Hardian Health

Innovate UK

Health Innovation Network South London

Module 4: Quality Assurance

How to apply quality assurance to the development of medical device software and hardware.

Outline

This module will cover:

- *What* is Quality Assurance, and *why* apply it?
- *How* to apply Quality Assurance (Quality Management System)
- *When* to apply Quality Assurance to medical device software and hardware
- *Who* needs to apply Quality Assurance, and *where* is it to be applied
- Multiple choice questions

What is Quality Assurance, and why apply it?

- **Quality Assurance** = part of quality management focused on providing confidence that quality requirements will be fulfilled
- **Quality management** = coordinated activities to direct and control an organization with regard to quality
- **Quality** = degree to which a set of inherent characteristics fulfils requirements
  - Characteristic = distinguishing feature
  - Requirement = need or expectation that is stated, generally implied or obligatory
- ***Quality assurance*** *is the part of [the set of] coordinated activities to direct and control an organization with regards to [the] degree to which a set of distinguishing features [of the medical device] fulfils the needs or expectation that is [set out in applicable medical device regulations, to assure that medical devices are safe, effective and cybersecure]*

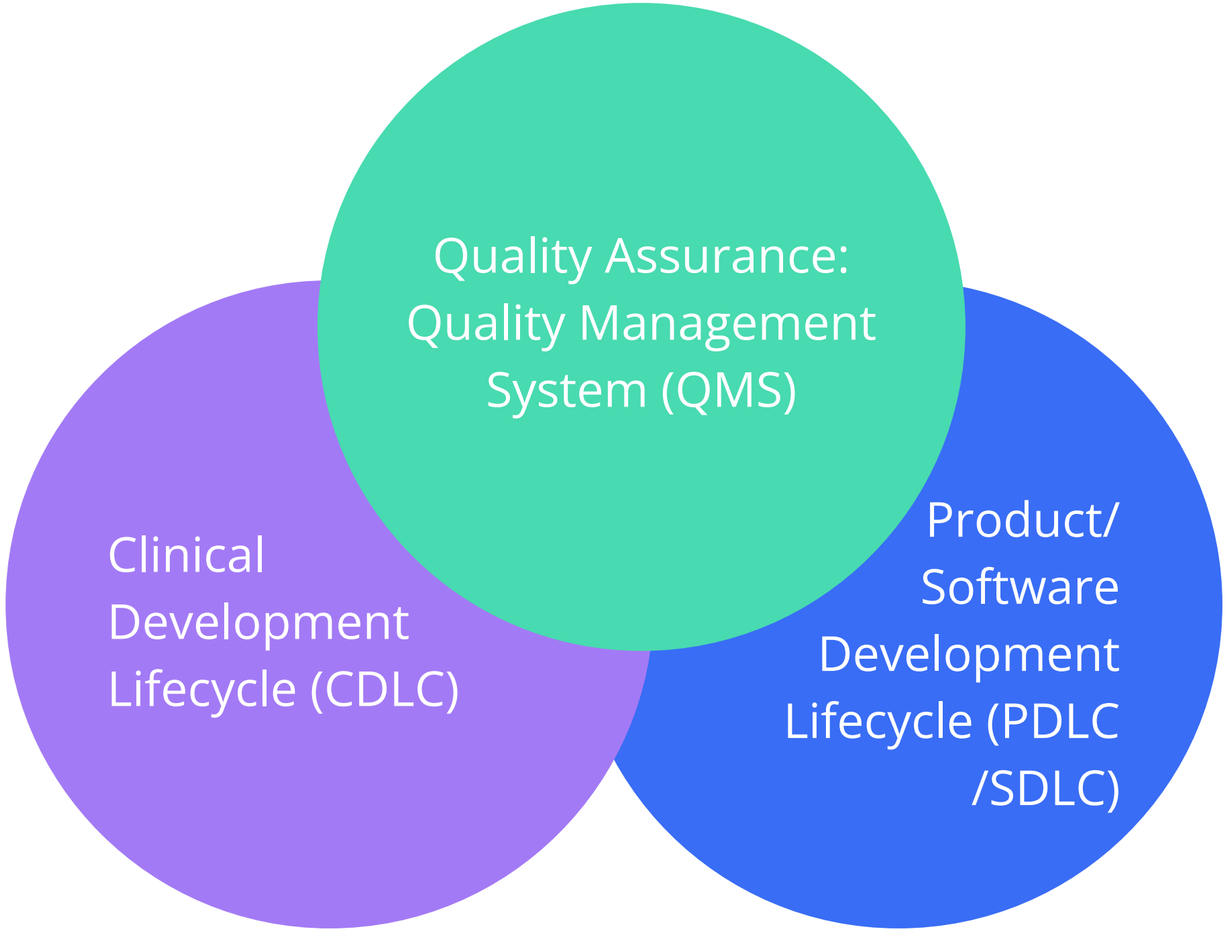
What is Quality Assurance, and why apply it?

“manufacturer” means—

(a) the person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party; or

(b) any other person who assembles, packages, processes, fully refurbishes or labels one or more ready-made products or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name, apart from a person who assembles or adapts devices already on the market to their intended purpose for an individual patient

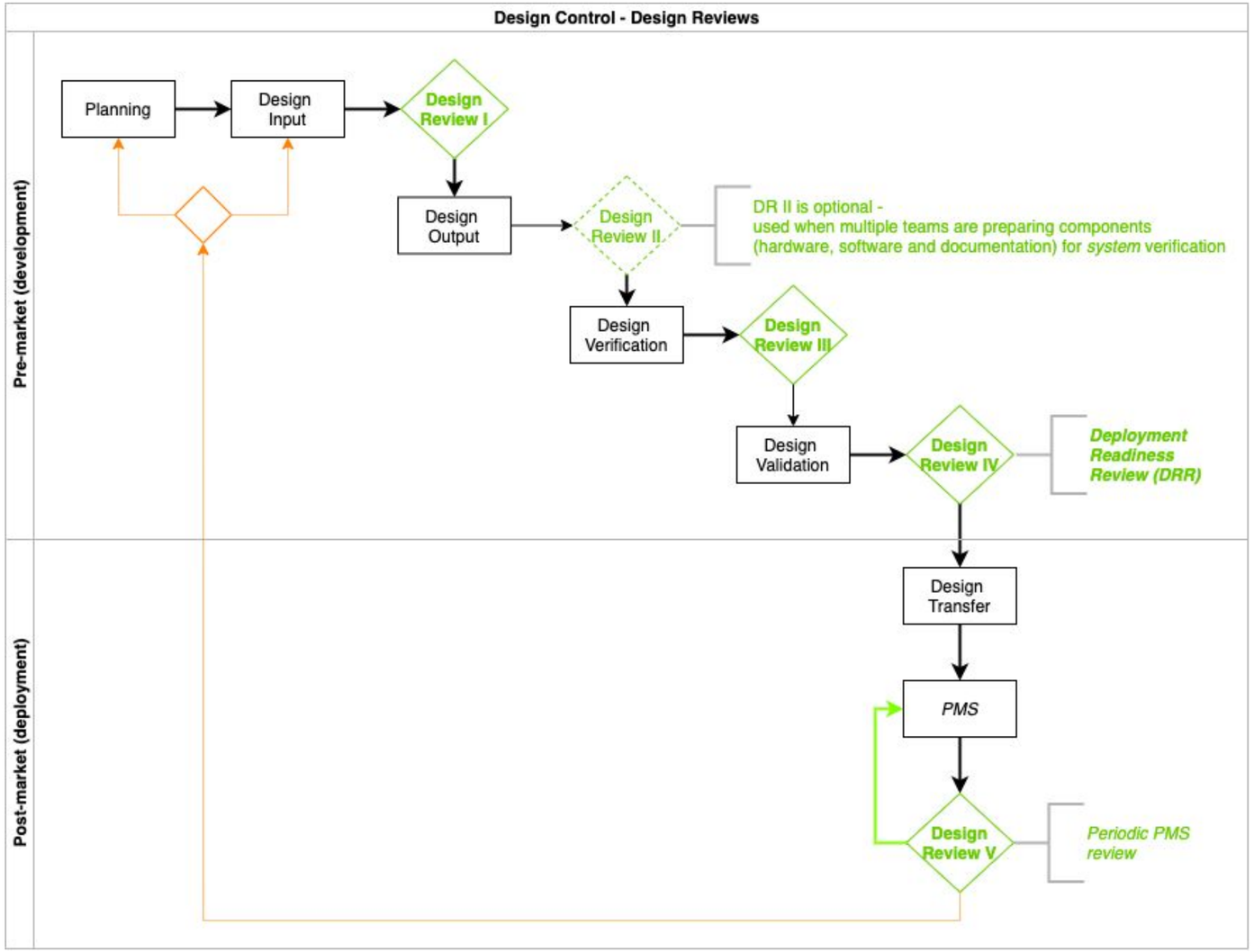
What is Quality Assurance, and why apply it?



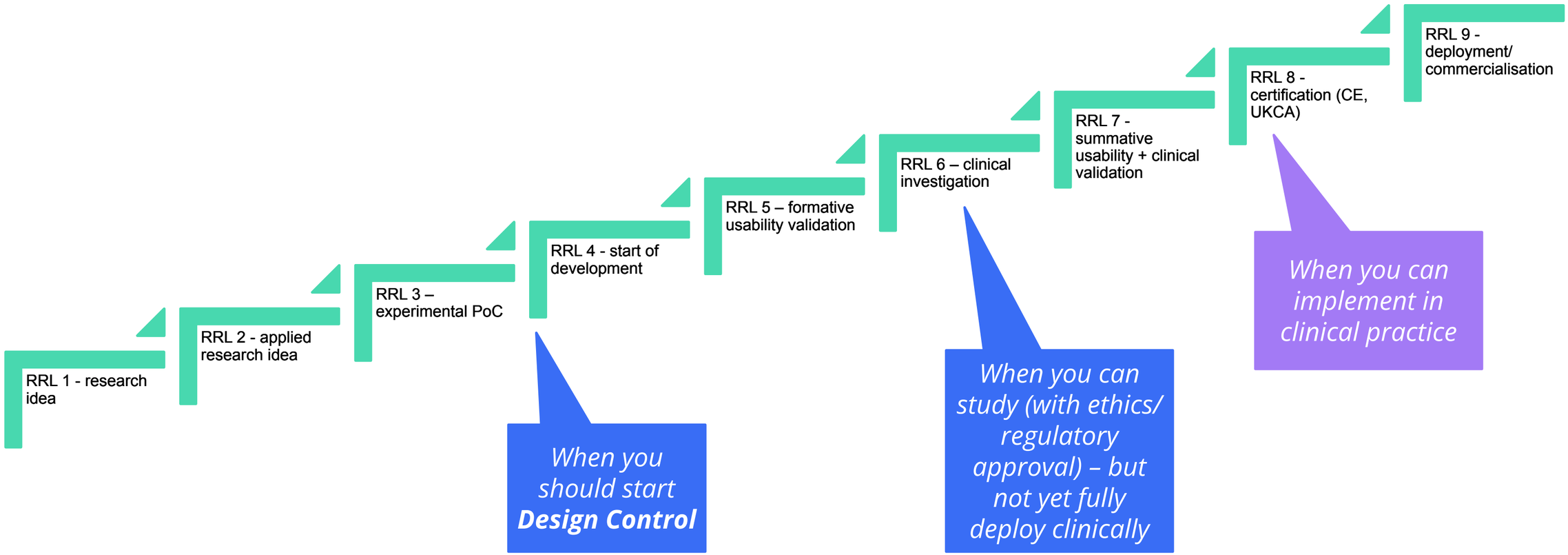
How to apply Quality Assurance (QMS)

Subsystem	Procedures and Processes
Management	• Quality Manual *including Quality Policy, Quality Objectives and KPIs* • Document and Record Controls • Human Resources, Infrastructure, Work Environment • Company & Product Risk Management, including disaster recovery/ business continuity
Measurement, Analysis and Improvement	• Auditing – Internal, Supplier, External and Unannounced • Corrective and Preventive action • Statistical techniques
Design and Development	• Design Controls • Clinical Evaluation (*Performance Evaluation for IVDs*)
Production and Service Controls	• Computer Software Validation • Production Control/ Installation and Servicing (if applicable)/ Nonconforming Product • Data Protection • Customer Management
Purchasing	• Supplier Management and Purchasing
Device marketing authorisation and facility registration; *medical device adverse events and advisory notice reporting*	• Post Market Surveillance (PMS)/ Feedback/ Complaint Handling/ Reporting • Establishment and Product Registration *Note: These procedures are jurisdiction specific e.g. UK, EU and USA would all have different procedures as their regulatory requirements and competent authorities*

How to apply Quality Assurance (QMS)



When to apply Quality Assurance



Who needs to apply Quality Assurance, and where is it to be applied?

Summary

Quality Assurance covers coordinated activities to direct and control an organization with regards to the degree to which a medical device is developed and deployed to be *safe, effective and cybersecure*

The key activities to be coordinated are *design control*, *clinical evaluation* and *risk management*

Design control, clinical evaluation and risk management really need to start once a *research* idea starts to be translated into a product *development*

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