

ISO 13485:2016 Transition Policy

Current Situation

ISO 13485:2003 EN ISO 13485:2012



Regulatory requirements

ISO 13485:2003

- CMDCAS
- Australia
- Japan
- MDSAP

• EN ISO 13485:2012

• EU



Co-existence period

 ISO 13485:2016, replaces ISO 13485:2003 and incorporates the Technical Corrigendum ISO13485:2003/Cor. 1:2009



Co-existence period

- ISO 13485:2003 & ISO 13485:2016
 will co-exist for a 3 year period
- Effective March 1st 2018, ISO 13485:2003 certificates will no longer be issued by NSAI



Co-existence period

- Effective March 1st 2019 all ISO 13485:2003 certificates will become invalid
- Effective <u>until</u> March 1st 2018 any new, modified or revised ISO 13485:2003 issued by NSAI will have an expiry date not to exceed 1st March 2019



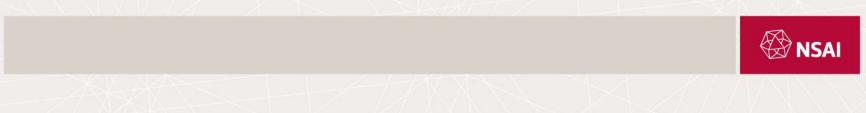
Manufacturer's responsibility

- Carry out a gap analysis between ISO 13485:2003 &ISO 13485:2016
- Update QMS to the requirements of ISO 13485:2016
- Request registration to ISO 13485:2016 from your registrar



Registrar's responsibility

- Develop a checklist to help the manufacturers meet compliance to ISO 13485:2016
- Carry out upgrade audits either at the next surveillance or re-assessment audit
- <u>Two years</u> following publication, new registrations will be issued <u>only</u> to ISO 13485:2016
- Three years following implementation of ISO 13485:2016, ISO 13485:2003 will be withdrawn



EN ISO 13485:2016

Refer to the Official Journal (OJ) for updates In the meantime EN ISO 13485:2012 remains valid

