



"Quality and Regulatory considerations in Medical Device and Diagnostic product realisation."

Jim Mackenzie MSc., MCQI CQP, MBCS CITP,
MTOFRA, IEEE, Quality Consultant, Medical Devices & In
Vitro Diagnostics

qualimedd@mac.com

QualiMedd

- QualiMedd is an independent, UK based consultancy established early in 1990 and working within the areas of Product Development, Regulatory Affairs related activities such as CE Marking and Food & Drug Administration registration and Quality Improvement such as assisting with the documentation and implementation of processes and procedures. QualiMedd specialises in the Medical Devices and In Vitro Diagnostics industries.

QMS for Medical Device Manufacturer ISO 13485:2012

- Title - Medical devices — Quality management systems — Requirements for regulatory purposes
- Accepted by, European Union, Australia, New Zealand, Japan etc. But NOT by USA!
- Mandated by Canada
- Is a Harmonized Standard
- Contains over 95% of ISO 9001:2008

QMS for Medical Device Manufacturer ISO 13485:2016

- Released only on 25th. Feb 2016 so very new
- 3 Year Transition period
- New Quality Management Systems should adopt immediately
- Is widely Risk based
- Not compatible with new EN ISO 9001:2015
- Will not be aligned
- Medical Device & In Vitro Diagnostics companies should avoid EN ISO 9001:2015

QMS for Medical Device Manufacturer USA 21 CFR--PART 820

- Title: PART 820—QUALITY SYSTEM REGULATION
- Last amended 22nd. May 2015
- Minor changes only
- Mandatory for selling in USA
- Overseas manufacturers subject to audit
- Must also have US agent

Medical Devices Directives

- **The Medical Devices Directives together cover all medical equipment.**
- **The Active Implantable Medical Device Directive - 90/385/EEC**
 - 1 January 1993 - in force.
 - 1 January 1995 - transition ended.
- **General Medical Device Directive - 93/42/EEC**
 - 1 January 1995 - in force.
 - 14 June 1998 - transition ended.
- **In Vitro Diagnostic Medical Devices Directive - 98/79/EC**
 - 7 June 2000- in force
 - 7 Dec. 2003 - transition ended.

Notified Body

- A Notified Body is required for CE marking of most Medical Devices but very few In Vitro Diagnostics at present
- These are Certification bodies or laboratories designated by a national Government for carrying out tasks related to the assessment conformity procedures.
- Designation is on the basis of minimum criteria for technical competence, professional integrity, independence, liability etc.



Competent Authority

- COMPETENT AUTHORITY Oversees Notified Bodies & Manufacturers
- Appointed by the Government to enforce the Directives.
- In the UK this is the Secretary of State for Health.
- The Secretary has delegated the day to day duties to the Medicines and Healthcare products Regulatory Agency (MHRA)
- MHRA is an executive agency of the Department of Health



CE MARK

- The CE marking of conformity, must appear in a visible, legible and indelible form on the device or its sterile pack, where practicable and appropriate, and on the instructions for use.
- Where applicable, the CE marking must also appear on the sales packaging.
- It shall be accompanied by the identification number of the notified body responsible for implementation of the procedures set out in Annexes II, IV, V and VI.

CE

0197

Medical Devices Regulations

- Will replace current Medical Devices Directives
- Unlike Directives that must be implemented into national laws, the Regulations will be directly applicable in all EU Member States.
- The Active Implantable Medical Device Directive will disappear
- There will be 2 Regulations – Medical Devices & In Vitro Diagnostics
- Proposals were published in Sept. 2012 but still not finalised
- The new legislation on medical devices will not take effect until 2017 at the earliest

Medical Devices Regulations

- According to the commission, the goals of the new regulations are to deliver greater consistency and safety to patients, and to bring medical device and IVD legislation up to speed with technological and scientific advancements that took place in the 20 years since the current legislation was adopted.
- Brought about by the PIP breast implant scandal, which was fraud, and the metal on metal joint implant issue

Medical Devices Regulations

- New Regulations will be much stricter
- For example: at present over 90% of In Vitro Diagnostics are self declaration
- Under the new Regulation over 90% will need Notified Body Intervention

USA Clearance Routes

- Food & Drug Administration control everything
- Products are not “Approved” by Food & Drug Administration but cleared for sale in USA
- Food & Drug Administration clearance has become more difficult over the last few years
- Most common route is via 510k where a predicate must be found. This should be a 90 day process but in practice takes much longer
- For new technologies the PMA (Pre Market Approval) route must be followed
- This is very costly and can, in some cases, take several years

USA Clearance Routes

- In some cases there is possibility of using the *de novo* classification process.
- This process provides a pathway to Class I or Class II classification for medical devices for which there is no legally marketed predicate device
- Does not apply to high risk devices (Class III)

Conclusions

- It is never too early to start
- First priority should be a Quality Management System (EN ISO 13485)
- Decide on your chosen markets early and research the Regulatory Requirements
- Seek outside assistance to avoid the 2 extremes of not enough or too much Documentation or indeed the wrong documentation

Any Questions?

