Translating Research into a Commercial Medical Product:

Bridging the Product Development Gap

IMed Consultancy

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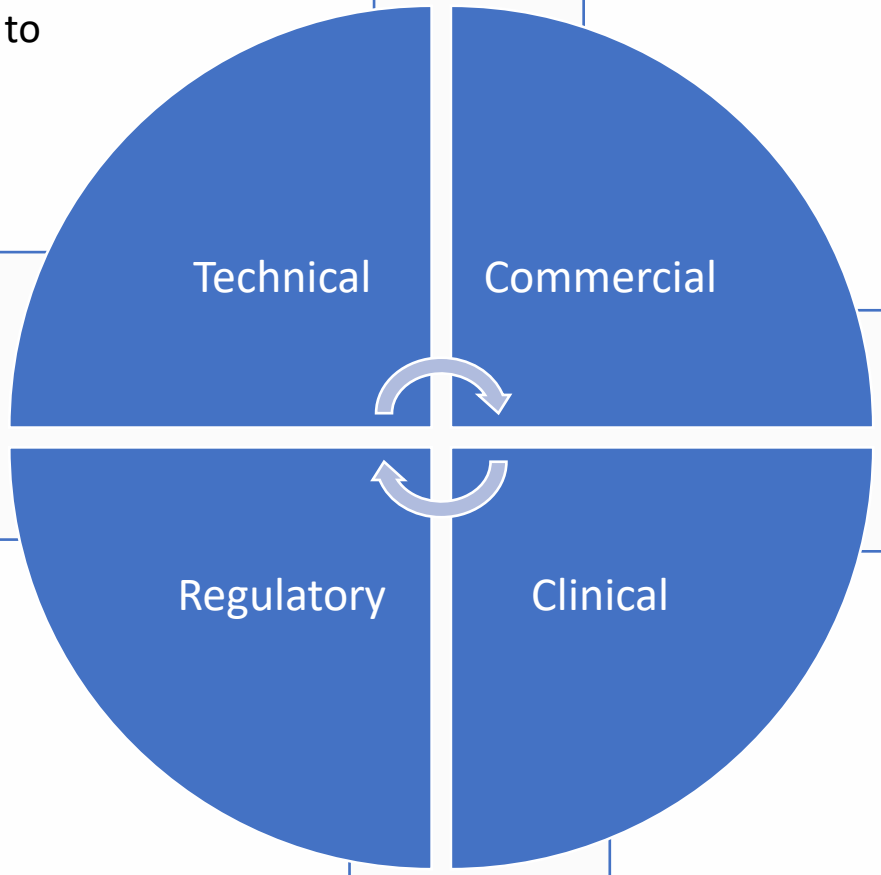
Bridging the Product Development Gap

Agenda

1. Considering the multiple objectives from development
2. Qualifying what regulatory system(s) apply?
3. Identifying regulatory and development pathway
4. Establishing requirements for the chosen regulatory pathway
5. Tips for successful medical device product development

Considering Multiple Objectives

- Is the design **technically deliverable** and manufacturable to price point?
- What features are needed for effective **performance** and necessary **safety**?



- How do we sell this product, at what **price points**, in what **target market** segments?
- What **Marketing claims** will we make to achieve that?
- **Intellectual Property** and design protection?

- What **evidence** is required to **legally** sell my product?
- How do I demonstrate it is **safe and effective** to regulators?

- How will this product **benefit patients**, and how do we demonstrate the benefit?
- How does it **integrate** into existing care?

Define - What is your product?

Project planning;

- What is your product's **intended purpose**?
- What is its **medical purpose**?
- Which **patient groups** is it intended to be used with?
- **How does it operate** to achieve its intended purpose?
- What **countries** do you want to sell the product in?

IMPORTANT: Consider these attributes for minimum viable product first, and product roadmap enhancements second.

What is 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 the regulatory pathway
5. What **evidence** you need to generate to meet requirements for product regulatory approval.

What Regulations & Requirements?

Wearable Fitness Sensor & Data Portal

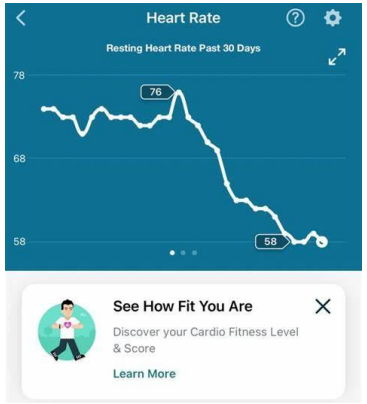
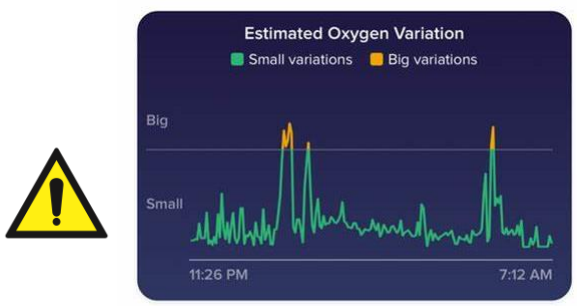
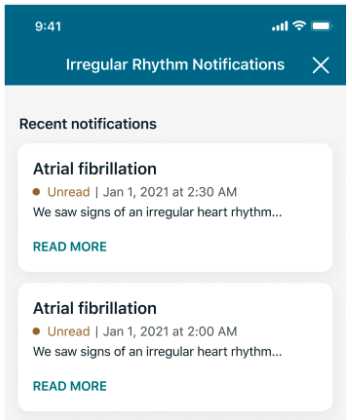
Generally used to track individual wellness and health data.

Health data may be used for medical purposes.

What regulations do I need to meet?

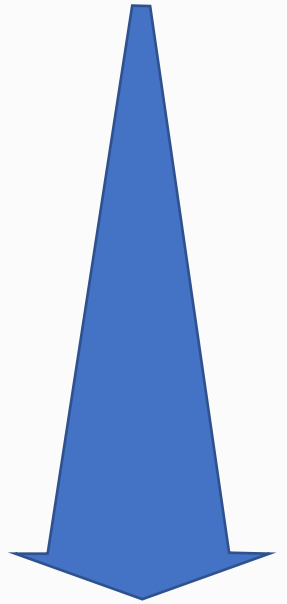
Regulatory Qualification – Practical Example

Wearable Fitness Sensor & Data Portal

Wellness Product	Digital Health / Borderline Medical Device	Medical Device
Exercise/ fitness heart rate	Oxygen Variation in sleep	Atrial Fibrillation Detection
Wellness & Fitness Data shown to user only	Product has clinical utility and risk, but not meeting device definition	Data used for diagnosis, condition monitoring, prognosis or treatment decisions/ actions
	 Note: advanced, nuanced regulatory positioning!	

Device Risk – Electronic Wearable Examples

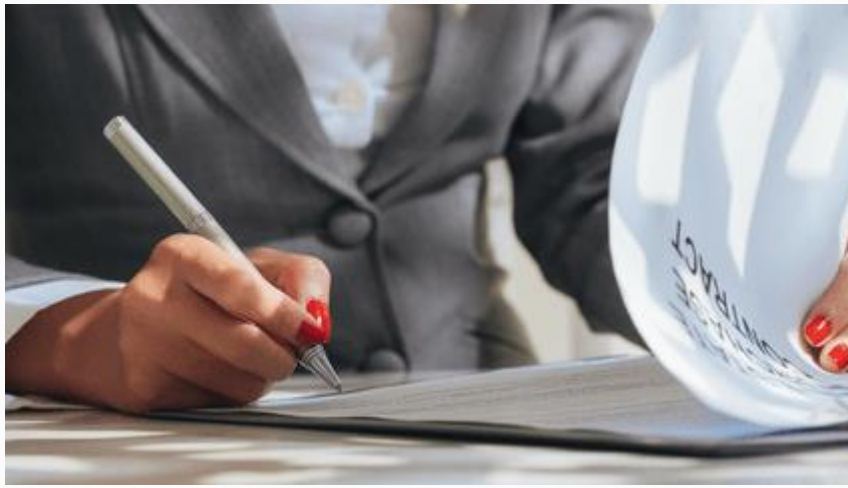
Claimed Intended Use	EU Risk Classification	Regulatory Risk Profile
Diagnostic – visible light illumination	Class I	Low risk
Diagnostic and therapeutic – TENS pain relief	Class IIA	Medium-low risk
Diagnostic – life threatening arrhythmia detection	Class IIB	Medium-high risk
Diagnostic and therapeutic – blood glucose monitoring and insulin delivery	Class III	High Risk



More evidence required for regulatory approval

Regulatory Pathway – Low Risk Device

Devices classified as low risk may not need to be fully assessed by the regulator before approval, if the regulatory pathway allows this.



The product needs to meet all regulatory and compliance requirements before declaring compliance.

The manufacturer can certify the product meets regulatory requirements, and registers the assessment and product with the national authorities.

Personal & company legal liability for person making declaration on product meeting regulatory requirements.

Regulatory Pathway – Medium and High Risk

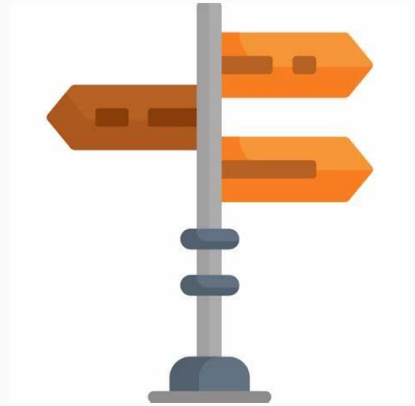
Medium and high risk devices usually need to be **fully assessed by the regulator** before approval – this requires generating high quality evidence in development.

Certification of the Quality Management system is required in UK, EU. Not required in USA.

Approval timelines can be significant. Factor into your regulatory and business project planning.

Product Development Requirements

- Evaluate the requirements of the regulation(s) & chosen pathway;
  - Processes to follow during development
  - Information required on technical design
  - Documentation required
  - Regulatory Submissions and registrations needed



- Evaluate the requirements for product regulatory and customer evidence expectations;
  - Technical Performance
  - Clinical Effectiveness
  - Minimum Safety Expectations
  - Current Standard of Care & Level of Innovation in your new product
  - Marketing claims you want to make

Tips for successful device development

- **Define your product** and its **clinical use** case(s) upfront.
- Identify **up front** the documented **regulatory deliverables** you need to create, and include in technical project planning.
- Identify and meet relevant **product standards** (ISO, EN, IEC etc) applicable to your product.
- Design, develop and document in a medical device **Quality Management System**.

Tips for successful development

- Consider **product changes** during development and **evaluate impact –** technical, clinical, commercial and regulatory.

- Integrate **regulatory assessment timelines** in your project planning.

- Speak with **clinicians and patients** to understand their needs, expectations and abilities. Consider at the heart of development the **clinical need** your product is targeted at.

Q&A

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