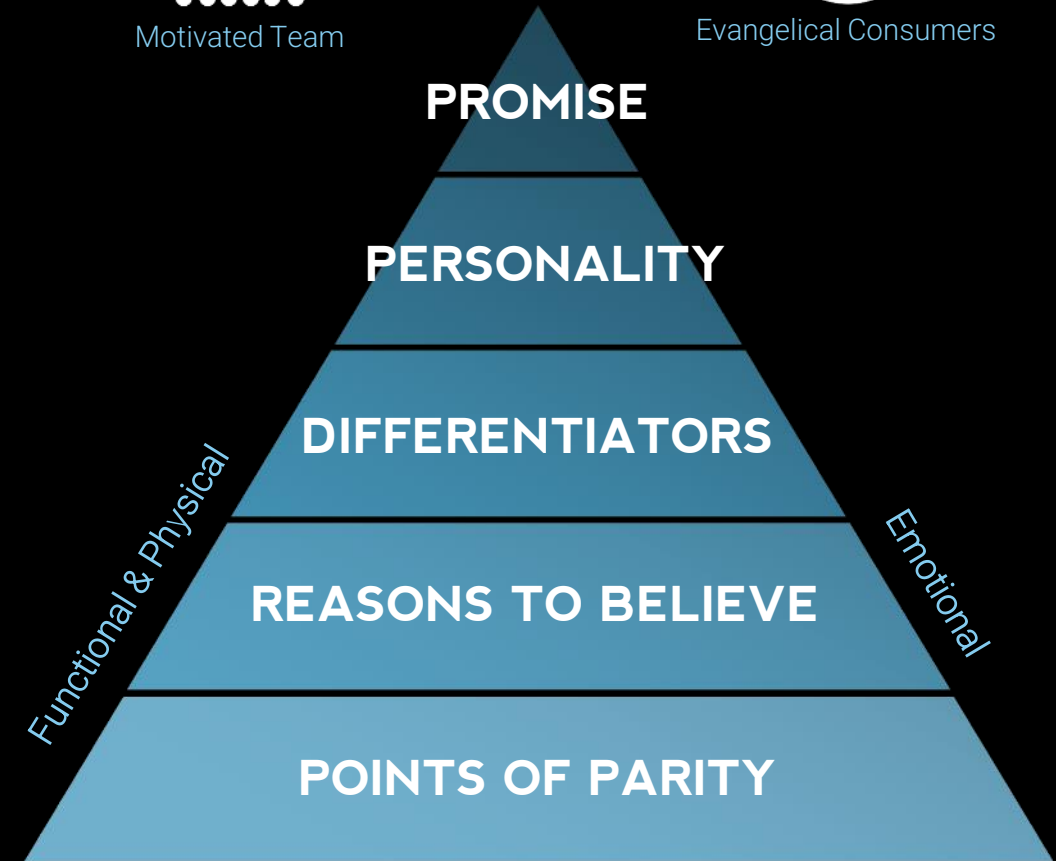
- Increased Value
- Brand Confidence
- Build Consumer Evangelism
- Capture Tomorrow's market
- Motivate & Inspire Internal Teams



Motivated Team



Evangelical Consumers





www.oxfordproductdesign.com

Andy Last

1-2 Cherry Barns, Harwell, OX11 0EY

al@opd.uk.com



Bulb Studios

Designing for humans.

bulbstudios.com

THE **INNOVATION**
CHALLENGE
Powered by TELUS

HEADLINE SPONSOR
SHAKESPEARE
MARTINEAU





THE **INNOVATION**
CHALLENGE
Powered by 

HEADLINE SPONSOR
 SHAKESPEARE
MARTINEAU

hello





Lee Garton

Design Director

THE **INNOVATION**
CHALLENGE
Powered by  TELECOM

HEADLINE SPONSOR
 SHAKESPEARE
MARTINEAU



We are Bulb Studios
an independent digital
product studio based in the
historic city of Leicester

THE **INNOVATION**
CHALLENGE
Powered by TELEAT

HEADLINE SPONSOR
+ SHAKESPEARE
MARTINEAU





Digital Strategy

Discover

Clarifying your mission and product needs by immersing ourselves in your business and your audience.

- Business Strategy
- User Research
- User Analysis & Testing

Digital Delivery

Design & Build

Creating beautiful digital products that evolve to meet the needs of people to deliver delightful human experiences.

- Websites
- Mobile Apps
- Web Applications
- Branding

Digital Engagement

Engage

Elevating your digital product and brand activities with copy, SEO, and digital marketing.

- Copywriting
- Social Media Marketing
- Search Engine Marketing
- Video & Motion Graphics



Designing for humans.

Designing digital products that provide

THE **INNOVATION**
CHALLENGE
Powered by 

HEADLINE SPONSOR
 SHAKESPEARE
MARTINEAU



Firstly, what is UX?



“User experience’ encompasses all aspects of the end-user’s interaction with the company, its services, and its products.”

Don Norman, co-founder of the Nielsen Norman Group



THE **INNOVATION**
CHALLENGE
Powered by 

HEADLINE SPONSOR
 SHAKESPEARE
MARTINEAU

Why is UX important?



How good UX can help you

Brand reputation

Being consistent with your brand/products and offering excellent user experiences is key to a building brand reputation.

Customer loyalty

When users find satisfaction in your brand/product they will continue coming back to it.

Increase conversion

Intuitive navigation, clearly organised content and well sign posted CTAs ensure users flow through your product efficiency removing barriers in conversion.



THE **INNOVATION**
CHALLENGE
Powered by 

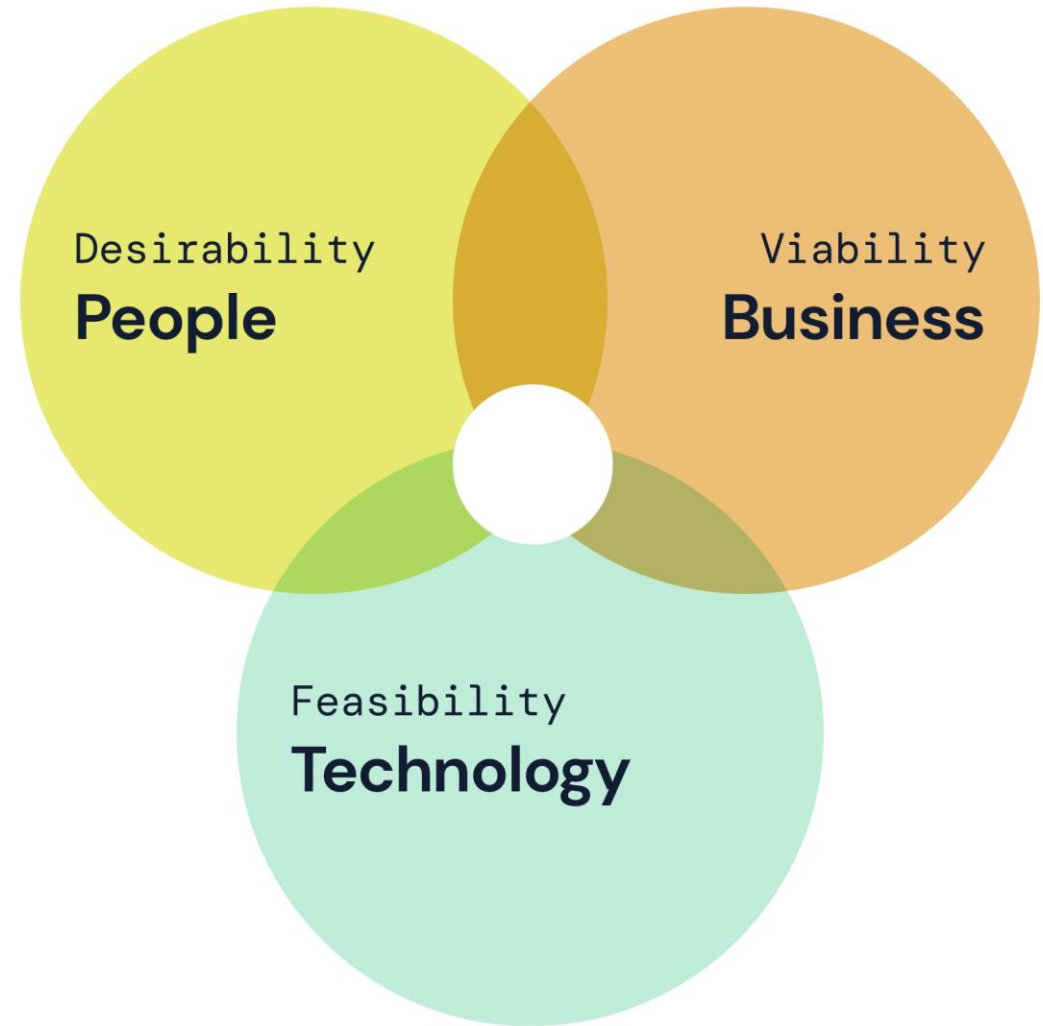
HEADLINE SPONSOR
 SHAKESPEARE
MARTINEAU

Applying UX design



Human-centred design

- Needs of people
- Requirements for business success
- Possibilities of technology





Identify & research

Empathise with people

Know the people you are designing for, so you can understand their needs better.

Define & design

Understand the problem

Define the problem you are trying to solve and understand the benefit to the people.

Test, review & iterate

Validate the solution

Prototype and test to gain invaluable feedback from the people that matter.

Empathise with people

Know the people you are designing for

Building a profile of the end customer to
develop empathy and build a better
understanding of their needs and motivations



“If you want to build a product that’s relevant to people, you need to put yourself in their shoes.”

Jack Dorsey, co-founder of Twitter & founder of Square

Understand the problem



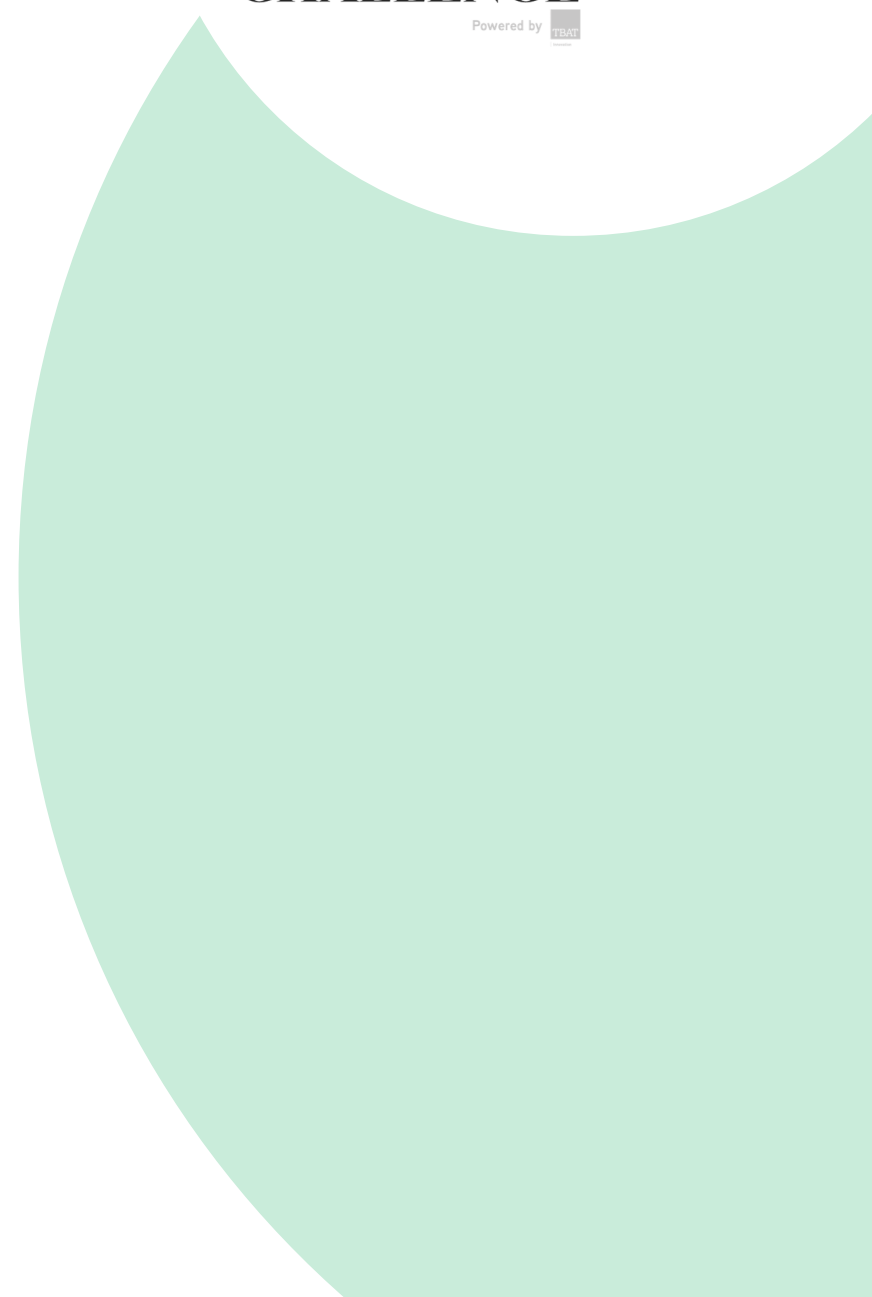
Define the problem you are trying to solve

Understand your value proposition at the core of your competitive advantage by combining Problem, Solution and Value statements.

Validate the solution

Validate the solution to gain valuable insight

Explore whether the design is the best solution for the user. This validation can have a big impact on the success of the product or service and can give us powerful insights into the target audiences.





Designing for humans.

Designing digital products that provide

THE **INNOVATION**
CHALLENGE
Powered by 

HEADLINE SPONSOR
 SHAKESPEARE
MARTINEAU



Good UX can help
you build trust

Empathise with people

Know the people you are designing for, so you can understand their needs better.

Understand the problem

Define the problem you are trying to solve and understand the benefit to the people.

Validate the solution

Prototype and test to gain invaluable feedback from the people that matter.



THE **INNOVATION**
CHALLENGE
Powered by 

HEADLINE SPONSOR
 SHAKESPEARE
MARTINEAU

Thank you



THE **INNOVATION**
CHALLENGE
Powered by TELUS

HEADLINE SPONSOR
SHAKESPEARE
MARTINEAU

Q&A

bulbstudios.com





Bulb Studios

Designing for humans.

bulbstudios.com

THE **INNOVATION**
CHALLENGE

Powered by TELUS

HEADLINE SPONSOR

SHAKESPEARE
MARTINEAU



Break

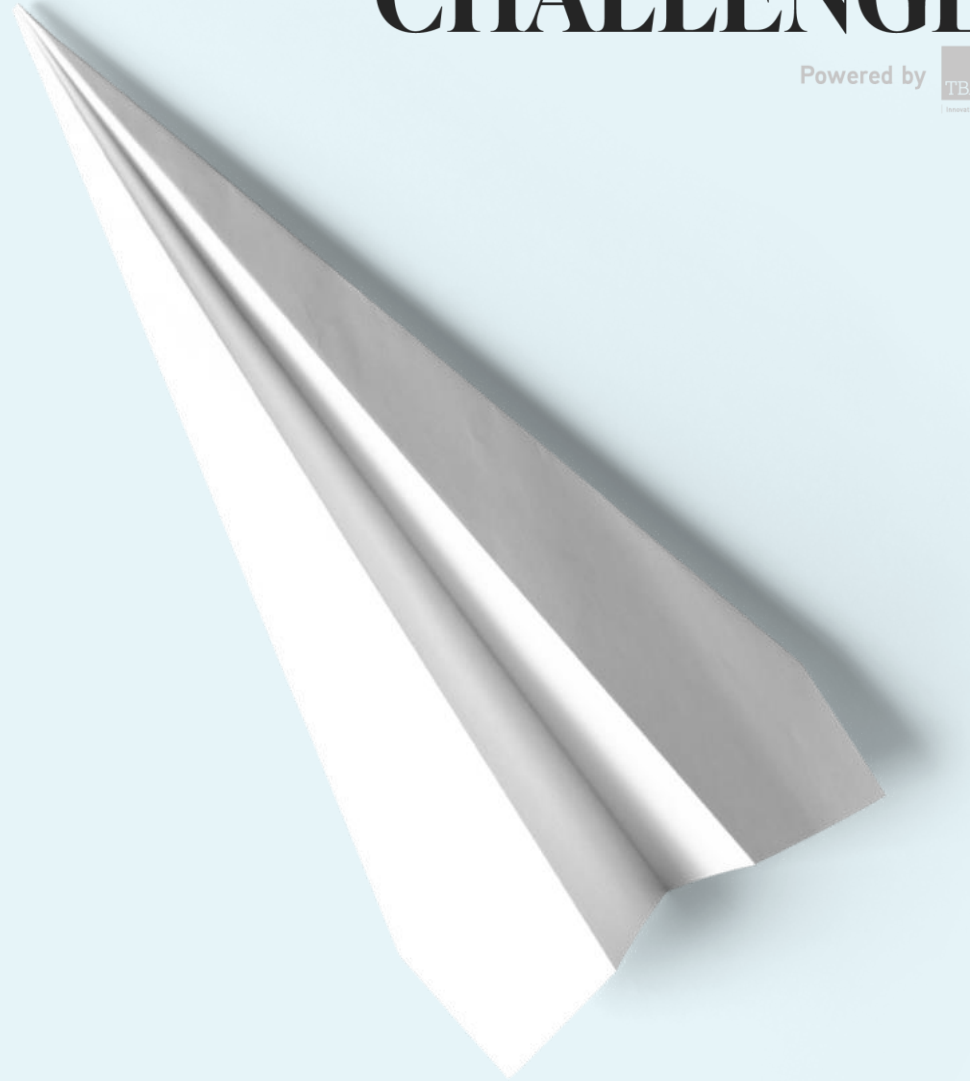
We will resume at 2:05pm

TBAT

| Innovation

THE INNOVATION
CHALLENGE

Powered by TBAT
Innovation





Electronics Product Design

Neil Carter
Managing Director





THE INNOVATION CHALLENGE
Powered by **TEAT**

HEADLINE SPONSOR:
SHAKESPEARE MARTINEAU



First Steps Before Full Development

- Market research, patents and product validation
- Simplify your product
- Proof-of-Concept (POC) prototypes
- Proof of Value



Understanding Customer Needs



Understand Your Customers

Are they a small private company or a big MNC?



What they do:

Understand their occupation and interest



When they buy:

Understand the purchase cycle of your customer



How they buy:

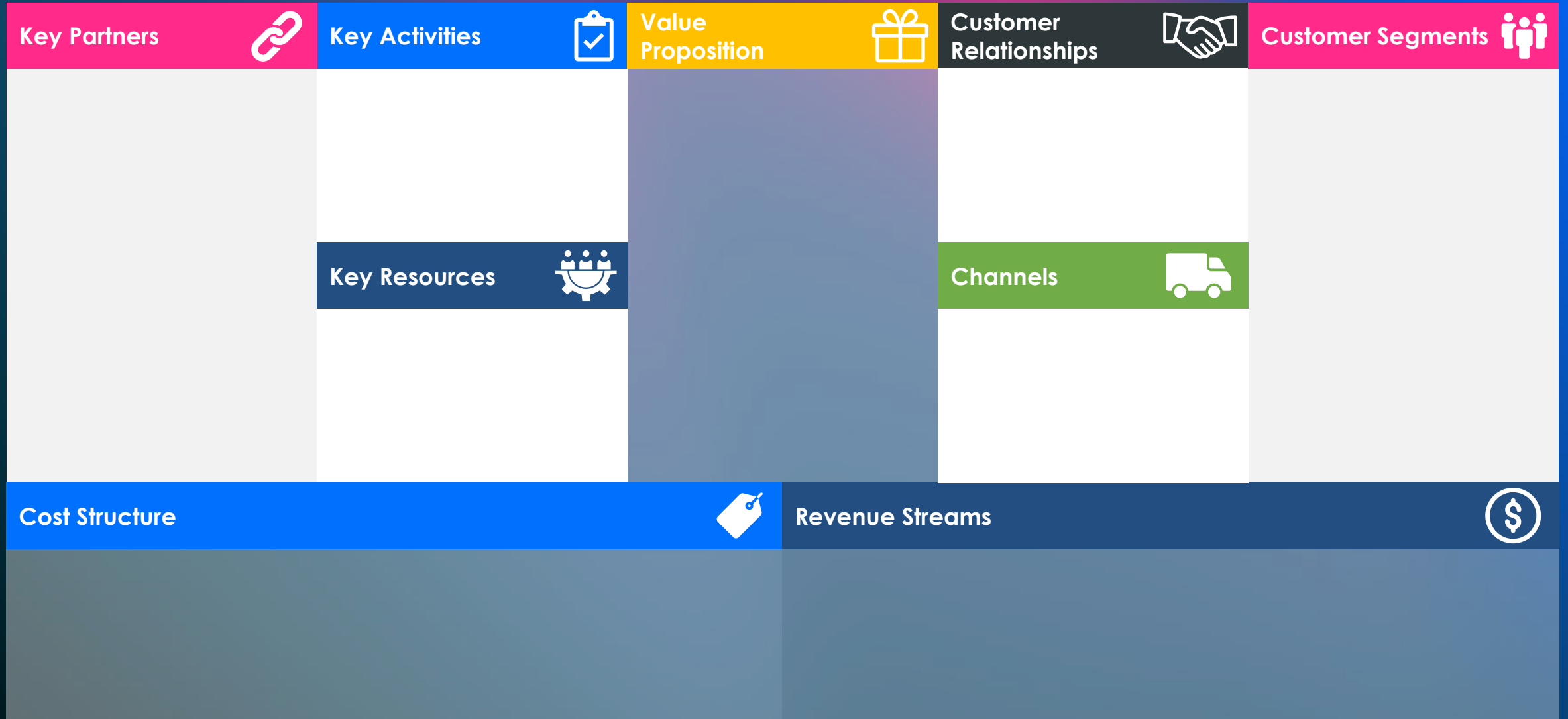
Website, App, In-person



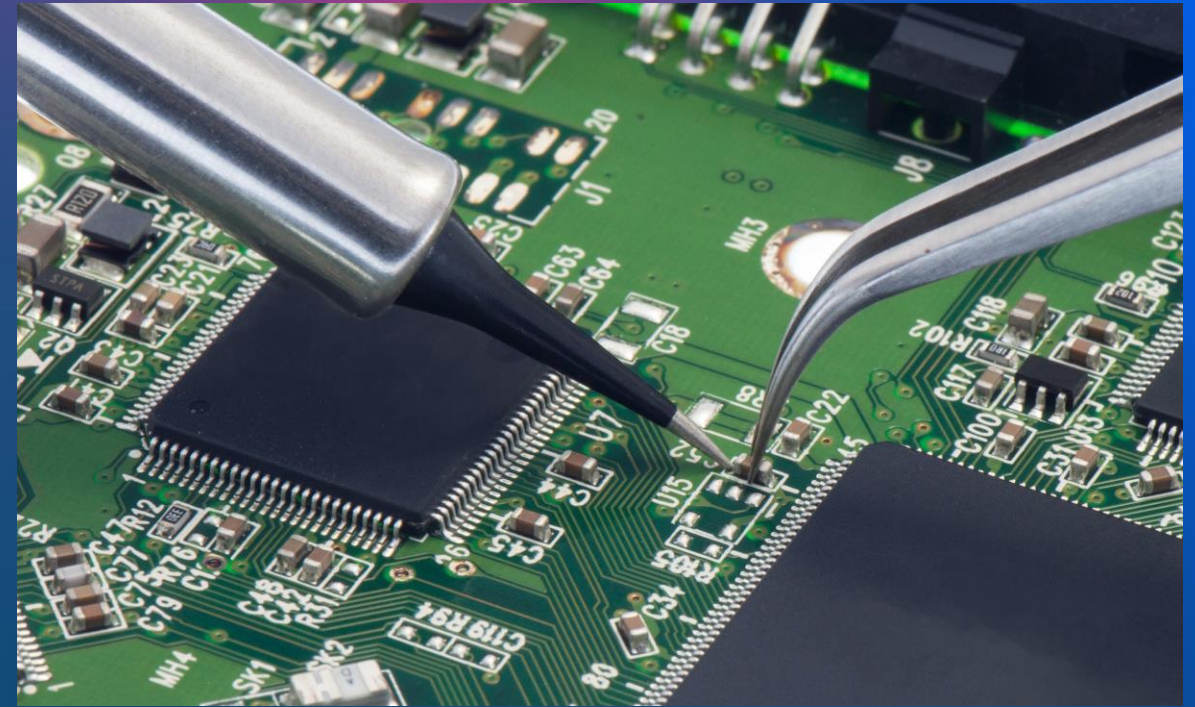
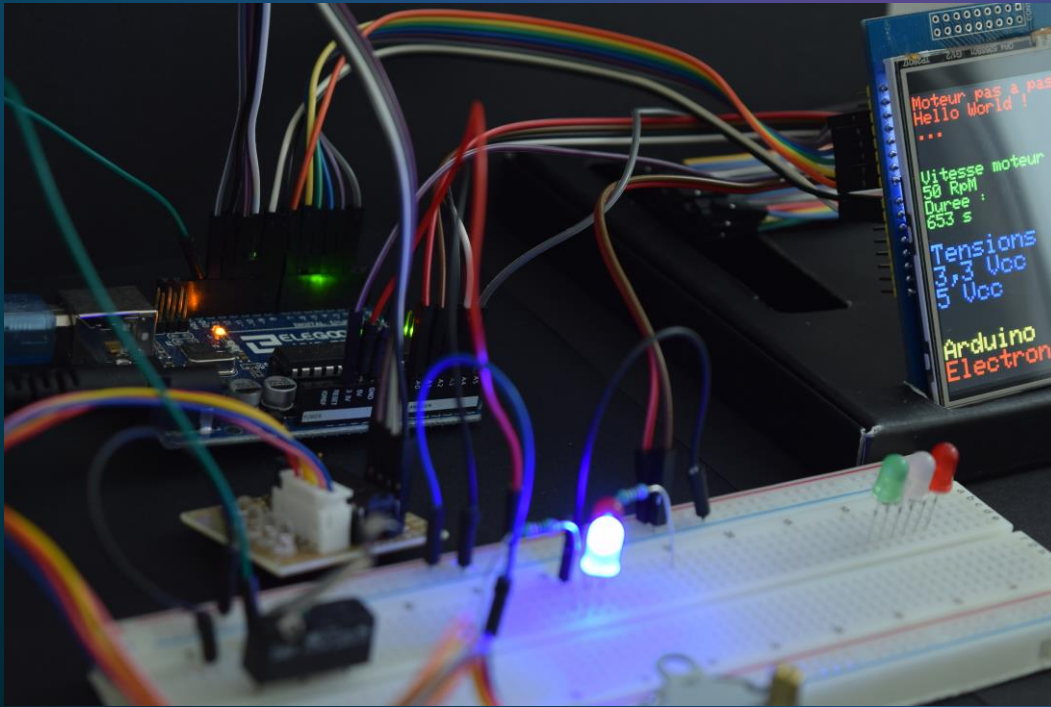
What they expect of you:

If your customers expect reliable delivery and you don't disappoint them, you stand to gain repeat business

Business Model Canvas



Devboards v PCB

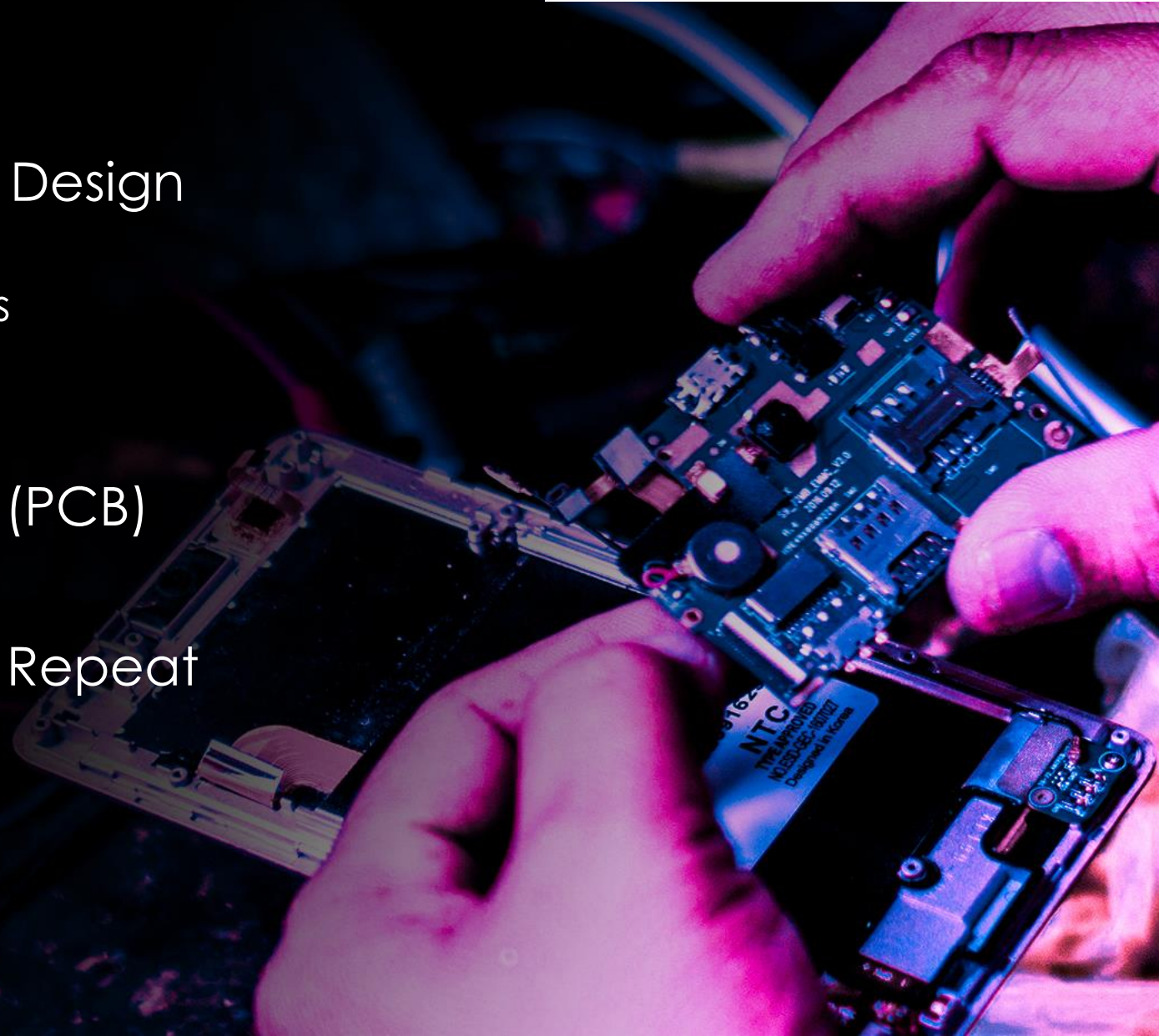


Product Development Strategies

- Develop the Product Yourself
- Bring on Technical Co-Founder(s)
- Outsource to Freelance Engineers .
- Outsource to a Development Firm .
- Partner with a Manufacturer

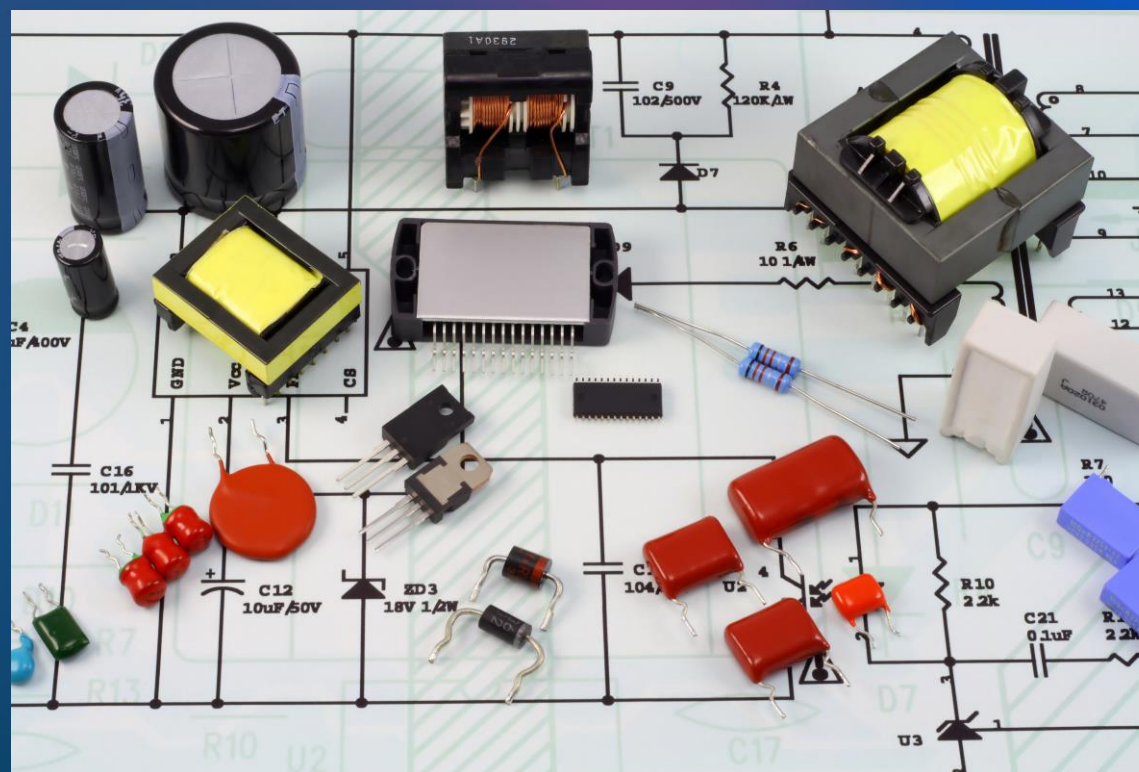
Develop the Electronics

- Create a Preliminary Production Design
 - System Block Diagram
 - Selection of Production Components
- Estimate the Production Cost
- Design the Circuit Diagram
- Design the Printed Circuit Board (PCB)
- Order the Prototypes
- Evaluate, Program, Debug, and Repeat

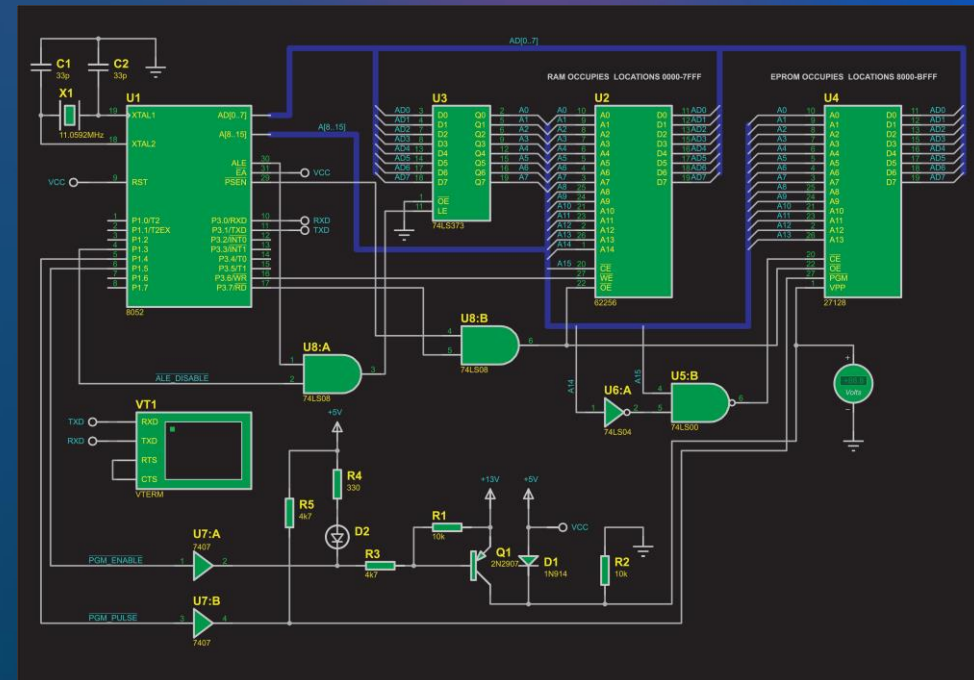


- Create a Preliminary Production Design
 - System Block Diagram
 - Selection of Production Components

- Estimate the Production Cost



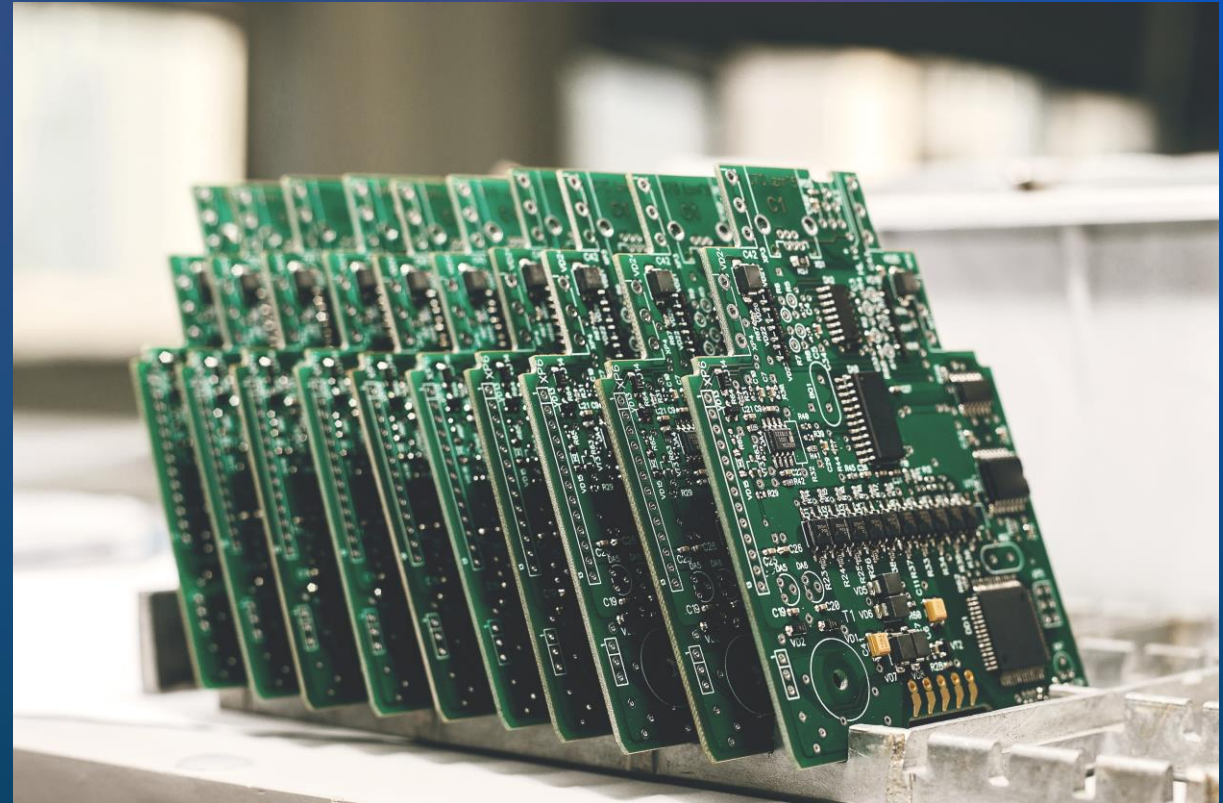
- Design the Circuit Diagram



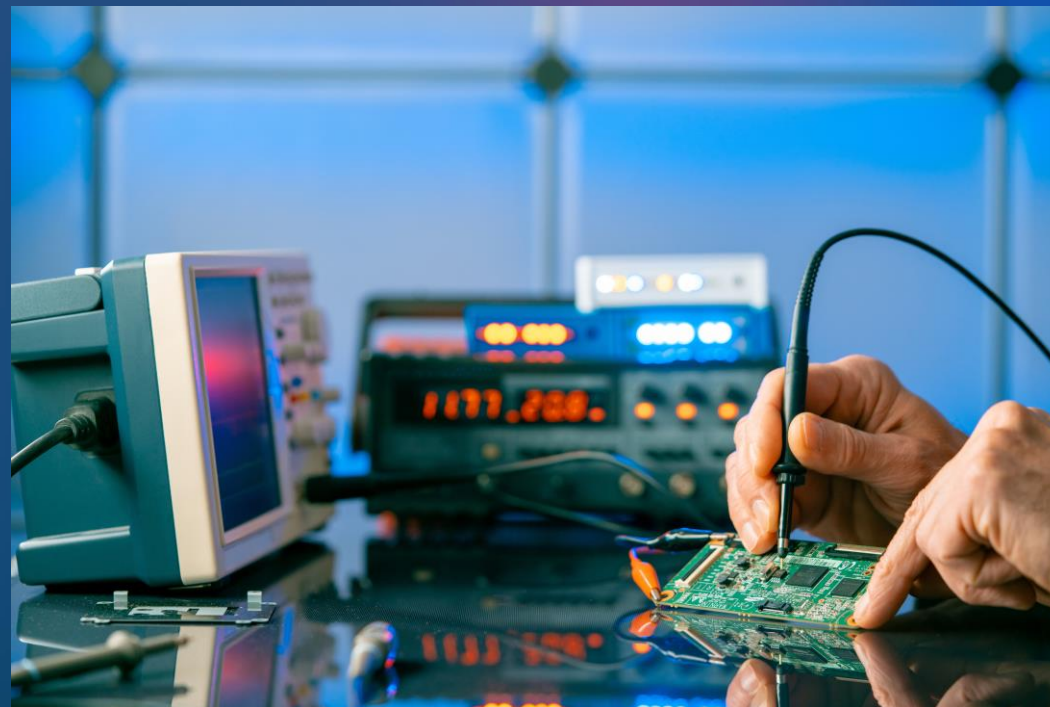
- Design the Printed Circuit Board (PCB)



- Order the Prototypes

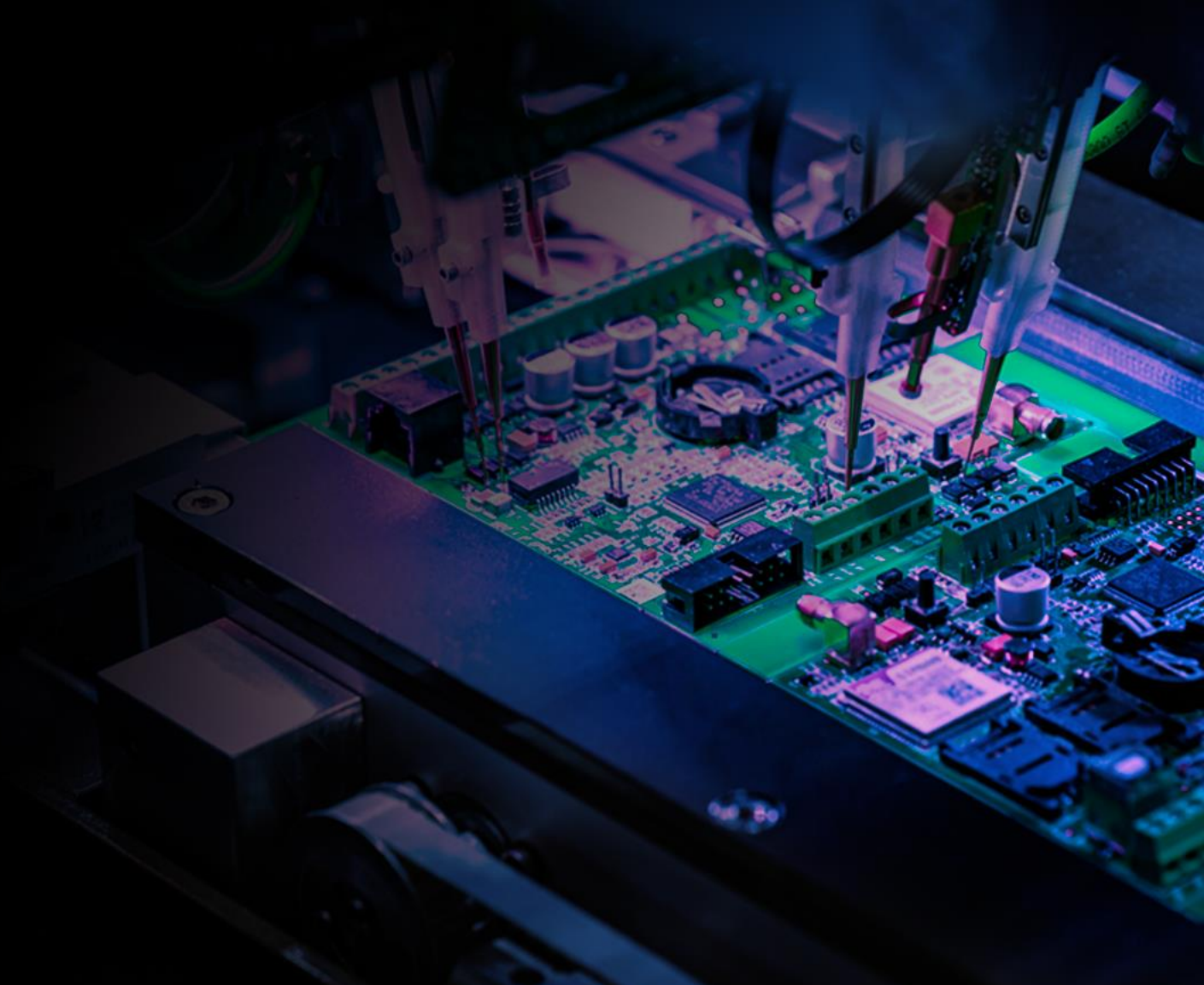


- Evaluate, Program, Debug, and Repeat



Develop the Software

- Paid or Open Source
- Choose Platform
- Choose Toolchain



Applications (Verticals)

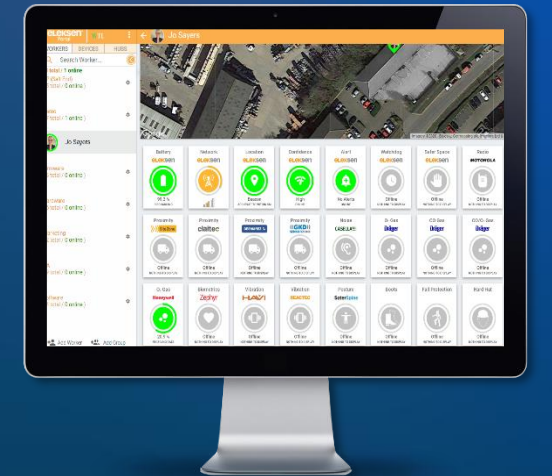
Personal Devices Wearable Computing: pebble, cookoo, fulcon, iM, striv, APX, MOTA Fitness: GARMIN, amigo, ifit, tomtom, wahoo Health: LUMO, HAPIfork, QUANTUS, remoo, aelan Family: FILIP, greatcall, menbaby, mimo	Lifestyle Sports: Sain Sentry, BIRESPIRE, ZEPP, InfoMotion, swingbyte, HAMMERHEAD Cooking: Smart Die Scale, ANOVA, drop, blossom, iDevices Pets: Whistle, PetPace, pinabeed, PetHub, tagg, BISTRO, hoytag, PetChatz Toys: KAROYZ, UBODOLY, MAKIES, oforms, seeo Music/Art/Video: ROLI, CA/CH, COPYD Garden: plantlink, BITPONICS, radio, EDYN, Greenbox, Koubachi	Connected Home Automation: Quirky, Radiator Labs, netatmo, LEVITON, Smartthings, Ubi, nest, LIFX, pecko, CRESTROM, smarthome, LUTRON Monitoring: lapka, sense, birdi, BlueMaestro, SUPERMECHANICAL, leo, knet, CUBESENSORS, tado, ambient Security: HomeMonitor, canary, ring, dropcam, butterflye, Lockitron, August, SCHLAGE, Flare, Kwikset, glabaisense, genie, INKEY, GOI, scout, SmartAlarm Tracker: Chipolo, linquet, Locca!, Tracker Hub: Homey, Control, Low's, NINJABLOCKS, STAPLES, NEXIA, muzzley, wink, zonoff	Industries Retail: bytelight, euclid, ROBOTIX, ANFIELD, mabaco, GIBRAL, PERCH, Bona, Pasaki Payment/Loyalty: Square, shopify, PayPal, Verifone, LevelUp, Daily Healthcare: VISI, Senseonics, STANLEY, VITALITY, MedBinder, AtheraTech, CENTRAK, Sotera Automotive: Zobie, nady, dash, waze, OpenXC Infra-structure: wavelink, Trimble, Robin, Agri-culture: adapt-N	Industrial Internet Robotics: Double Robotics, ROBOTIX, ABB, KUUKA, IRobot, LIBRO ROBOTICS, jibo Drones/Aerospace: 3DR, KPM, DJI, Purrli, Skybotix Green-tech: BigBelly, enlightened, Smart, eneo, compology, AMPY 3D Scany/Print: MakerBot, MakerBot, Formlabs, RepRap, NextEngine, RepRap, Ultimaker, Solidoodle Smart Grid: GRIDNET, e-on, Itron, Trilliant Asset Tracking:
--	--	---	---	---

Platforms & Enablement (Horizontals)

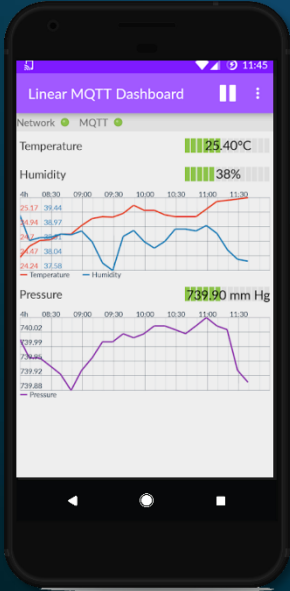
Connectivity/Dev Platforms spark, kynotk, pinaccio, iobridge, Ayla Networks, resin.io, Tessel, bluecity	Software/Data Platforms EXOSITE, iControl, Thingsquare, carriers, NewAer, BERO, Axaedo, Yaler.net, RaccoWireless, IFTTT, wot.io, alluux, Yo, ThingWorx, DNZK, IOTEL, CANOPI, baugsworm, Tempio, evercam.io, covisint, Jasper	Open Source Platforms webinos, openMAB, ThingSpeak, GRID2HOME, SAFECAST, placemeter, MotionLoft	Personal Interfaces wit.ai, LEAP, gestigon, speech, EMOTIV, Reemo, Oculus	Security inside, SafeNet, utimaco, escrypt, gemalto, BASTILLE NETWORKS, MOCANA	Corporates amazon, hp, LG, intel, htc, PHILIPS, IBM, SAMSUNG, Google, WIND RIVER, BOSCH, ARM, LogMeIn, Microsoft, Honeywell, SONY, Atmel, SIEMENS, QUALCOMM, CISCO, TOSHIBA, SHARP
---	--	---	---	--	--

Building Blocks

Protocols Bluetooth, Wi-Fi, ZigBee, omo, wave, enModus, HART, MiWi, M-Bus, 2G, 3G, 4G, LTE, CoAP, 6LoWPAN, LWM2M, BITXmI	M2M Networks KORE, stream, aeric, WINDRIVER, M2M	Portable WiFi Open Garden, GOODESPEED, BRICK, karma	Telecom at&t, boostmobile, Verizon, T-Mobile, Sprint, US Cellular, Vodafone, airtel	M2M artesio, wireless seed, ecenais, Telit		
Cloud Google Cloud Platform, amazon, redhat, ORACLE, Microsoft Azure	Mobile iOS, Android, Windows Phone, BlackBerry	Processors/Sensors Raspberry Pi, Arduino, BeagleBoard.org, Intel, TI, ST, Freescale, ARM, MIP2, Freescale	Parts/Kits SAM, littleBits, reo, mate, Tinkerforge, Wifibots	Services sculpteo, makey, dragon, WEARABLE WORLD, RGA Accelerator, TechStars	Funding KICKSTARTER, indiegogo, MedStartr	Distribution angel.am

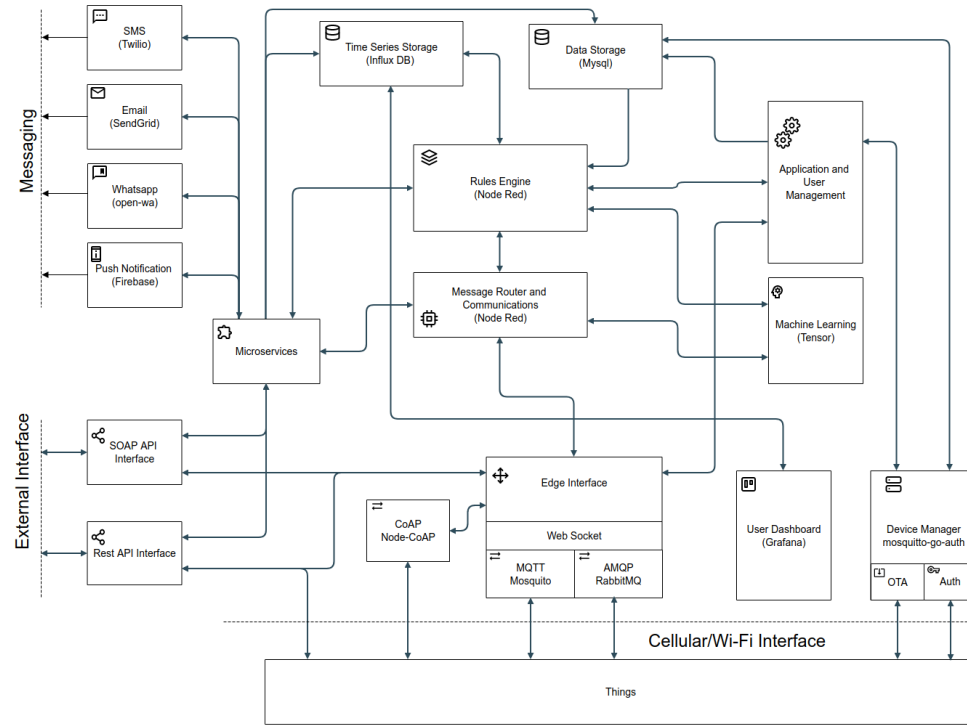


Ignys



Rev 1.1

IoT Platform



Neil Carter 30/3/21



Microsoft Azure IoT Platform

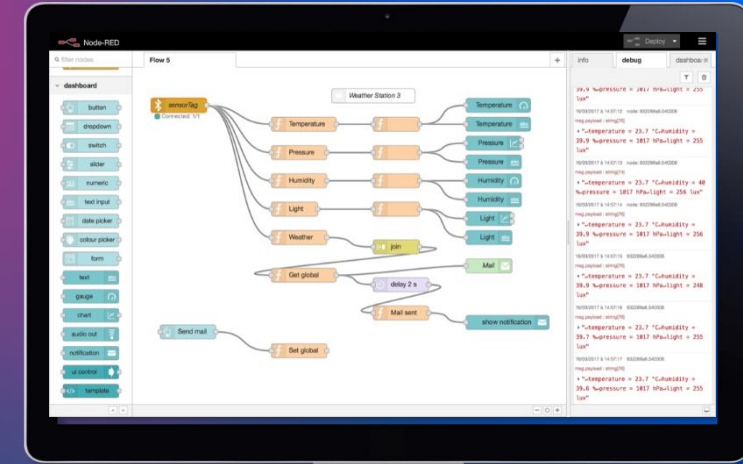


THE INNOVATION CHALLENGE

Powered by TB&T

HEADLINE SPONSOR

SHAKESPEARE MARTINEAU



Ignys

Develop the Enclosure

- Create 3D Model
- Order Case Prototypes (or Buy a 3D Printer)
- Evaluate the Enclosure Prototypes
- Transition to Injection Molding

Certify your product

- FCC (Federal Communications Commission)
- UL (Underwriters Laboratories) / CSA (Canadian Standards Association)
- UKCA
- CE (Conformité Européene)
- RoHS
- Lithium Battery Certifications (UL1642, IEC61233, and UN38.3)
- PTCRB

Things to remember



Beware of Data for Data's sake

Prehistory to 2005 :130 Exabytes

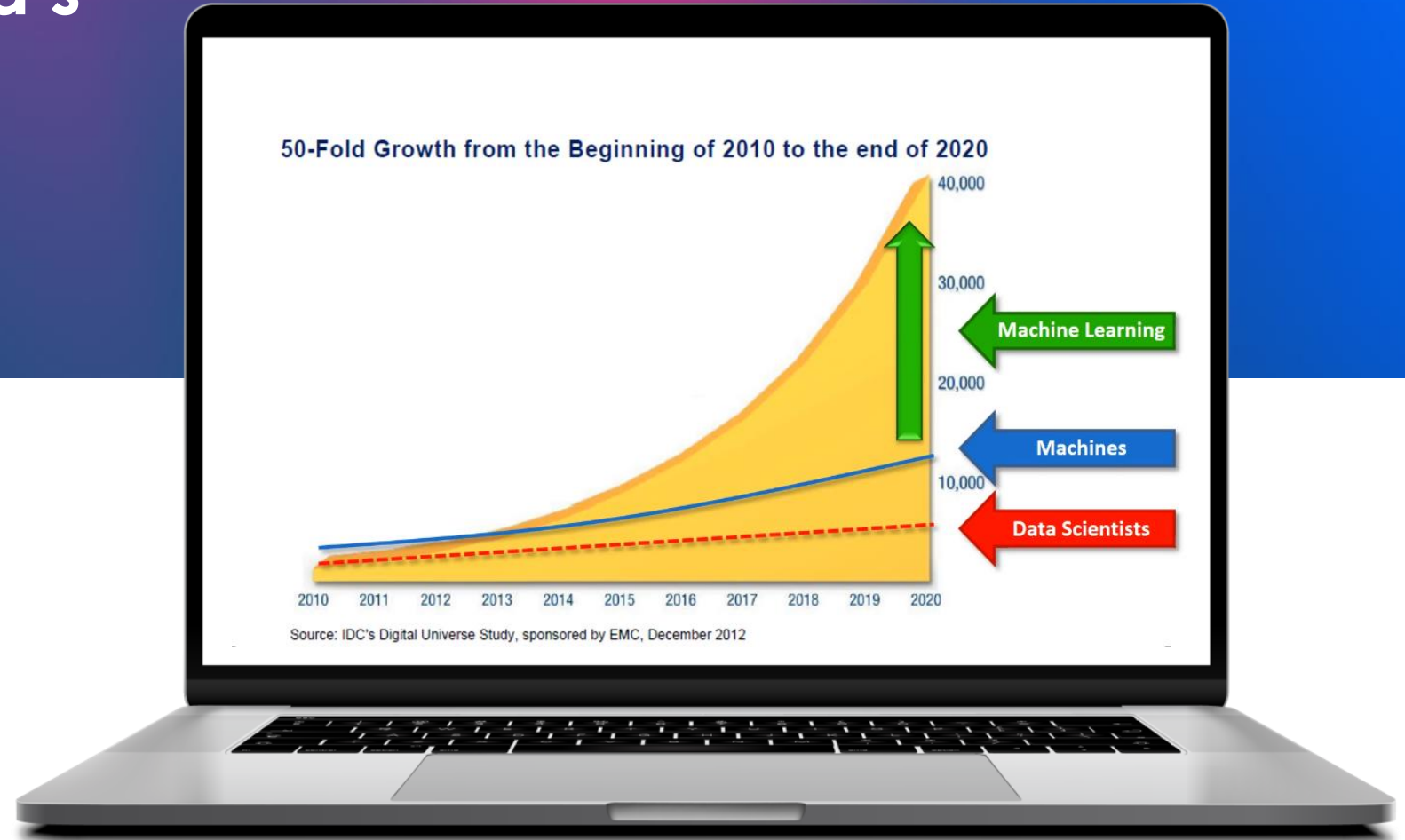
2010: 1200 Exabytes

2015: 7900 Exabytes

2020: 40900 Exabytes

2025: 73100 Exabytes or

73,100,000,000,000,000,000 bytes



“Data is the new oil.”

Clive Humby - 2006



“Data is the new oil. It’s valuable, but if unrefined it cannot be used. It has to be changed into gas, plastic, chemicals, etc to create a valuable entity that drives profitable activity; so must data be broken down, analysed for it to have value”

Clive Humby - 2006

“We have an economy based on a resource that is not only renewable, but self-generating. Running out is not a problem, drowning in it is.”

John Naisbitt - 1982

The Laws of Physics



Design for
Manufacture/Test/Availability/
Battery Life



Beware the Snail-Pace
expert



Too Many Cooks Spoil
the Project



Fletcher's Law of Prototyping

$$q \propto \frac{1}{p}$$

*“the higher the number of
prototypes initially made,
the worse the product and
those prototypes will be.”*





The Electronics Design and Software Development Consultancy With a Heart

Neil Carter

LinkedIn [HTTPS://WWW.LINKEDIN.COM/IN/NEIL-J-CARTER/](https://www.linkedin.com/in/neil-j-carter/)



Effective Product Regulatory Strategies

IMed Consultancy

Timothy Bubb, Technical Director



Effective Product Regulatory Strategies

Agenda

1. Overview of Regulation
2. Defining what is your product?
3. What regulatory system(s) apply?
4. Identifying regulatory pathway for approval
5. Establishing requirements for chosen pathway
6. Tips for successful strategy implementation

Why regulate products and services?



European Parliament



HM Government



Defining - What is your product?

Regulatory project planning for medical devices;

- What is your product's **intended purpose**?
- Who is it to be used by?
- **How does it operate** to achieve its intended purpose?
- **What countries** do you want to sell the product in?



What is a Regulatory Strategy?

Product attributes assessed to determine;

1. **What regulations** your product needs to meet
2. What level of **regulatory risk** is associated with the product
3. What **regulatory pathways** are suitable for your product
4. What technical, regulatory and process **requirements** need to be met for regulatory pathway
5. What **evidence** you need to generate to meet requirements for product regulatory approval.



Regulatory Strategy Considerations

- Different countries have different technical and regulatory requirements.
- **Regulatory requirements & expectations** should be established at the **start of the project**, to ensure designed product meets technical and regulatory requirements to gain approval.
- **Regulatory risk, and which regulations apply - can change based on product claims made.**
- Some companies skip this step at their peril
 - Significant time to market delays in not designing to meeting regulator expectations, can be a start-up killer.



Regulatory Qualification – Example

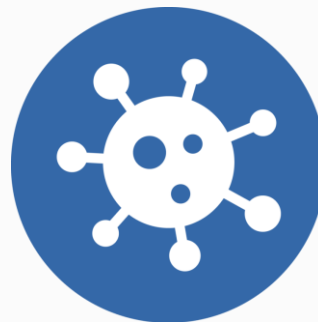
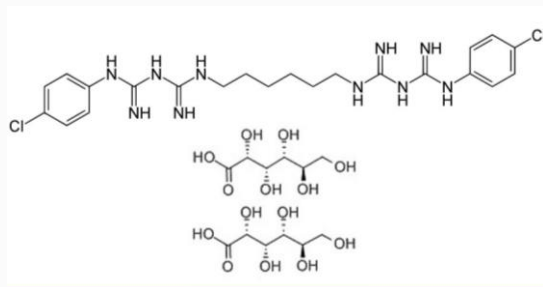


What regulatory system does your product sit in?

Chemical: Chlorhexidine Gluconate

Anti-microbial and disinfection properties

How is it used?



Regulatory Qualification – Example

Chemical: Chlorhexidine Gluconate

Claimed Use	EU/ UK Product Qualification
Mouthwash No antimicrobial claims made	Cosmetic Product
Mouthwash With antimicrobial effect claim	Medicinal Product
Integrated into Cleaning Wipe	Biocide Product
Integrated into Surgical Skin Wipe	Medical Device
Integrated into wound dressing	Medical Device & Medicinal Product



Regulatory Qualification – Example 2

What regulatory system does your product sit in?

Software: Fitness Tracker & Data Portal

Generally used to track individual wellness and health data.


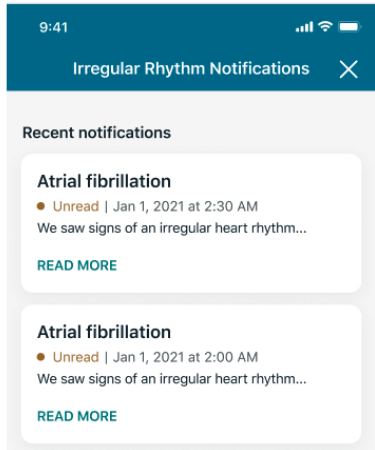
Health data may be used for medical purposes.



Regulatory Qualification – Example 2

Software: Fitness Tracker & Data Portal



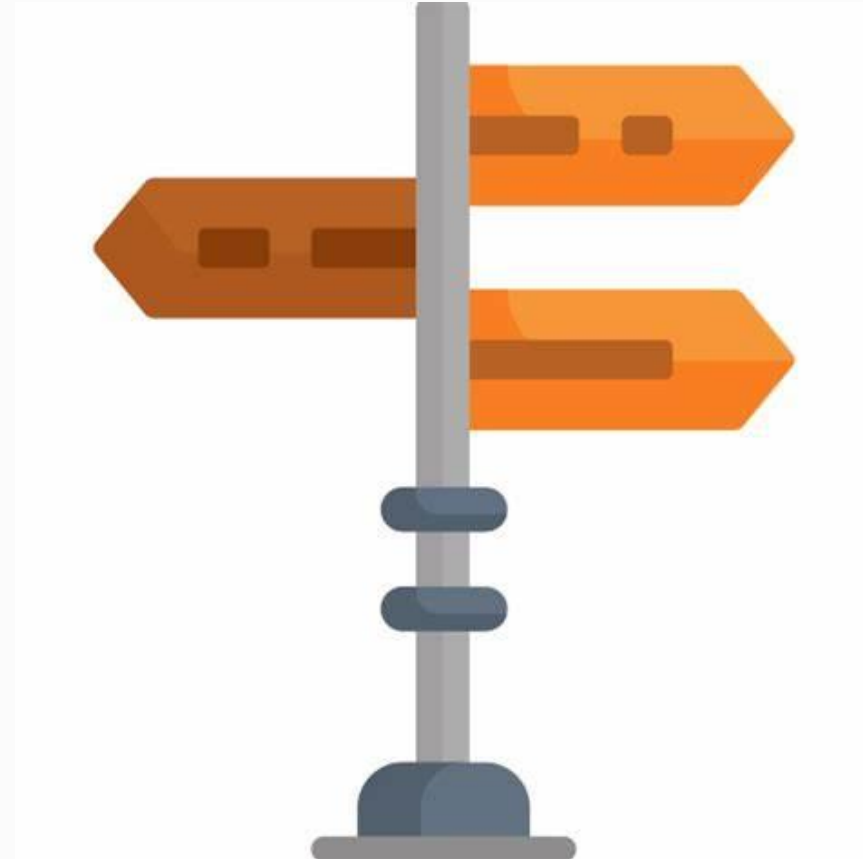
Product Qualification	General Consumer Product	Medical Device
Product claimed use:	Exercise/ fitness heart rate information No claimed medical use.	Atrial Fibrillation Detection Data used for diagnosis of a medical condition
		

Regulatory Pathways

Once the regulation is identified, review level of regulatory risk & technical characteristics.

This is scoping the **regulatory pathway** for your product;

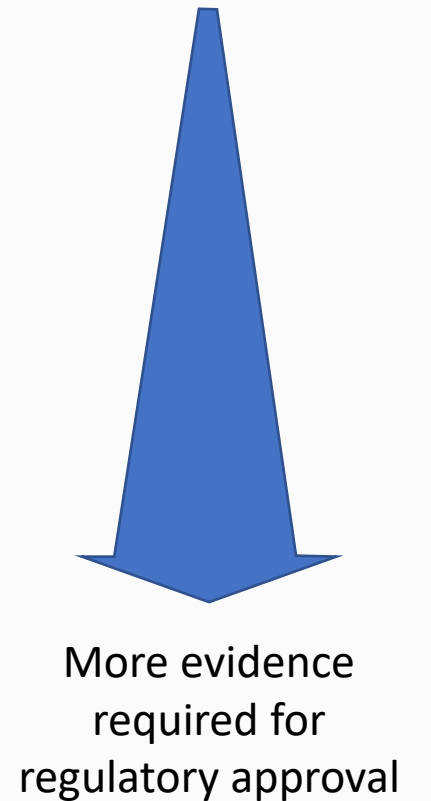
- What do you need to do to get your product to market?
- What submissions and registrations are required before you can legally sell?



Medical Device Risk – Scalpel Blade Example



Claimed Intended Use	EU Risk Classification	Regulatory Risk Profile
Cut paper as part of crafting	Not a medical device	Cannot be used for a medical purpose – no medical harm
Shave hair as part of surgical prep	EU Class I	Low risk of harm
Cut into skin as part of surgery	EU Class IIA	Medium risk of harm
Cut into brain tissue as part of surgery	EU Class III	High risk of harm

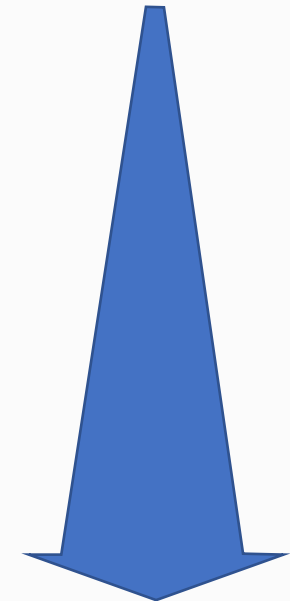


Product Risk – Bluetooth Communication

Requirement: Radio Equipment Regulations



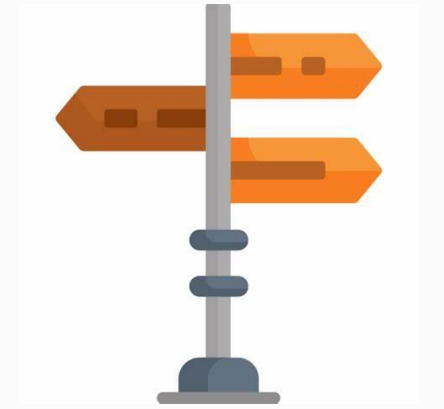
Implementation	Regulatory Risk Profile
Follows and meets specific EU product standards for Bluetooth radios	Low risk – no external oversight needed
Alternative methods of compliance	Higher risk – requires approval by Notified Body



More evidence required for regulatory approval

Regulatory Pathway – Establishing Requirements

- Evaluate the requirements of the regulation & chosen pathway;
 - Processes to follow
 - Information required
 - Documentation required
 - Regulatory Submissions and registrations needed
- Evaluate the requirements for product regulatory expectations;
 - Technical Performance
 - Minimum Safety Expectations
 - Level of Innovation in your new product



Tips for successful strategy implementation

- **Early engagement with experienced regulatory professionals** to develop a regulatory strategy.
- Identify **up front** the **regulatory deliverables** you need to create legal compliance, and include in project planning.
- Identify **product standards** (ISO, EN, IEC etc) applicable to your product.
- For medical products - Design, develop and document in a **Quality Management System**.



Tips for successful strategy implementation

- Consider **design changes**, and **evaluate impact** on the existing regulatory strategy.
- Consider **timeline expectations** between submission and regulatory approval in your planning.



Summary – Effective Regulatory Strategy

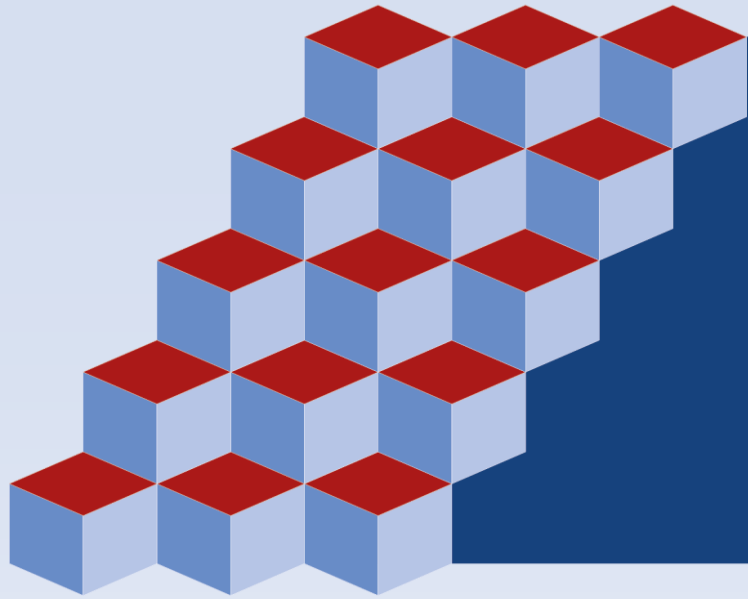
- **Start early** - Establish regulatory strategy in project planning.
- Identify **applicable regulations** your product needs to meet
- Identify **regulatory pathway** needed to legally sell your product
- Identify regulated product **characteristics & deliverables** required;
 - Technical standards, performance tests, safety and regulatory documentation



IMed consultancy is a quality and regulatory consultancy specialising in Medical Devices and In-vitro Diagnostics. We can support you in all aspects of getting your product to market, and keeping it there.

Queries? Contact: tim@imedconsultancy.com

Chris Wordley
Senior Consultant
25th May 2023



CE (and UKCA) marking

Authorised Representative service

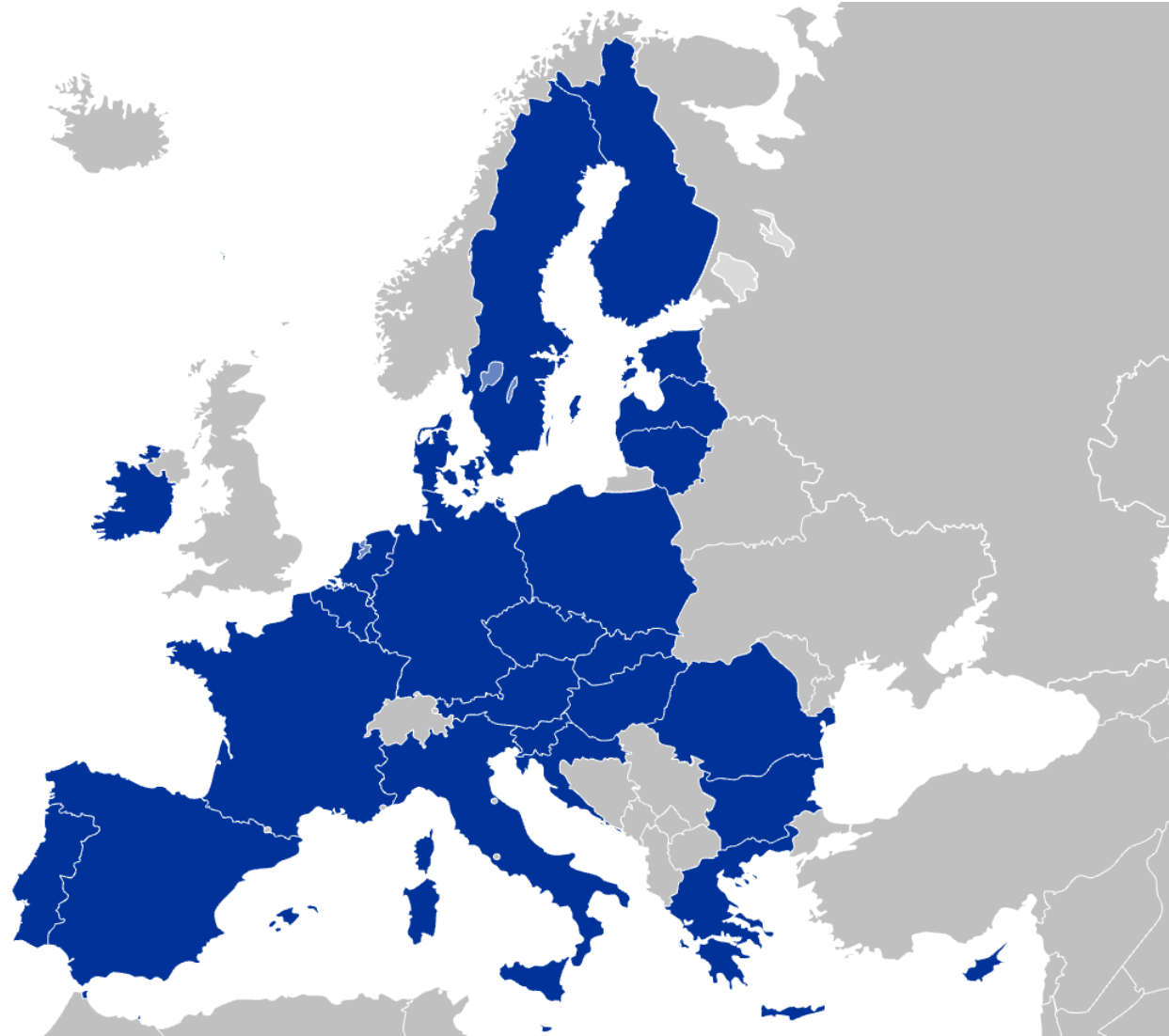


Conformance
the CE marking specialists

What is CE marking?

CE

- ▣ Mandatory European mark
- ▣ Free circulation
- ▣ Directives and Regulations
- ▣ EU27 and beyond



Products Covered



Products / Areas Covered







Legislation Commonalities

- Scope
- Economic operator duties
- Essential requirements
- Role of standards
- Conformity assessment
- Information
- Declaration of Conformity
- CE marking rules
- Technical documentation



Economic Operators

-  Manufacturer
-  Importer
-  Distributor
-  Authorised Representative
-  Fulfilment Service Provider



Process - Step 1 - Legislation

- Which applies?
- Product type and features
- Scope – some disapply others

27.6.2014

EN

Official Journal of the European Union

L 189/164

DIRECTIVE 2014/68/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 15 May 2014

on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment



Step 2 - Standards

- ❑ Detailed technical specifications
- ❑ EN prefix – same in all languages
- ❑ Harmonised standards
- ❑ Presumption of Conformity
- ❑ Which apply?

BS EN 60204-1:2018 — **Tracked changes**
compares BS EN 60204-1:2018
Incorporating corrigendum November 2018
with BS EN 60204-1:2006+A1:2009
Incorporating corrigendum February 2010






**Safety of machinery -
Electrical equipment of machines**

Part 1: General requirements



Step 3 - Conformity Assessment

-  Check compliance
-  Self-declare?
-  Notified bodies

CE 0123



Step 4 – Technical Documentation

- Describe equipment
- Conformity assessment results
- Ongoing production
- 10 years retention
- Enforcement authority access



Step 5 - Declaration

ABC Company Ltd.

EU Declaration of Conformity (No. 1234)

In accordance with European Parliament and Council Decision No 768/2008/EC Annex III

1. *Product model / product:*

Product Testing station
Model/type 789

2. *Manufacturer*

Name ABC Company Limited
Address 1 Main Road, Nicetown, Great County, NT1 9XY, United Kingdom

3. *This declaration is issued under the sole responsibility of the manufacturer.*

4. *Object of the declaration:*

Product Equipment for testing wotsits
Specification 230V 50Hz 45W

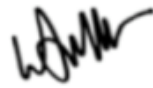
5. *The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:*

2014/35/EU The Low Voltage Directive
2014/30/EU The Electromagnetic Compatibility Directive
2011/65/EU The Restriction of Hazardous Substances Directive

6. *References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared:*

Reference & Date	Title
EN 61010-1:2010	Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 1: General requirements
EN 61326-1:2013	Electrical equipment for measurement, control and laboratory use — EMC requirements — Part 1: General requirements
EN 50581:2012	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

7. *Additional information*

Signed for and on behalf of: ABC Company Limited
Place of issue: Nicetown
Date of issue: 1st April 2019
Name: John Smith
Position: Technical Director
Signature: 








Step 6 – Mark and Serial Manufacture

CE








EU Market Surveillance Regulation

-  Most CE marked products
-  Responsible EU economic operator
-  Contact details
-  Enforcement
-  **Authorised Representative**
service



Brexit






-  Separate market
-  Independent regime
-  Similarities and differences
-  1st January 2025
-  Northern Ireland

UK
CA



Expert Guidance



-  Experience
-  Confidence
-  Learn from being led
-  Tailored advice
-  Consultancy, assessments, training, web shop materials, update service...



Chris Wordley - Senior Consultant



HEADLINE SPONSOR:
SHAKESPEARE
MARTINEAU

Thank you
Any questions?

Conformance Limited.

Great Hucklow, Buxton,
Derbyshire. England, SK17 8RG

tel: +44 1298 873800

fax: +44 1298 873801

<http://www.conformance.co.uk>



Conformance
the CE marking specialists


Break

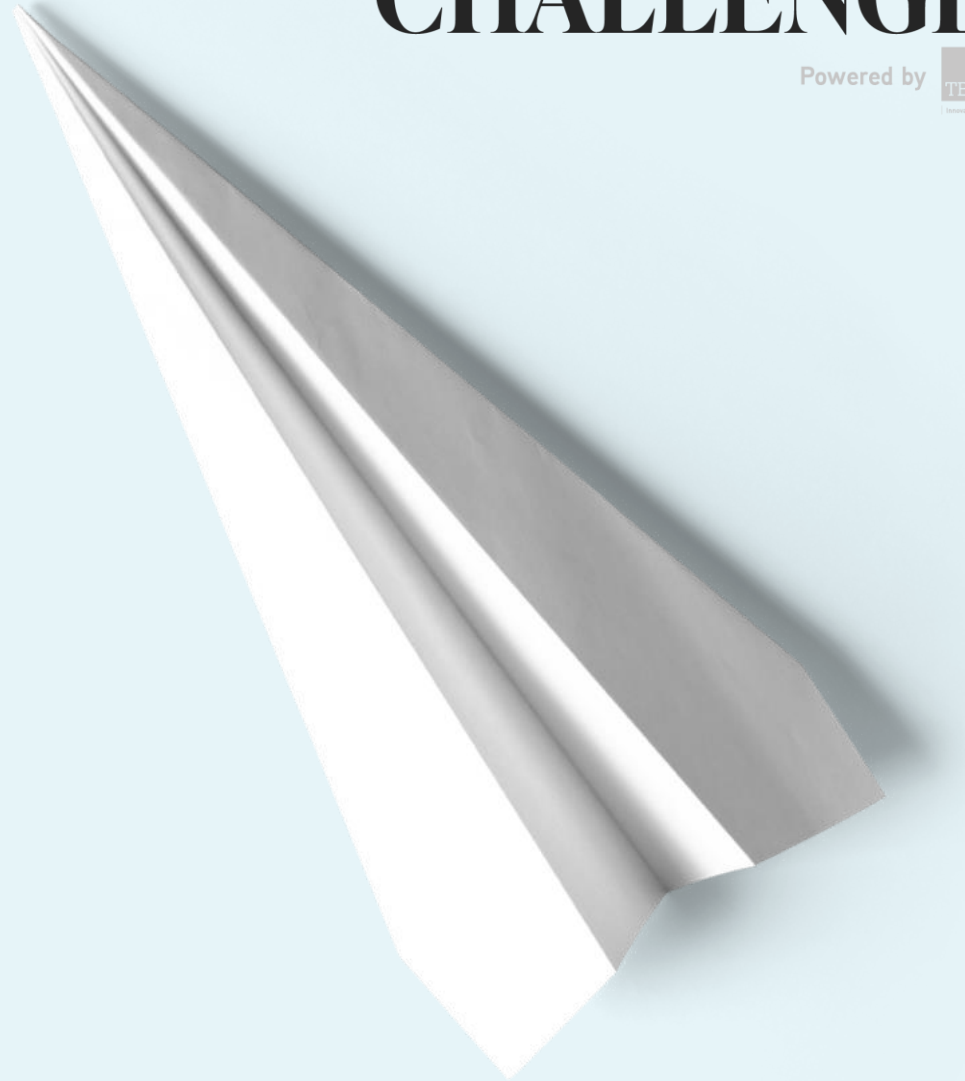
We will resume at 3:30pm



| Innovation

**THE INNOVATION
CHALLENGE**

Powered by  TBAT
Innovation



Overview of IP Protection

Dr Jagvir Purewal

Gregory Smith

25 May 2023

About Forresters

- Specialist firm of patent & trade mark attorneys
- 4 offices (Birmingham, Liverpool, London and Munich)
- Established 1884
- Strong technical & legal capabilities; all technical areas
- Open and friendly



A little about us

- SME Midlands client practice
- Experience broad range technologies
- Number of advisory strategy roles
- Work alongside strong network to support clients



Dr Jagvir Purewal
Partner - Birmingham
UK Chartered Patent Attorney
European Patent Attorney
jpurewal@forresters-ip.com



A little about us

- Work with whole spectrum of clients – from start ups through to multi-nationals
- Experience broad range technologies
- Particular experience in MedTech and fast moving consumer goods



Gregory Smith
Senior Associate - Birmingham
UK Chartered Patent Attorney
European Patent Attorney
Unified Patent Court Representative
gsmith@forresters-ip.com



What is Intellectual Property?

Appearance

- Design rights

Branding

- Trade marks

Software

- Copyright
- Patents?



Functionality

- Patents

?

- Trade secrets

Expertise

- Know-how



How IP fits into a business strategy

- Intellectual property rights can be used to help a business succeed:
 - protect the business proposition
 - increase value
 - secure investment or grant funding
 - commercialisation opportunities
 - reduce tax (Sam is talking on this later)
- Intellectual property rights are best utilised when they are aligned to a business strategy



How IP fits into a business strategy

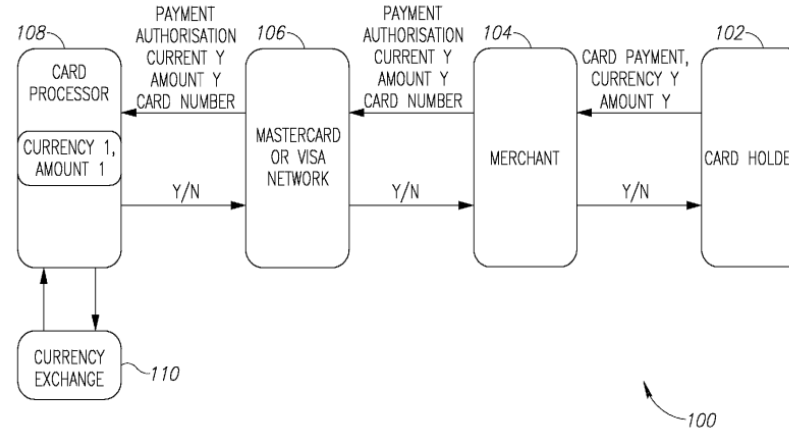
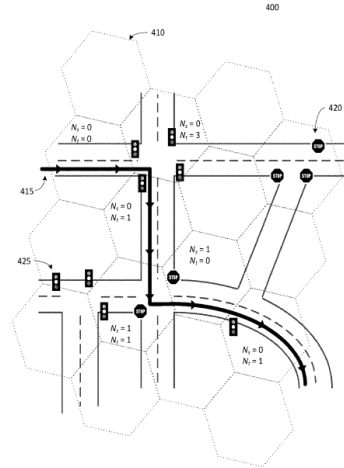
- A business journey will likely include steps that will involve IP considerations



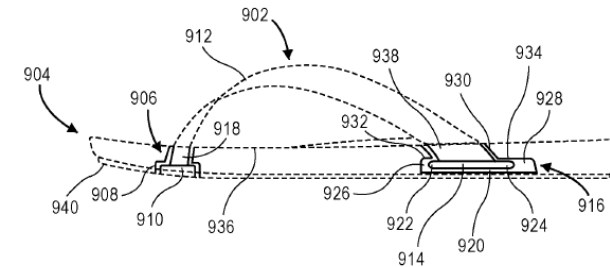
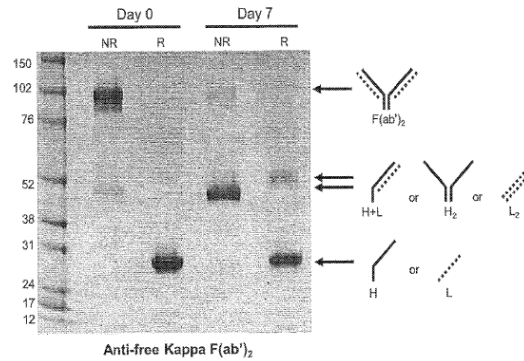
Innovate UK



Patents



Provide protection for technical innovations



Patents

- Protect technical innovations
- Last up to 20 years if renewal fees paid
- For an invention to be patentable it must be:
 - new; and
 - have an inventive step
- Confidentiality is important
- Software can be complicated – should always get a professional opinion (can relate to macro or micro)
- Territorial



Trade Marks

What is a Trade Mark?

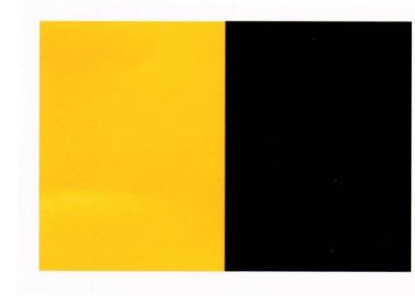
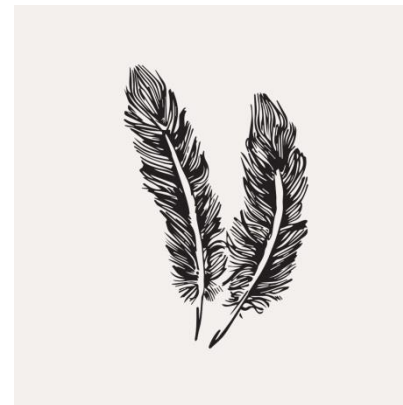
- A trade mark will distinguish a business's goods and services from those of its competitors. It's a business's brand.
- Trade marks can be words, logos, slogans, sounds, holograms, shapes etc.



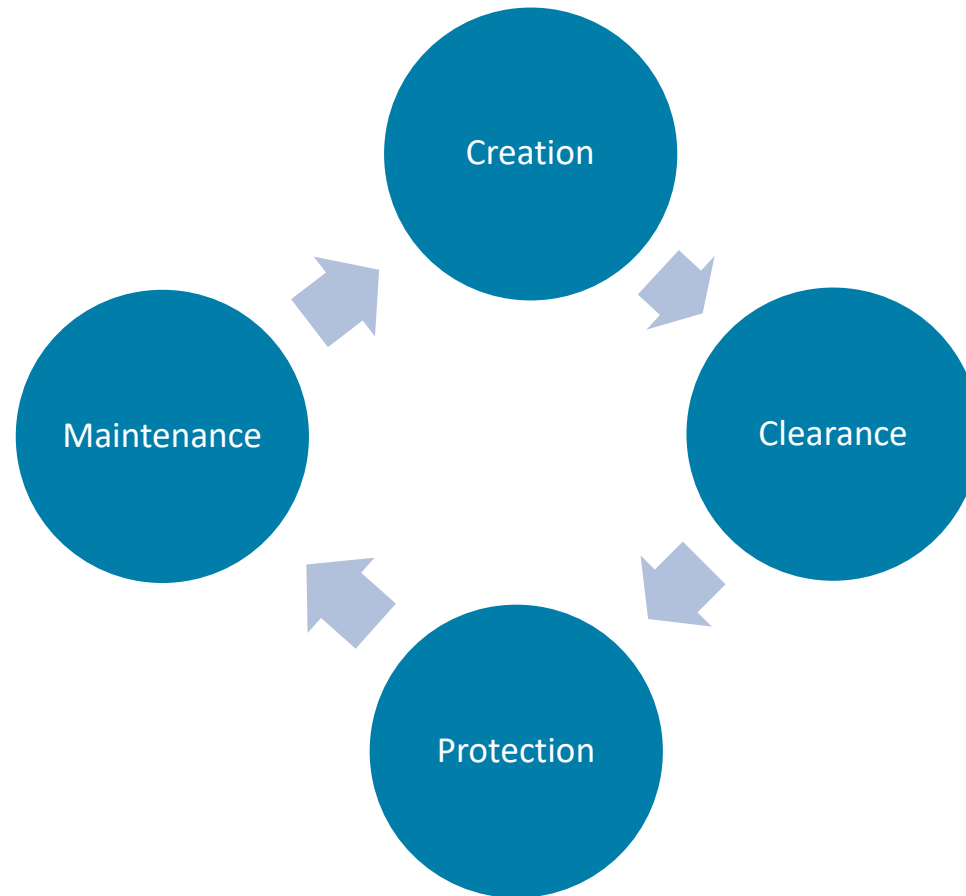
REVOLUT



JUST DO IT



Trade Mark life cycle



Registered Trade Mark protection

- Protection can be for perpetuity if renewal fees are paid and the mark is properly used / maintained
- Territorial



Designs

What are Registered Designs? (UK/EU)

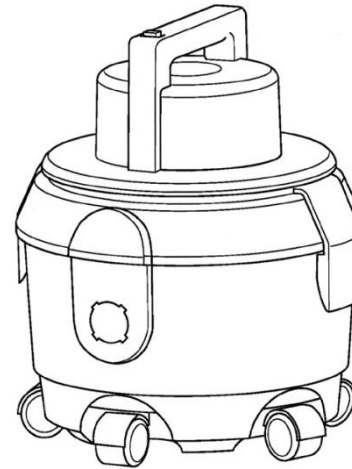
- Definition: the appearance of the whole or part of a ‘product’ and/or its ornamentation (surface decoration)
- Duration is 25 years (longer than a patent)
- Renewal fee every 5 years
- Relatively low cost (especially if multiple design application)



Registered Designs - Examples



Packaging of products



Products

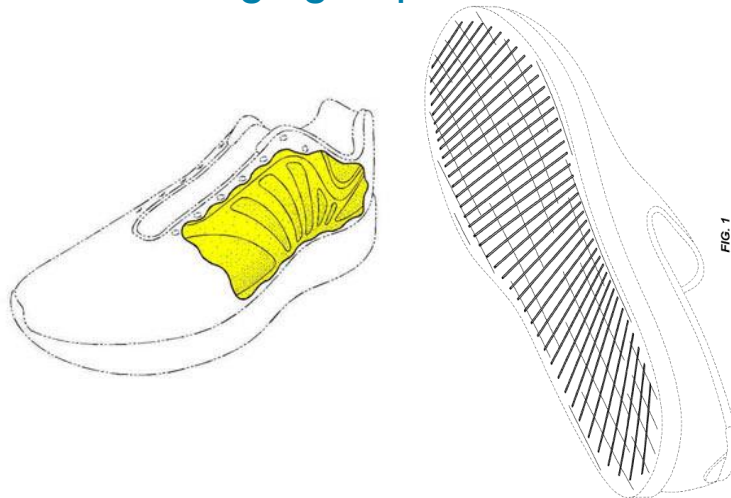
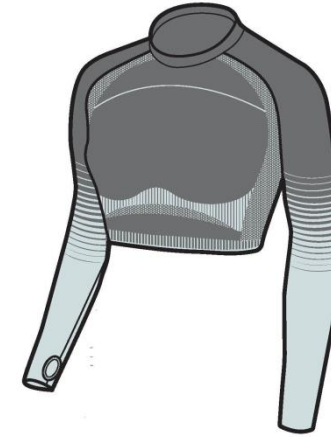
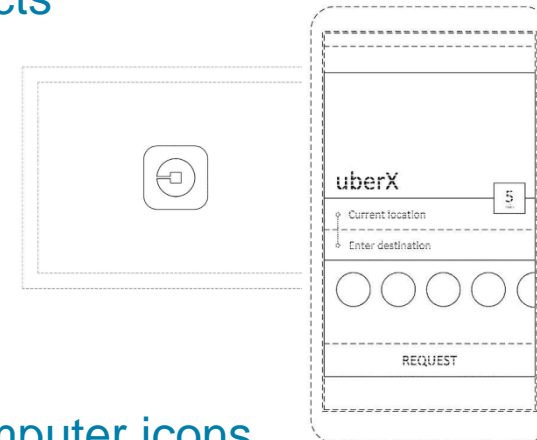


FIG. 1

Part of a product



Logos



Computer icons



Copyright

- Covers enormous variety of creations – in broad terms it protects the expression of an idea not the idea itself
 - original literary, dramatic, musical and artistic work, including illustration and photography
 - original non-literary written work, such as software, web content and databases
 - sound and music recordings
 - film and television recordings
 - broadcasts
 - the layout of published editions of written, dramatic and musical works
- Automatic protection against copying
- Narrow protection
- Long duration – generally 70 years from end of calendar year of creators' death
- All businesses will have some form of copyright
- Most important for software, digital businesses and websites



Ownership of IP Rights

Ownership of IP rights

- Generally...
- If an employee generates an IP right in the course of their employment it belongs to their employer;
- If someone is commissioned to generate an IP right then it belongs to the creator of the IP right (think about getting an agreement in place if you use a consultant).
- Grant funding / investment agreements & IP ownership



IP and Third Parties

Freedom-to-operate

- Third party rights
 - Do any of the business's activities potentially infringe on a third party's IP?
 - Different levels of analysis can be conducted
 - Trade mark clearance
- Ownership of IP
 - Who owns the various IP rights?
 - Legal situation is clear but can be complicated in practice...
- Access to IP
 - Does the business rely on the ability to use a third party's IP?
 - Does the business have written agreements in place?



Thank You



jpurewal@forresters-ip.com

gsmith@forresters-ip.com

www.forresters-ip.com

Follow us on:



Patent Box

Sam Stephens
TBAT Innovation



What is Patent Box?

Patent Box is an HMRC incentive designed to reward companies who commercially exploit patented (or similar) technology and processes.

Patent Box can reduce your corporation tax rate to as little as 10%



To be eligible



Patents – product
or process



Must be liable to
pay UK
Corporation Tax



Must own
qualifying patents
or exclusive
licences to those
patents



Patent – UK, EU
and others inc.
Japan, USA etc

About the patent

You should consider:



Does the patent cover a minor or major part of a product

Does the patent cover a process that is essential to the manufacture of a product

Do you have the necessary record keeping in place to track costs/sales/profits/R&D/Marketing etc

How much turnover will the patented product or process generate?

The process

You will need to:



Apply for a Patent/Licence in IP

Elect into Patent Box

Track sales of products that are associated with a patent

Assess whether to elect into the Small Claims Treatment

Let's look at the actual calculation

There are 9 key steps to the calculation

1. Stream your income
2. Allocate Costs
3. Calculate profit Streams
4. Calculate the Routine Profit Deduction and apply to the Profit = Qualifying Residual Profit
5. Identify the Marketing Asset Return (Small Claims Treatment – Option)
6. Work out the Nexus Fraction – All about the ongoing R&D
7. Calculate the Patent Boc Deduction
8. Work out the tax saving
9. Congratulate yourself on a job well done and have a cup of tea

1. Stream your income

		Patent Income	Other income	Total
Step 1	Income Streams	£2,129,423.62	£812,125.23	£2,941,548.85
		72%	28%	



2. Allocation of Costs

		Patent Income	Other income	Total
Step 1	Income Streams	£2,129,423.62	£812,125.23	£2,941,548.85
		72%	28%	
Step 2	Allocation of Costs			
	COGS	932040.08	355463.92	1287504.00
	Admin - Ratio of T/O	296985.05	113264.95	410250.00

3. Calculate Profit Streams

		Patent Income	Other income	Total
Step 1	Income Streams	£2,129,423.62	£812,125.23	£2,941,548.85
		72%	28%	
Step 2	Allocation of Costs			
	COGS	932040.08	355463.92	1287504.00
	Admin - Ratio of T/O	296985.05	113264.95	410250.00
		Patent Profit	Other Profit	
Step 3	Profit Streams	£900,398.49	£343,396.36	
	Profit %	72%	28%	

4. Routine Profit Deduction – Routine Return

		Patent Income	Other income	Total
Step 1	Income Streams	£2,129,423.62	£812,125.23	£2,941,548.85
		72%	28%	
Step 2	Allocation of Costs			
	COGS	£932,040.08	£355,463.92	£1,287,504.00
	Admin - Ratio of T/O	£296,985.05	£113,264.95	£410,250.00
		Patent Profit	Other Profit	
Step 3	Profit Streams	£900,398.49	£343,396.36	
	Profit %	72%	28%	
Step 4	10% Routine Profit Deduction	£626,612.00		
	10% Deduction @ 72%	£45,361.22	As legislation	
	Qualifying Residual Profit	£855,037.27		

Routine Deductions		Year	2021	Notes
Head 1	Capital allowances		£202.00	Tax Comp = Net Cap Allow
Head 2	Premises Cost - rent/rate/repair/maint		£58,194.00	
Head 3	Personnel Costs - salaries, NI, Pension		£520,441.00	
Head 4	Plant and Machinery - Leasing/Modifying		£0.00	No leasing costs
Head 5	Prof Services - inc accounting - not IP legal services		£27,651.00	
Head 6	Miscellaneous Services - Comp/utilities/telecom/post		£20,124.00	
		Total	£626,612.00	

5. Marketing Asset Return

		Patent Income	Other income	Total
Step 1	Income Streams	£2,129,423.62	£812,125.23	£2,941,548.85
		72%	28%	
Step 2	Allocation of Costs			
	COGS	£932,040.08	£355,463.92	£1,287,504.00
	Admin - Ratio of T/O	£296,985.05	£113,264.95	£410,250.00
Step 3	Profit Streams	£900,398.49	£343,396.36	
	Profit %	72%	28%	
Step 4	10% Routine Profit Deduction	£626,612.00		
	10% Deduction @ 72%	£45,361.22	As legislation	
	Qualifying Residual Profit	£855,037.27		
Step 5	Marketing Asset Return			
	25% Small Claim Treatment	£213,759.32		
	Residual Profit	£641,277.95		

As QRP is £1m or less - elect in to Small Claims Treatment

6. Nexus Fraction

From Tax Computation April 2022	Meaning	Note
Total R&D	£508,680.00 Used in R&D Tax Claim	Eligible R&D For R&D Tax
D	£508,680.00 In-house qualifying R&D	Staff/Materials/S/Ware
S1	0 Qualifying R&D on subcon to 3rd Party	No Costs
S2	0 Qualifying R&D on subcon to connected party	No Linked companies
A	0 Expenditure on Acquisition of R&D	Developed in house
Nexus Fraction	130%	
Nexus Fraction Cap	100%	

		Patent Income	Other income	Total
Step 1	Income Streams	£2,129,423.62	£812,125.23	£2,941,548.85
		72%	28%	
Step 2	Allocation of Costs			
	COGS	£932,040.08	£355,463.92	£1,287,504.00
	Admin - Ratio of T/O	£296,985.05	£113,264.95	£410,250.00
Step 3	Profit Streams	£900,398.49	£343,396.36	
	Profit %	72%	28%	
Step 4	10% Routine Profit Deduction	£626,612.00		
	10% Deduction @ 72%	£45,361.22	As legislation	
	Qualifying Residual Profit	£855,037.27		
Step 5	Marketing Asset Return			
	25% Small Claim Treatment	£213,759.32		
	Residual Profit	£641,277.95		
Step 6	Nexus Fraction			
	Calc = $((D+S1) \times 1.3)/(D+S1+S2+A)$ or 1	100%		
	Residual Profit	£641,277.95		

7. Marketing Asset Return

		Patent Income	Other income	Total
Step 1	Income Streams	£2,129,423.62	£812,125.23	£2,941,548.85
		72%	28%	
Step 2	Allocation of Costs			
	COGS	£932,040.08	£355,463.92	£1,287,504.00
	Admin - Ratio of T/O	£296,985.05	£113,264.95	£410,250.00
Step 3	Profit Streams	£900,398.49	£343,396.36	
	Profit %	72%	28%	
Step 4	10% Routine Profit Deduction	£626,612.00		
	10% Deduction @ 72%	£45,361.22	As legislation	
	Qualifying Residual Profit	£855,037.27		
Step 5	Marketing Asset Return			
	25% Small Claim Treatment	£213,759.32		
	Residual Profit	£641,277.95		
Step 6	Nexus Fraction			
	Calc = ((D+S1) x 1.3)/(D+S1+S2+A) or 1	100%		
	Residual Profit	£641,277.95		
Step 7	Patent Box Deduction			
	RP x (Corp - Patent Box)/Corp	£303,763.24		

8. Tax Saving

		Patent Income	Other income	Total
Step 1	Income Streams	£2,129,423.62	£812,125.23	£2,941,548.85
		72%	28%	
Step 2	Allocation of Costs			
	COGS	£932,040.08	£355,463.92	£1,287,504.00
	Admin - Ratio of T/O	£296,985.05	£113,264.95	£410,250.00
Step 3	Profit Streams	£900,398.49	£343,396.36	
	Profit %	72%	28%	
Step 4	10% Routine Profit Deduction	£626,612.00		
	10% Deduction @ 72%	£45,361.22	As legislation	
	Qualifying Residual Profit	£855,037.27		
Step 5	Marketing Asset Return			
	25% Small Claim Treatment	£213,759.32		
	Residual Profit	£641,277.95		
Step 6	Nexus Fraction			
	Calc = ((D+S1) x 1.3)/(D+S1+S2+A) or 1		100%	
	Residual Profit	£641,277.95		
Step 7	Patent Box Deduction			
	RP x (Corp - Patent Box)/Corp	£303,763.24		
Step 8	Equivalent Tax Saving			
	Corporation Tax Rate		19%	
	Tax Saving	£57,715.02		

No Patent Box

Tax on Patented Products = £171,076

With Patent Box

Tax on Patented Products = £113,361

Equivalent Tax Rate = 12.5%

Top Tips

Consider when patenting – are you protecting your device, or just interested in patent box?

Elect in when you have filed your patent and you are selling product

You can go back and elect into Patent Box two years

Think carefully how you will track turnover, costs and profit

Will there be ongoing R&D activity

Consider a patent even if licencing/selling your IP – the recipient may be more interested in Patent Box than the IP protection

Model the costs of patenting and the likely income generated to see if it is all worthwhile

The legislation is extensive – consider external help



- ✦ TBAT Innovation Challenge
2023 – Workshop 3 (Licensing
In & Third Party Involvement)
- ✦ Ed Wright, Shakespeare Martineau LLP
- ✦ 25 May 2023

- # Ed Wright
- # Partner
- # Commercial IP Team
- # Shakespeare Martineau LLP,
Waterfront House, 35 Station Street,
Nottingham NG2 3DQ



- # Mobile :07855 747 902
- # Email : ed.wright@shma.co.uk

Overview

- ✦ Ownership of IP – need to acquire vs need to licence in?
- ✦ Pre-contractual confidentiality
- ✦ Heads of terms preceding resulting agreement?
- ✦ Considerations when approaching licensing in/third party involvement
- ✦ Mixing up IP – “background” vs “foreground”

Ownership of IP

- # Right to sue normally vested in owner (or licensee in some circumstances)
- # Patents – inventor
- # Designs – designer or employer
- # Trade marks – applicant
- # Copyright – author or employer



Confidentiality

- # Must be preserved when pre-contractually disclosing any know-how, trade secrets or other confidential information
- # Impact on patentability
- # Make sure collaborators and other third parties involved also bound by same obligations (tension with academics)
- # Obligations to remain in force post-termination



Confidentiality II

- # No disclosure avoids any misuse – not always practical
- # What do you actually need to disclose to allow the relationship to work?
- # An NDA better than nothing
- # Bargaining position?



Heads of terms

- # Legally binding or not?
- # “Subject to contract”
- # Usually sets out the main terms
- # Exclusivity period?
- # Termination



Types of resulting agreement

- # Consultancy
- # Agency/Distribution
- # Manufacturing
- # IP assignment or licence
- # R&D or other collaborative cross-licensing arrangement
- # Joint venture



Approach to licensing in/third party involvement?

- # How and when was the IP created?
Extent to which IP rights in question can be licensed? Licensor's entitlement and rights reservations?
- # What is your organisation's IP policy?
- # Ownership vs licensing
- # Nature of licence in – applicable terms?
- # Improvements later down the line



Mixing Up IP – “Background IP”

- ⌘ Generally remains with party providing it
- ⌘ Expressly identify if and to extent possible
- ⌘ If “background IP” needed after project completion, consider option to licence in return for appropriate royalty fees/lump sum or other consideration
- ⌘ Due to charitable objectives, universities tend, when assigning or licensing IP rights, to obtain licence in return or retain right to use same for non-commercial academic/research purposes



Mixing Up IP – “Foreground IP”

- ⌘ Joint ownership of IP is not generally advisable where commercialisation envisaged
- ⌘ When determining ownership entitlement, consider:
 - which party will invest the most, both financially and in terms of know-how/expertise?
 - which party best able to commercially exploit IP?
 - who has responsibility for registering any IP rights? At whose cost? Will any assistance be required?



“Foreground IP” continued

✦ Consider:

- retaining IP rights, with option to assign or license IP on project completion to party who intends to commercially exploit IP subject to agreement of lump sum or royalties on fair and reasonable terms
- where licensed, consider long stop period within which commercial exploitation of IP must commence



Summary

- # Try not to tread on anyone else's toes
- # Protect your own IP – analyse what you have
- # Don't disclose it unless you need to
- # Put NDAs in place
- # Be up front about collaboration obligations
- # Unpicking it later is always more difficult
- # Be bold!





Thank you

- # Ed Wright
- # Partner
- # Commercial IP Team
- # Shakespeare Martineau LLP,
Waterfront House, 35 Station Street,
Nottingham NG2 3DQ



- # Mobile :07855 747 902
- # Email : ed.wright@shma.co.uk

Final Workshop



Commercialisation: Successfully heading to market

Thursday 15 June (1-5pm)

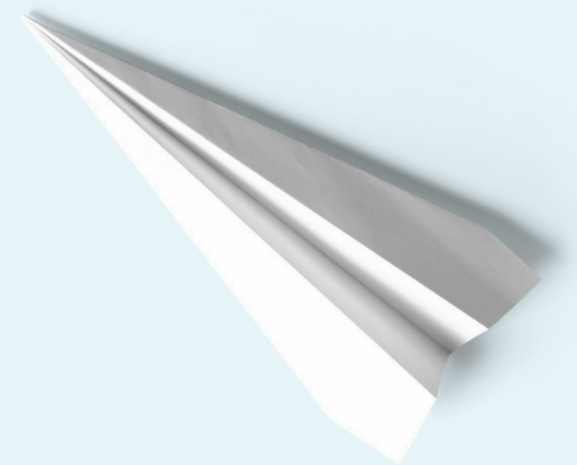
To register, please visit: <https://tbat.co.uk/the-innovation-challenge/>



| Innovation

Working in partnership with

SHAKESPEARE
MARTINEAU



Next Steps



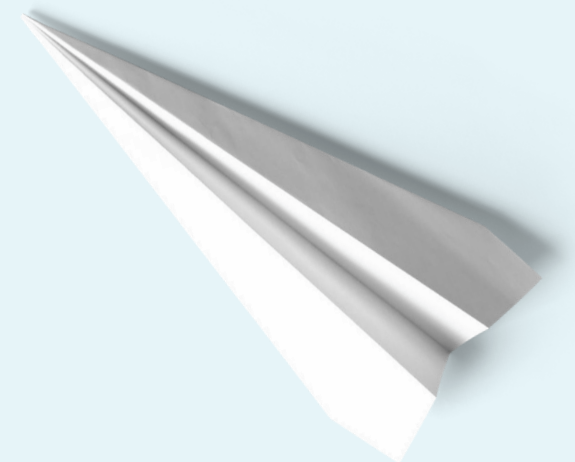
Full Application Stage

- Submit your business plan and further information, for a chance to be selected to pitch at the final showcase on 11th October and have a chance to win the prize package.

Apply here: <https://tbat.co.uk/the-innovation-challenge-application/>

Prize Package includes:

- £5000 cash
- Support from selected partners based on the winner's requirements
- 2 runners up will also receive support from partners



Thank you

The Innovation

Challenge

Product Development & Protection Workshop – How to design and protect your innovation



| Innovation

THE **INNOVATION**
CHALLENGE

Powered by 

Headline Sponsor



Workshop Sponsor



Presenters

