References & Recommended Reading

International Council for Harmonisation (ICH) Guidelines:

- **ICH Q7 - Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients (APIs)**
- **ICH Q8 (R2) - Pharmaceutical Development**
- **ICH Q9 - Quality Risk Management (QRM):**

U.S. Food and Drug Administration (FDA) Regulations

- **21 CFR Part 211 - Current Good Manufacturing Practice (CGMP) for Finished Pharmaceuticals:**
  - **§211.100 - Recording and Reporting:**
  - **§211.190 - Retrospective Review:**

Other Resources

- **PIC/S Guide to Good Manufacturing Practice (GMP) for Medicinal Products**
- **Regulatory agency guidance documents**
- **Industry Associations**