Medicines & Healthcare products Regulatory Agency

Regulatory standards

What benchmarks need to be met for IVDs?

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Medicines &
Healthcare products
Regulatory Agency

We are the UK regulator of medicines, medical devices and blood components for transfusion. We are responsible for making sure these products meet set standards for safety, quality and efficacy.

The MHRA is an Executive Agency of the Department of Health and Social Care.

MHRA British Pharmacopoeia UK Stem Cell Bank
Yellow Card NIBSC CPRD

What are

the standards

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the standards

Safety

Essential Requirements: General Requirements

- Design and manufacture that will not compromise the clinical condition or safety of the patients, users, other persons or property
- Risks are weighted against benefits
- High levels of protection of health and safety
- Conforms to safety principles, considering generally acknowledged state-of-the-art

Quality

Essential Requirements: Design and Manufacturing Requirements

- Chemical, physical and biological properties, incl. infection and microbial contaminations
- Manufacturing and environmental properties
- Protection against radiation, mechanical and thermal risks
- Specific requirements for devices for self-testing
- Packaging & labelling including instructions for use

Efficacy

Essential Requirements: General Requirements

- Analytical sensitivity & specificity
- Clinical (diagnostic) sensitivity & specificity
- Accuracy, repeatability, reproducibility
- Control of relevant interferences
- Limits of detection

In the regulation

STATUTORY INSTRUMENTS

2002 No. 618

CONSUMER PROTECTION

The Medical Devices Regulations 2002

Made	*20th May 2002*
Laid before Parliament	*21st May 2002*
Coming into force	*13th June 2002*

The IVD regulations transposes the IVD Directive clauses.

The IVD Directive was in place across the EU until 2017 and was replaced by EU IVDR (2017/746) that came into effect since May 2022.

The UK exited the EU in 2019 and before the coming into effect date of the IVDR and therefore IVDR **does not apply in Great Britain**.

https://www.legislation.gov.uk/uksi/2002/618/introduction

PART IV In Vitro Diagnostic Medical Devices

When are the standards to be applied?

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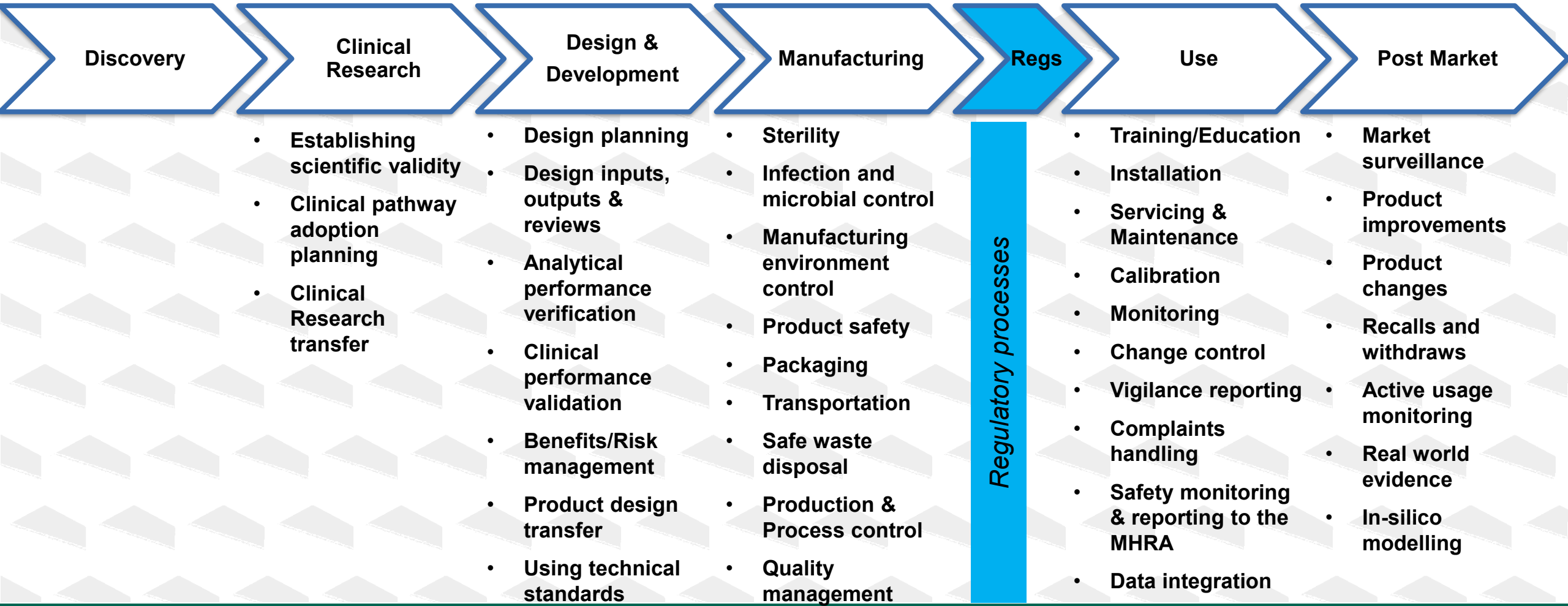
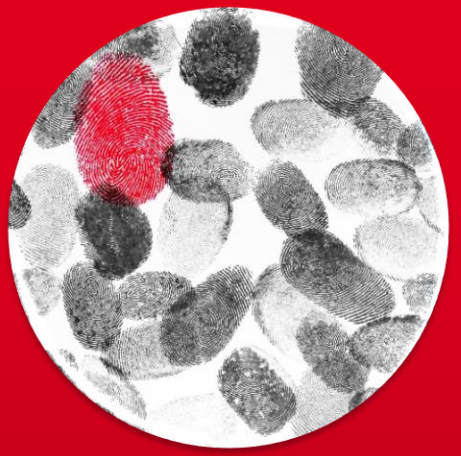


Expected Outcomes

Well-defined Intended Use

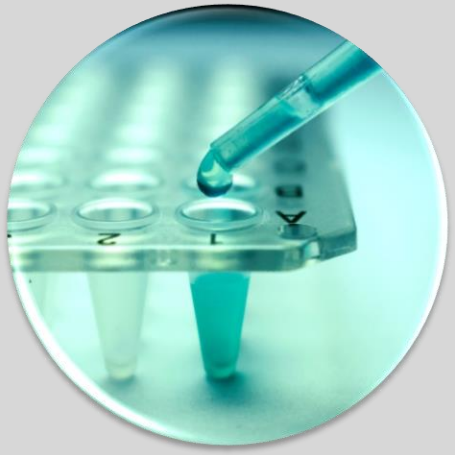
Established Clinical Evidence



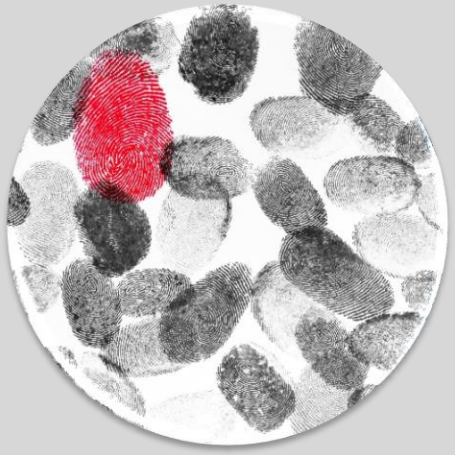
Reliable Results Data

Expected Outcomes

- The objective intent of the IVD
- A general description of the disease or condition
- Identify users and environment
- Safe usage practices
- Test procedure described
- Precautions and warnings given
- Results interpretation



Established Clinical Evidence



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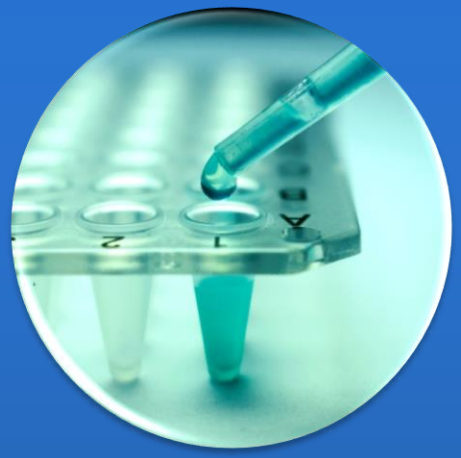
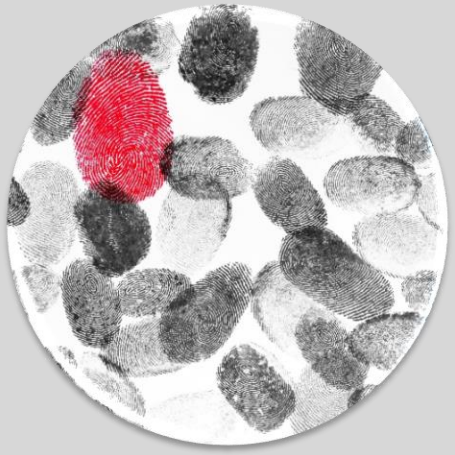


- Analytical performance / verification testing
- Clinical performance / validation testing
- Human factors testing
- Use valid statistical techniques
- Adopt Technical Standards
- Claims based on scientific data



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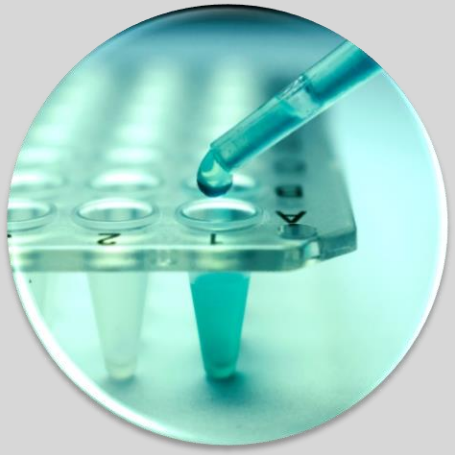

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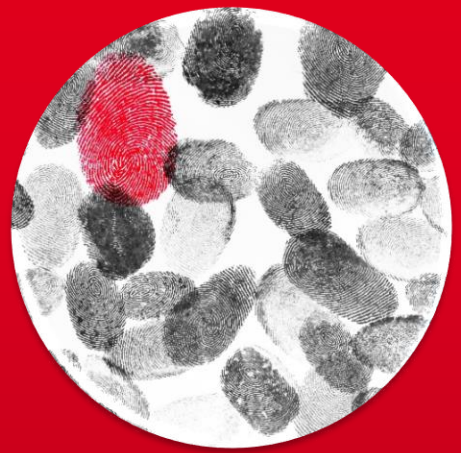

- Clinical validity to accurately and reliably detect/predict a clinical condition or disease for the target patient population
- Demonstrates accuracy (incl. Trueness, Repeatability & Reproducibility) of measurement methods and test results
- Test is fit for the intended purpose

Regulators are your best friends too

- We are normal human beings.
- We apply the applicable legislations, technical standards and guidance.
- Regulations are simply the standards for Safety, Quality and Efficacy

So…

1. **Learn and apply the regulations**
2. **Seek help to understand the meanings of each regulation**
3. **Inform us when something isn't working**

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