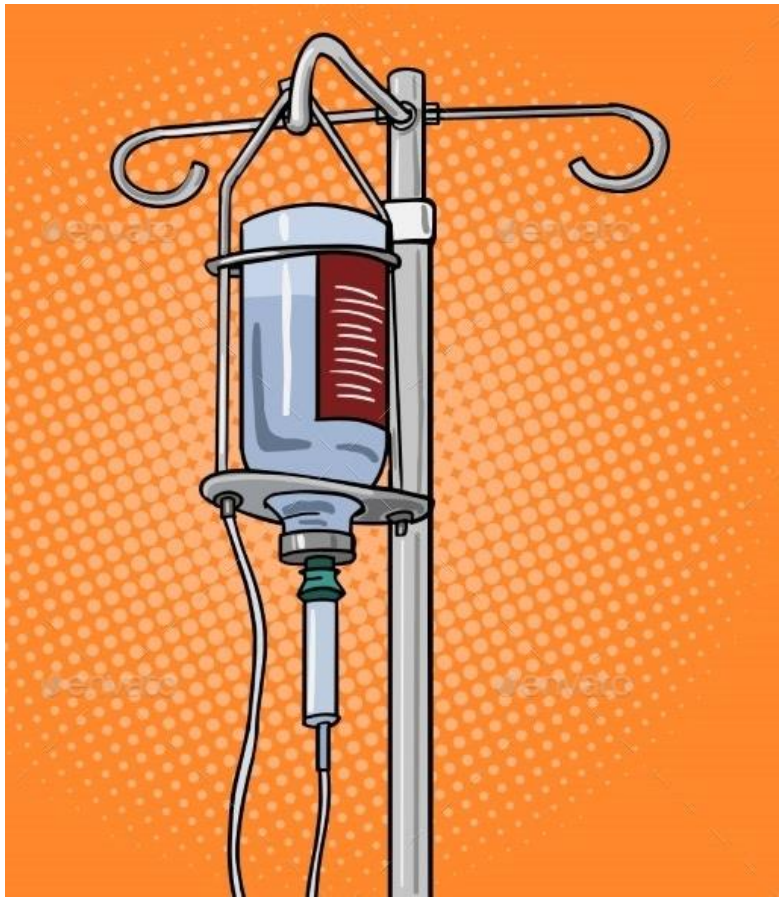
Role of regulation in accelerating innovation

Michael Kipping

DEFINITION OF A MEDICAL DEVICE
REGULATION EU 2017/745 MDR



"any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

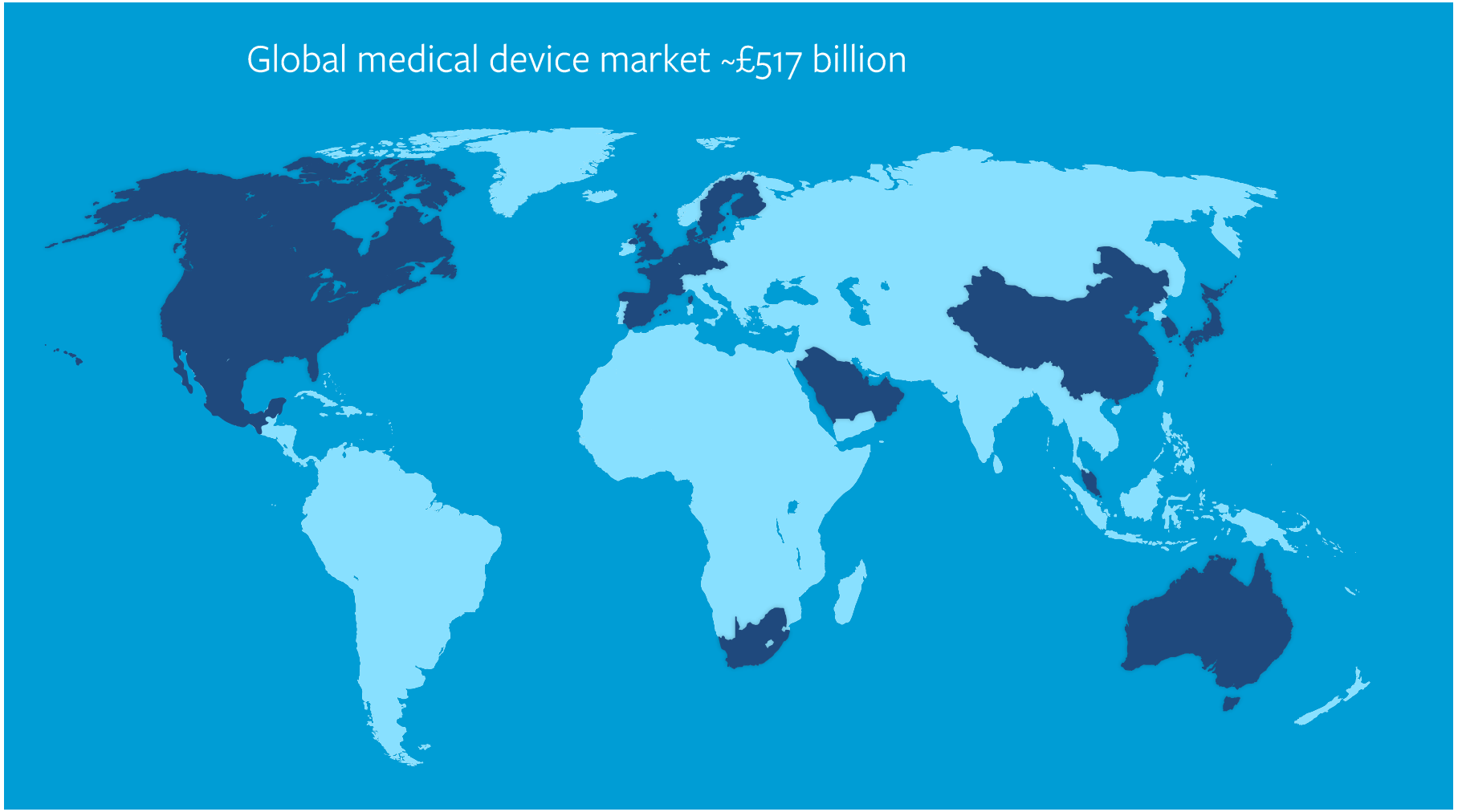
- *diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,*
- *diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,*
- *investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,*
- *providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,*

and which does not achieve its principal intended action by **pharmacological, immunological** or **metabolic means**, in or on the human body, but which may be assisted in its function by such means."

DO **NOT** ASSUME THAT YOUR PRODUCT IS A MEDICAL DEVICE IN ALL GEOGRAPHICAL JURISDICTIONS.

DEFINITIONS MAY VARY!

GLOBAL MEDICAL DEVICE MARKET



41.6% (£215bn)

24.3% (£126bn)

7.4% (£38bn)

7.2% (£37bn)

3.3% (£17bn)

16.2% (£84bn)
(RoW)

GLOBAL MEDICAL DEVICE MARKET

MEDICAL TECHNOLOGY

#1 sector patents granted EU

14,200 EPO patents 2020

£9.5bn invested UK 2019/20

Innovation

33,000 businesses

95% SMEs

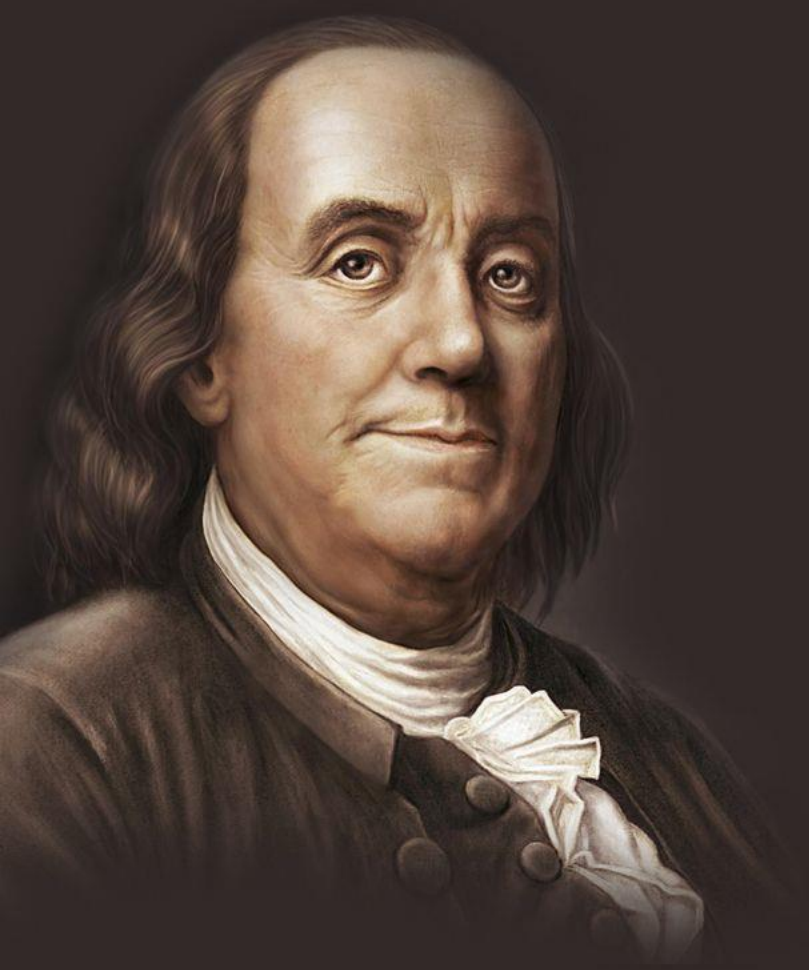
800,000 employees

Industry

>600,000 unique products

70% 'connected' by 2030

Products



In this world
nothing is certain
but death and taxes.

....and regulation

Benjamin Franklin

Increasing regulatory requirements ≠ increased patient safety

ZERO REGULATORY REQUIREMENTS

High patient safety risk due to lack of evidence

VERY HIGH REGULATORY REQUIREMENTS

Increased patient safety risk due to stifled innovation and reduced product access

ESSENTIAL PRINCIPLES

MEDICAL TECHNOLOGY

1. Design

2. Clinical evaluation

Safe and performs as intended through-out its life-cycle

3. Manufacturing

4. Labelling

- Software
- Radiation
- Biological materials

Applies to all risk classes

BENEFIT / RISK
KEY FOCUS

MEDICAL TECHNOLOGY

*"the **analysis** of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose, when used in accordance with the intended purpose given by the manufacturer"*

(EU) 2017/745 Article 2 (24)

CONFORMITY ASSESSMENT

MEDICAL TECHNOLOGY

TECHNICAL FILE REVIEW

+

QUALITY MANAGEMENT SYSTEM AUDIT

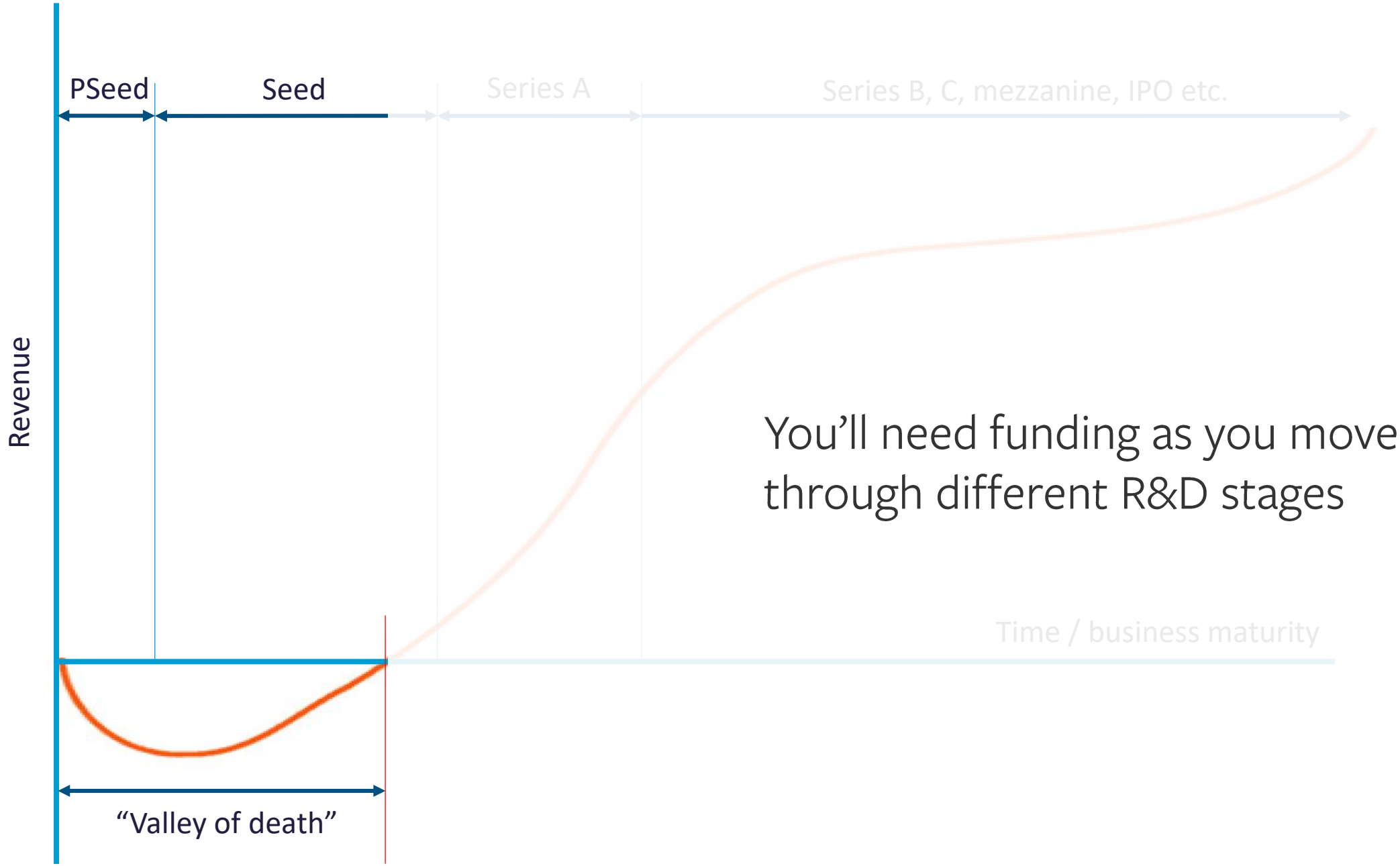
ISO 13485, MDSAP

=

FDA

CE

UK CA



You'll need funding as you move through different R&D stages

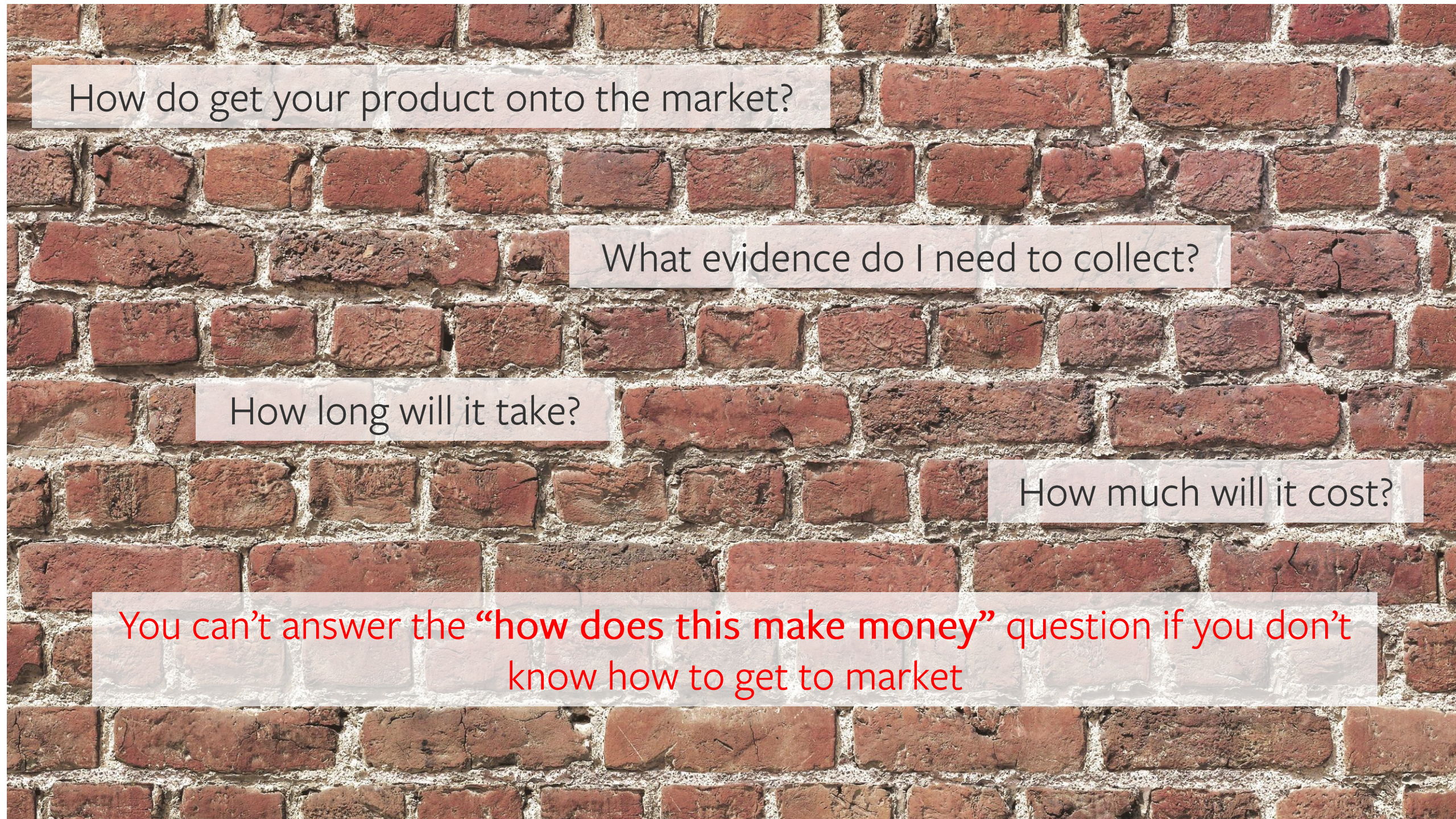
“How does this make money?”

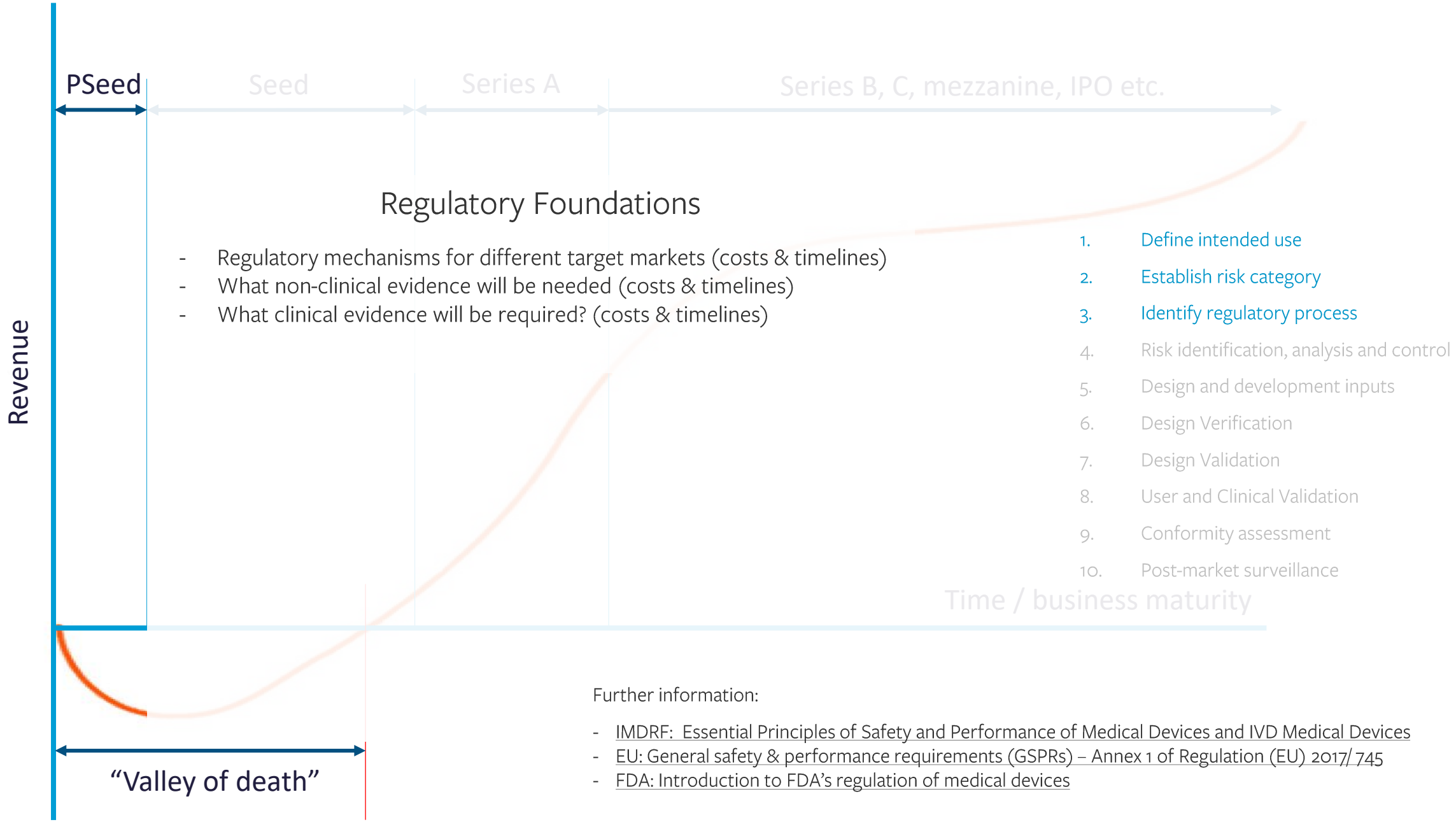
Market potential - cost to access market = Commercial opportunity

HOW TO IDENTIFY MARKET OPPORTUNITIES Innovate UK EDGE

- Calculating market size - is there enough market demand?
- Competitor analysis - who are the major players already out there in the market?
- Market potential - is this the **best market for your innovation**?
- Market growth opportunities - is the market likely to grow?
- Identifying any barriers to entry - what are the potential pitfalls?
- External environment - upcoming technology updates, policy and regulatory developments or social influences that could affect your success?

How to identify market opportunities


How do get your product onto the market?
What evidence do I need to collect?
How long will it take?
How much will it cost?
You can't answer the "how does this make money" question if you don't know how to get to market



Regulatory Foundations

- Regulatory mechanisms for different target markets (costs & timelines)
- What non-clinical evidence will be needed (costs & timelines)
- What clinical evidence will be required? (costs & timelines)

1. Define intended use
2. Establish risk category
3. Identify regulatory process
4. Risk identification, analysis and control
5. Design and development inputs
6. Design Verification
7. Design Validation
8. User and Clinical Validation
9. Conformity assessment
10. Post-market surveillance

Further information:

- IMDRF: Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices
- EU: General safety & performance requirements (GSPRs) – Annex 1 of Regulation (EU) 2017/ 745
- FDA: Introduction to FDA's regulation of medical devices

GRANT FUNDING QUESTIONS

Innovate UK

Question 1. Applicant location (not scored)

Question 2. Health or Healthcare Need or challenge

Question 3. Scientific or Technical Evidence

Question 4. Innovation

Question 5. Technical approach

Question 6. Freedom to operate (FTO)

Question 7. Outcomes and route to market

Question 8. Technical, commercial and environmental risks

Question 9. Skills and experience

Question 10. Resources required

Question 11. Financial support and added value

GRANT FUNDING QUESTIONS

Innovate UK

element

Question 1. Applicant location (not scored)

Question 2. Health or Healthcare Need or challenge → Intended purpose, current clinical 'gold standard', medical conditions, indications

Question 3. Scientific or Technical Evidence

Question 4. Innovation → State of the art, medical device rationale, target product profile

Question 5. Technical approach → Principle of operation, product characteristics

Question 6. Freedom to operate (FTO)

Question 7. Outcomes and route to market → What geography are you targeting & relevant legislation? Cost of compliance vs commercial opportunity

Question 8. Technical, commercial and environmental risks → Implications of regulatory pathway on costs, time to market, evidence requirements etc.

Question 9. Skills and experience → Do you have regulatory/quality skills in the team? If not, how will you obtain expert input?

Question 10. Resources required → How much will different segments of the regulatory pathway cost?

Question 11. Financial support and added value

INTENDED PURPOSE

- claims about what the product does (explicit and implicit)
- primary intended purpose of the product
- whether there are any similar licensed or registered products on the market
- how it is presented to the public through labelling, packaging, promotional literature and advertisements

KitchenCraft Cooking Syringe / Meat Injector

by KitchenCraft

168 ratings | 4 answered questions

Amazon's Choice for "meat syringe"

Price: £2.49 prime FREE Same-Day

Pay £2.49 £0.00: get a £20 gift card upon approval for the Amazon Platinum Mastercard. Terms apply.
Note: This item is eligible for **click and collect.** Details

New (11) from £2.49 prime FREE Delivery

Item Package Quantity: **1**

1	2	3
£2.49 prime	£12.41	£19.29

Colour Name: **White/Transparent**

- Infuse meat and poultry with mouth-watering flavours. This syringe injects marinades deep into the flesh for powerful flavour impact
- It's easier and quicker than traditional marinades. And the flavour stays in the meat, so it won't wash away and the meat stays moist
- It's so easy to use. Try injecting the Christmas turkey with a garlic marinade, or adding a spicy kick to barbecued chicken
- It's also great for baking. Fill it with jam, syrup or custard to fill doughnuts and cupcakes, or liqueur to finish a Christmas pudding
- Generous 2 oz (57 ml) capacity, with measurement markings so it's easy to follow recipes. Comes with KitchenCraft's 12 month guarantee

› See more product details

Cooking equipment

PRODUCT DESCRIPTION

Pure Pens was established by Niche Pens in 2011. With director Ross Adams initially entering the fountain pen market in 2004 and becoming the first UK retailer of the German brand Pelikan, it was decided a number of years later to expand the Welsh retailer's offering. As a result, Pure Pens now stand as one of the UK's leading online pen shops and have one of the widest selections on offer today.

Ink syringes are the perfect instrument to use to fill a fountain pen that doesn't take ink cartridges. This ink syringe has a capacity of 2ml and comes with a blunt needle.

Show Less

− 1 + £1.99 | (£1.66 ex) Add to Cart

ADD TO WISHLIST (6)

Buy now, pay in 30 days with Klarna. Learn more

Hand writing equipment

Integrated Safety System Syringes

The new technology **guarantees patient's safety** and **reduces the customers' Total Cost of Ownership** through:

- prevention of needle stick injuries
- reduction of non-quality costs (missed activation and wrong functionality)
- reduction of logistic space (incoming and outcoming)
- lower impact on secondary packaging (blister and carton box)
- minimization of regulatory impact
- investment for safety device assembling machines

The ISS Platform is designed to be customizable to meet the needs of different drug products applications such as Biotech, Heparin, Small Molecules, and Vaccines.

Customization is related to:

- Plunger Stopper ISO Standard design
- Plunger rod and backstop
- Other customizable features on demand

ISS is designed to be supplied in a standard Nest and Tub configuration for easy processing on existing fill-finish lines.

Medical device

ISOTONIC NACL PREFILLED SYRINGES

Sku # SC1-0.5

CC 1

FILL VOL. 0.5

CLICK HERE TO REQUEST A QUOTE

CLICK HERE FOR THE ORDER FORM

Prefilled syringes for flushing, locking or sampling through an i

Combination product

STATE OF THE ART
IMDRF

“Developed stage of current technical capability and/or accepted clinical practice in regard to products, processes, and patient management, based on the relevant consolidated findings of science, technology, and experience.”

Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices (imdrf.org)

Regulatory Strategy

- Detailed strategy on how you will demonstrate compliance.
- Specific plan to address safety, performance & quality
- Quality management system (ISO 13485)
- Submission strategy

1. Define intended use
2. Establish risk category
3. Identify regulatory process
4. Risk identification, analysis and control
5. Design and development inputs
6. Design Verification
7. Design Validation
8. User and Clinical Validation
9. Conformity assessment
10. Post-market surveillance

REGULATION
EASY AS 1, 2, 3

element

STEP 1

NAVIGATING YOUR REGULATORY PATHWAY

WHAT IS CHALLENGE?
STATE OF THE ART?
HOW WILL INNOVATION ADDRESS CHALLENGE?

EVIDENCE REQUIREMENTS?
REGULATORY APPROVAL PROCESS?

STEP 2

GATHER EVIDENCE

NON-CLINICAL EVIDENCE

CLINICAL EVIDENCE

STEP 3

CONFORMITY ASSESSMENT

QUALITY MANAGEMENT SYSTEM (ISO 13485, MDSAP)

TECHNICAL FILE

Class I

- Self-declaration of conformity
- Affix CE Mark or UKCA to product
- Register with EUDAMED / MHRA

Quick process
Inexpensive

Class Is, Class IIa, Class IIb, Class III

- Notified Body or UK Approved Body undertakes conformity assessment (QMS and technical file)
- 34 EU Notified Bodies
- 4 UKABs: BSI, SGS, DEKRA and UL
- Affix UKCA or CE to product
- Register with MHRA or EUDAMED

~18-24 months to obtain CE or UKCA Mark (for each)

£50K to £100K for CE Mark process

REGULATORY CONSULTANTS

MEDICAL TECHNOLOGY

RAPS REGULATORY AFFAIRS PROFESSIONALS SOCIETY

TOPRA

THANK YOU

Q&A

Michael Kipping

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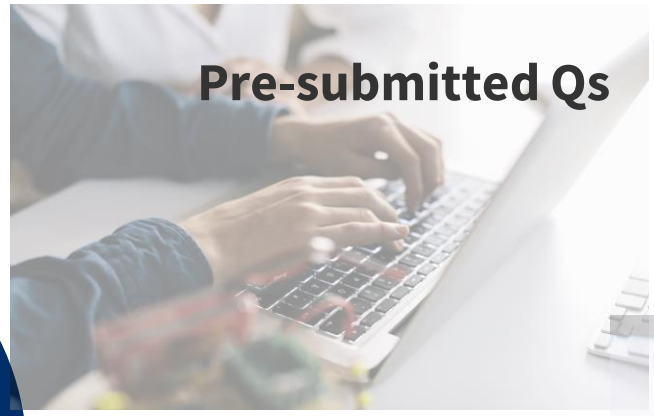

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