

*Attachment 6***PHASES OF A CONFIDENCE BUILDING PERIOD**

The determination of the equivalency of the GMP compliance programmes by the Joint Sectoral Group will be designed around the following three phases :

1. Review and evaluation of documentation (exchange of documentation)
 - Legal Instruments (regulations/legislation/directives)/guidelines on GMPs
 - Inspection programmes (scope, policies, directives, procedures)
 - Crisis management systems (scope, criteria, policies, directives, procedures)
 - Requirements for inspection reports
 - Analytical laboratory systems
 - Alert reports

2. Evaluation of processes and procedures
 - Audit of systems and procedures
 - Exchange/evaluation of reports
 - Monitoring of alert systems including handling of recalls
 - Joint inspections of manufacturers to determine equivalency of inspection methods
 - Exchange of inspectors or organization of joint workshops (optional)

3. Decision making on the success of the exercise and conclusions
 - Evaluation of results of the confidence building exercise
 - Action to take, development of options and solutions to address issues
 - Determination of competent agencies that meet evaluation criteria
 - Establishment of the conditions and mechanisms for on-going maintenance of the certification programme (develop quality management system, audit mechanism and a consultation/on-going dialogue process).

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