Health Canada Santé Canada

Canada

Regulatory Oversight of Manufacturing Quality in the Medical Device Industry

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Generic Regulatory Framework

Three pillars of a sound regulatory framework

- Of the three pillars, manufacturing quality spans the entire lifecycle of a medical device.
- Quality generally also encompasses requirements related to both pre- and post-market activities.

Two Approaches to Quality

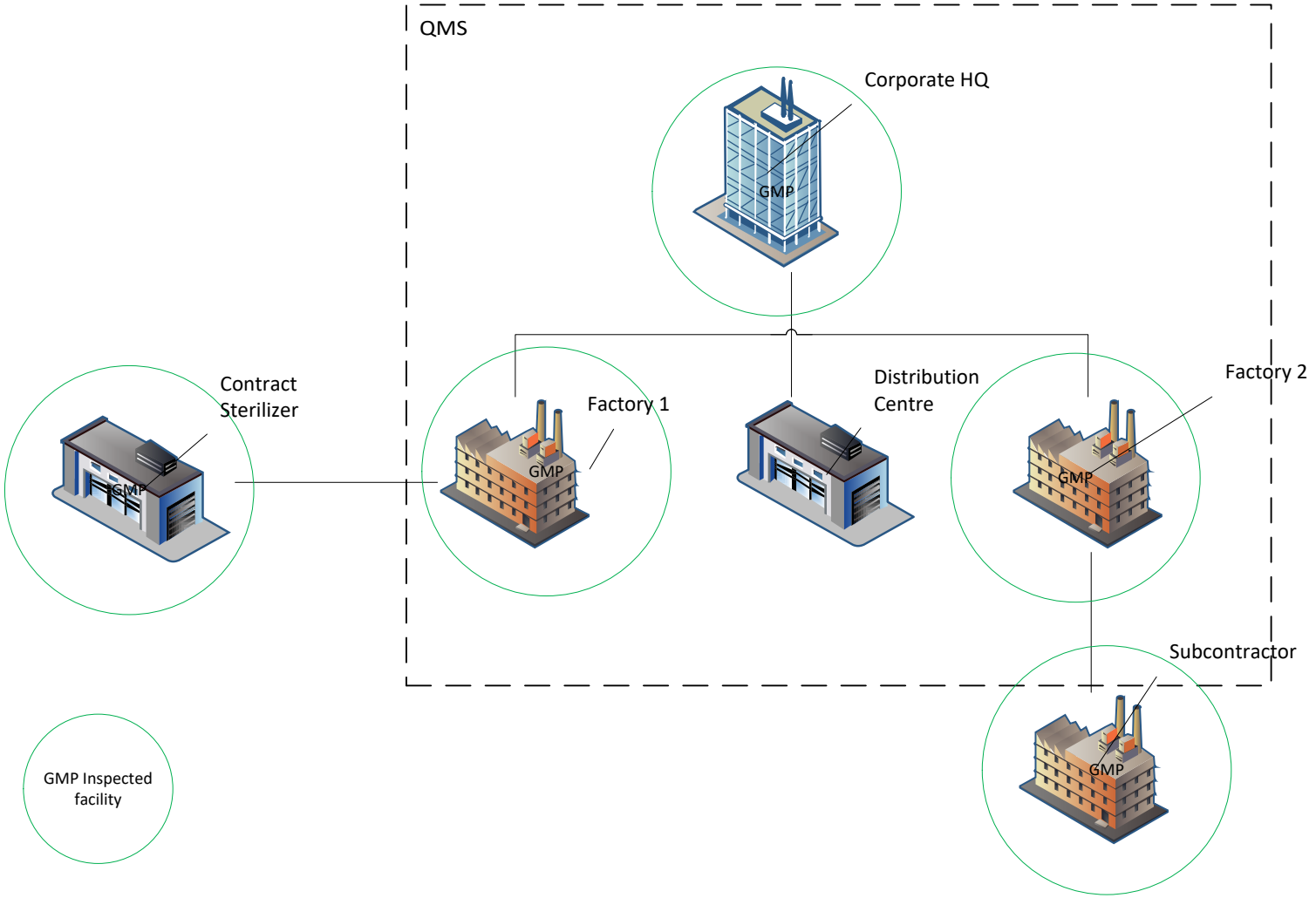
Good Manufacturing Practices (GMP)

- Typically codified in regulations (e.g. 21 CFR 820 “QSR”)
- Applied at the facility level
- Oversight usually conducted by Regulator

Quality Management System (QMS)

- Generally uses external consensus standards (e.g. ISO 13485)
- Applied at the organisation level
- Oversight usually conducted by authorised/recognised third-party organisations

Application of GMP vs. QMS



Types of QMS Certification

- Unaccredited
- Accredited
  - With specialised scope
- Regulatory Program (i.e. MDSAP, EU NB, etc.)
  - Similar to accreditation with specialised scope but involves regulator

Certification Cycle