

9. Alert and Crisis Systems
 - Alert mechanisms
 - Crisis management mechanisms
 - Alert performance standards (appropriateness and timeliness of alert)
 10. Analytical Capability
 - Access to laboratories with capacity to handle necessary analysis
 - Standard Operating Procedures for analytical support
 - Processes for validation of analytical methods
 11. Surveillance Programme/Measures (used by manufacturers and by regulatory authorities)
 - Sampling and audit procedures
 - Recall monitoring (including effectiveness controls and verifications of procedures)
 - Consumer complaint systems/procedures
 - Adverse incident reporting systems/procedures
 12. Quality Management Systems
 - Quality management/assurance systems/procedures to ensure the ongoing suitability and effectiveness of policies, procedures, guidelines and systems used to achieve the objectives of the conformity assessment programme, including establishment of standards and annual audit and review.
- B. INTER-COMPARISON EXERCISE
- Audit of Systems and Procedures.
 - Conduct of Parallel Evaluations (double blind)
 - Criteria for Clinical Trial Data