

Appendix 4

COMPONENTS OF A GMP COMPLIANCE PROGRAMME

1. **Legislative and Regulatory Requirements and Scope**
 - Empowering legislation and regulations including authority to enforce laws and regulations, powers given to inspectors to conduct inspections, authority to remove violative products from the market, etc
 - Suitable controls on conflict of interest

2. **Regulatory Directives and Policies**
 - Procedures for designating inspectors
 - Enforcement policies/guidelines/procedures (inspection, re-inspection, corrective action)
 - Codes of conduct/ethics
 - Training/certification policies/guidelines
 - Alert/crisis management policies/procedures/guidelines
 - Organizational structure, including roles, responsibilities and reporting relationships