# Impact of Brexit on Medical Device Reglations

# What's the Buzz?

ICR GCP & Ethics Forum - December 2021

Keith Summerhayes BSc (Hons), FICR, CSci, MILM.
Managing Director, MDCRQ Solutions Ltd

14th December 2021

# For Discussion:

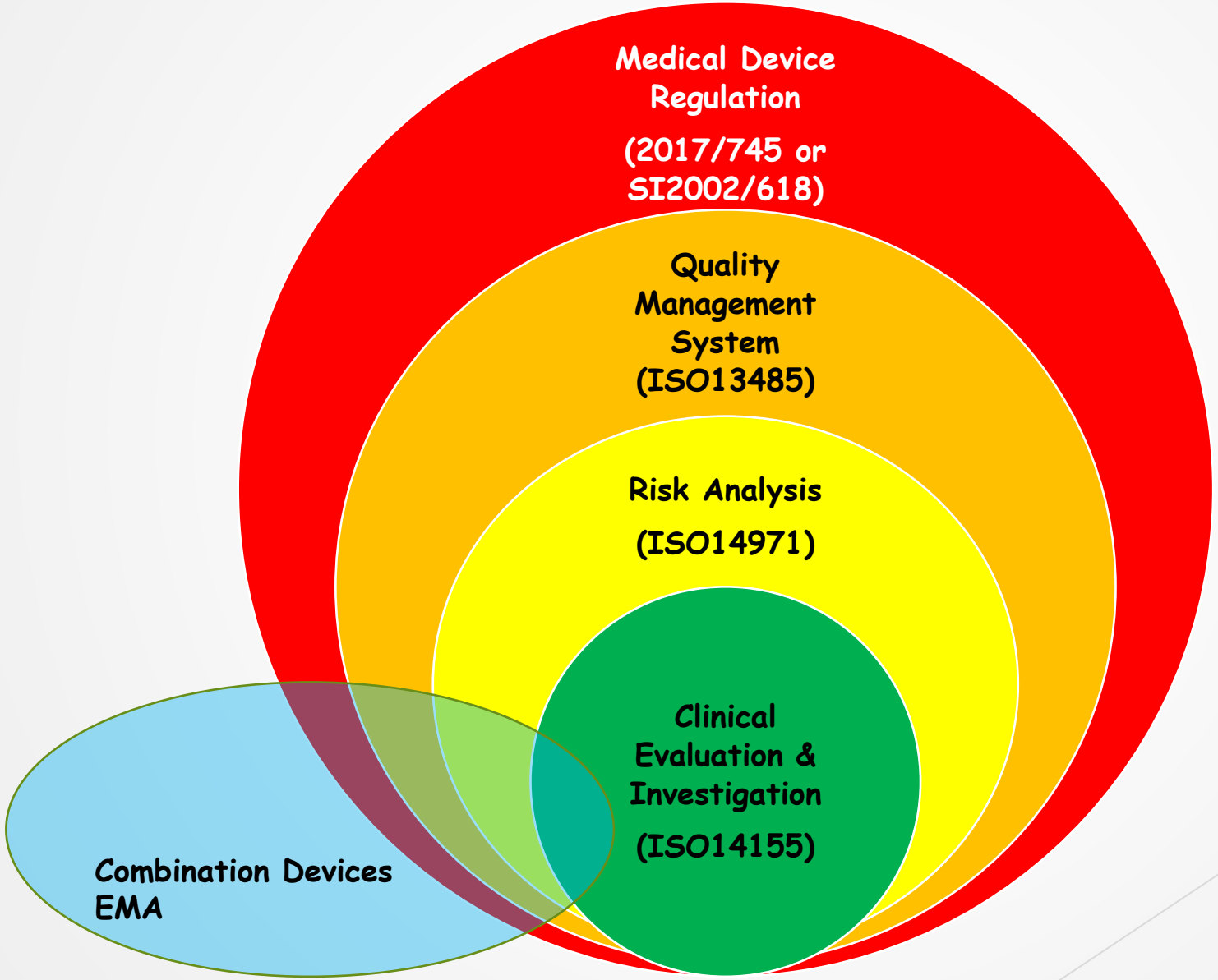
- 2017/745 MDR
  - The Medical Device Regulation – Replaces Directives
    - 93/42/EEC (MDD)
    - 90/385/EEC (Active MDD)
- SI 2002/618

# For Discussion:

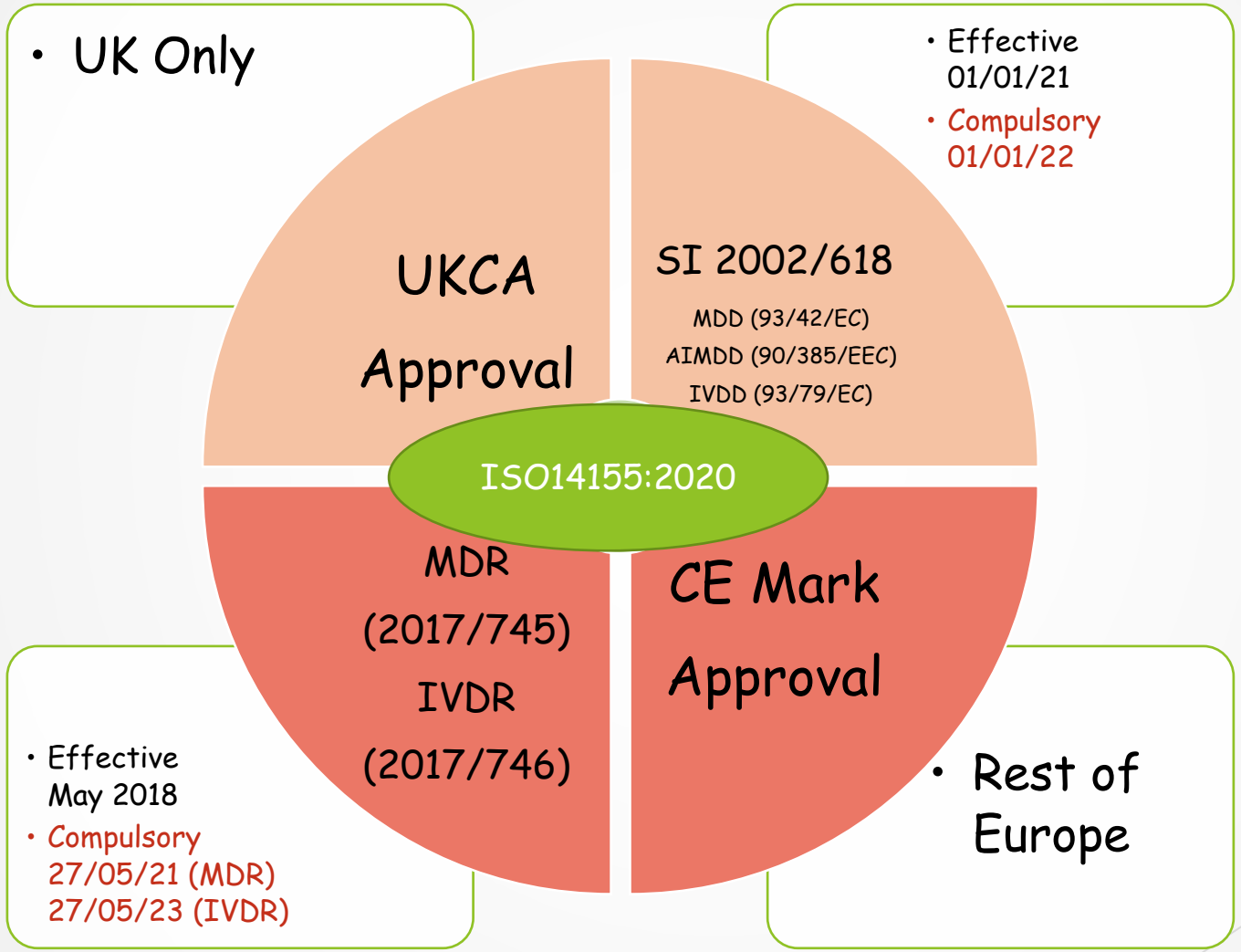
- Why didn't we automatically move to MDR at the same time as everyone else after all that transition work/grief?
- Is there likely to be a subsequent change in the near future?
- What are the key implications ofcompliance with both systems>

# Applicable Regulations, Directives, Standards & Guidelines

# Overall Regulatory Framework



# Impact of Brexit



# Medical Device Definitions

## Article 2: MDR 2017/745

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

- 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 process or pathological process or state
- Providing information by means of *in vitro* examination of specimens derived from the human body
- Control or support of conception
- Disinfection or sterilization of any of the above-mentioned products

And which does not achieve its principle intended action by a pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its function by such means

# Cancellation of MDR Changes for UKCA Mark

- **General Safety & Performance Requirements** - Essential Requirements
- **stricter control for high-risk devices** via a new pre-market scrutiny mechanism with the involvement of a pool of experts at EU level
- **reinforcement of the criteria for designation and processes for oversight of notified bodies**
- **inclusion of certain aesthetic devices** that present the same characteristics and risk profile as analogous medical devices under the scope of the regulations
- **improved transparency** through a comprehensive EU database (EUDAMED) on medical devices and a device traceability system based on unique device identification

# Cancellation of MDR Changes for UKCA Mark

- **introduction of an 'implant card'** for patients containing information about implanted medical devices
- **reinforcement of the rules on clinical evidence**, including an EU-wide coordinated procedure for authorising multi-centre clinical investigations
- **strengthening of post-market surveillance** requirements for manufacturers
- **improved coordination mechanisms** between EU countries in the fields of vigilance and market surveillance
- **Responsible Person Role (QP)**

# Other Directives

- Reg 536/2014
  - Medicinal Products Clinical Trials Regulation
- EC/1394/2007
  - Advanced Therapy Medicinal Products Regulation (was 2009/120/EC)
- 2004/27/EC
  - Clinical Trials Directive (GCP)
- *21CFR ….*
  - *US FDA IDE Regulations*

# Medical Device Standards
## (Applicable Versions)

- ISO 10993 series – Preclinical Biological Requirements for testing
- ISO 13485:2016 – Quality Management System
- ISO 14971:2019 – Risk Analysis
- ISO 14155:2020 – Conduct Clinical Investigation
- ISO 15223:2020 – Labelling
- CEN EN 60601 series – Electrical Equipment
- CEN EN1041 – Instructions For Use
- CEN EN 2304 – Medical Device Software
- CEN EN 62366 – Usability Engineering
- UDI System

# Where to Find Information and Plans

- Obviously - .Gov website under MHRA
- Relevant Notified Bodies such as BSI
- Trade Organisations like ABHI
- White papers and publications from some of the larger CRO organisations like Emergo, MEDDEV Solutions, NAMSA used as part of their marketing strategy or directly generating sales revenues for access.

# MHRA Guidelines

- New guidance and information for industry from the MHRA - GOV.UK (www.gov.uk)
- Whole range of Guidance Documents effective Jan 2021 including
  - Clinical trials
  - Devices
  - Importing and exporting
  - IT systems
  - Legislation
  - Licensing
  - Pharmacovigilance
  - Paediatrics

# Implications of All These Documents

- Complexity
- Overlap
- Inconsistency
- Confusion over Priority of Importance
- Frequency of Update

# Regulatory Overview

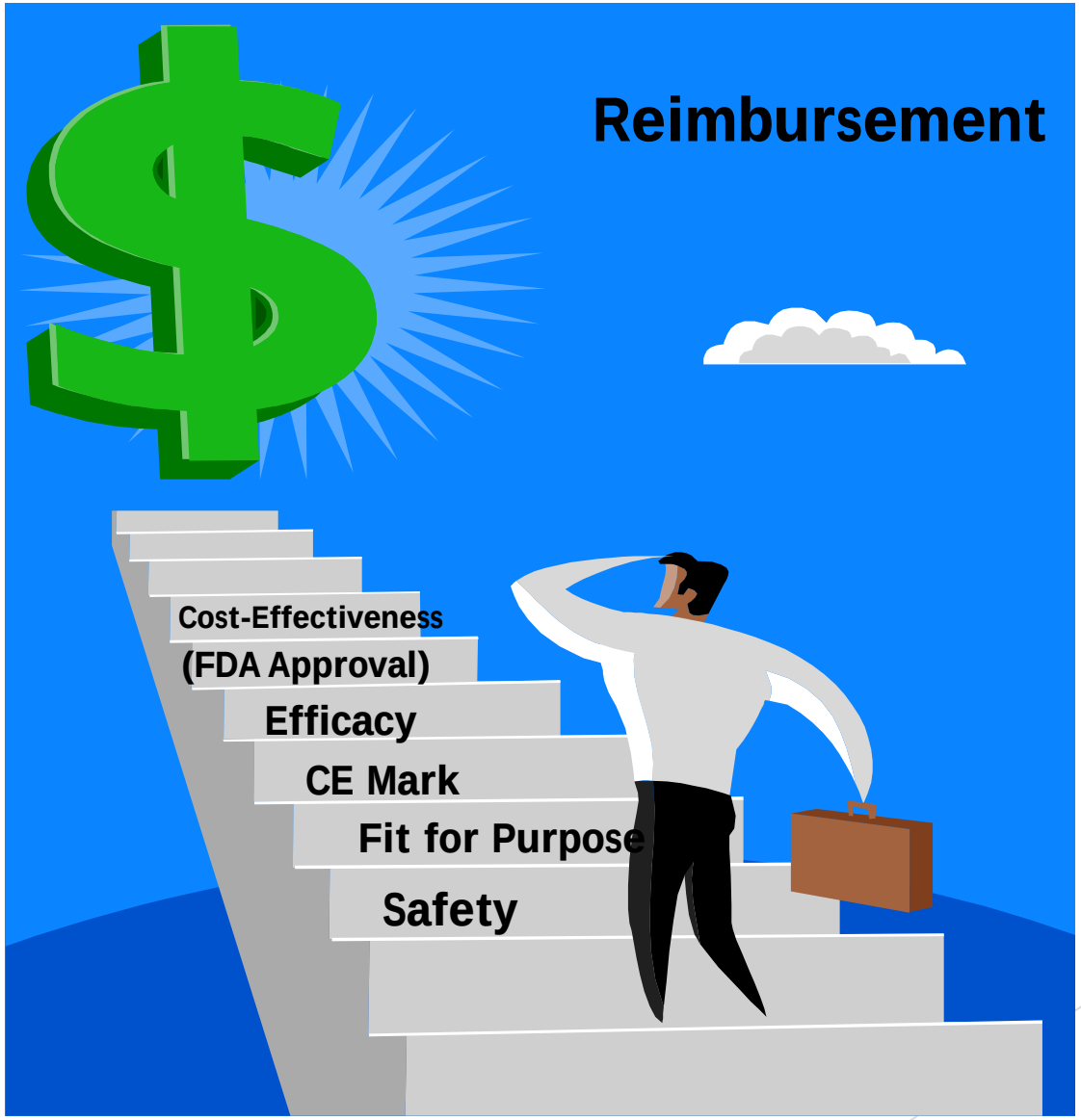
# Key Processes

- QMS System
  - Accreditation to ISO13485 Standard
  - Risk Analysis to ISO14971 Standard
  - Framework for Regulatory Approval
- Controls the Overall Process
  - Concept & Voice of Customer (Design Inputs)
  - Feasibility Evaluation (Design Outputs)
  - Risk Analysis to identify problems and gaps in knowledge
  - Quality control of Preclinical testing
  - Quality control of Clinical Assessments
  - Design Verification and Validation
  - Quality Documentation for Submission

# Technical File

- Description and drawings of Device
- Quantitative formulations of ALL materials in contact with tissues
- Information on previous experience with materials
- Reports of Biocompatibility tests (ALL materials & finished product)
- Reports of Mechanical & Electrical/Software tests (finished product)
- User Engineering Testing
- FMEA Risk Analyses
- Sterilisation, Packaging, Shelf Life
- Labelling & IFU Translations

# Don’t forget the Target




Thank You