3. Good Manufacturing Practices (GMP) Standards

- Scope/details of GMPs necessary for the control of the manufacturing of drug products

- Process validation requirements

4. Inspection Resources

- Staffing – initial qualifications, certification of inspectors

- Number of inspectors in relation to size of industry (in-house, contract, third Party)

- Training/certification programmes/processes (e.g. frequency of training)

- Quality assurance mechanisms to ensure effectiveness of training programmes