

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
- Exchange/evaluation of reports
- Monitoring of alert systems including handling of recalls.
- Joint audits of manufacturers to determine equivalency of audit methods.
- Exchange of evaluators/auditors or organization of joint workshops (optional).