Annex 5:

REGULATORY REQUIREMENTS

1. Auditor/Lead auditor Pharmaceuticals

- EudraLex - Volume 4 Good manufacturing practice (GMP) Guidelines Part I-III, Including Annexes referencing following governing directives:
    - Commission Directive 2003/94/EC, of 8 October 2003, laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use
    - Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products
- 21 CFR 210 and 211 Current Good Manufacturing Practice for Finished Pharmaceuticals (US)
- 21 CFR 4 CGMP for Combination Products (US)
- ICH publications, primarily related to CGMP such as ICH Q2, Q7, Q8, Q9, Q10 and Q11
- PIC/S publications related to GMP Compliance

2. Auditor/Lead auditor Medical Devices

- Medical Devices Directive – 93/42/EEG
- Active Implantable Medical Devices Directive - 90/385/EEG
- In Vitro Medical Devices Directive - 98/79/EG
- EN ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes referencing following governing directives:
- EN ISO 14971 - Medical devices -- Application of risk management to medical devices
- 21 CFR 820 Quality System Regulation (US)
- 21 CFR 4 CGMP for Combination Products (US)
- GHTF and IMDRF publications related to Quality Systems