



**NSAI**

# **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 1<sup>st</sup> 2018, ISO 13485:2003 certificates will no longer be issued by NSAI**

# Co-existence period

- **Effective March 1<sup>st</sup> 2019 all ISO 13485:2003 certificates will become invalid**
- **Effective until March 1<sup>st</sup> 2018 any new, modified or revised ISO 13485:2003 issued by NSAI will have an expiry date not to exceed 1<sup>st</sup> 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
- **Two years** following publication, new registrations **will be issued only** 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- Three years following implementation of ISO 13485:2016, ISO 13485:2003 will be withdrawn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