

## ANNEX I

### PART A

#### **REVISED GUIDES FOR COMPLIANCE MONITORING PROCEDURES FOR GLP** Components of good laboratory practice compliance monitoring procedures

##### Administration

A (national) GLP compliance programme should be the responsibility of a properly constituted, legally identifiable body adequately staffed and working within a defined administrative framework.

Member States should:

- ensure that the (national) GLP Monitoring Authority is directly responsible for an adequate ‘team’ of inspectors having the necessary technical/scientific expertise or is ultimately responsible for such a team,
- publish documents relating to the adoption of GLP principles within their territories,
- publish documents providing details of the (national) GLP compliance programme, including information on the legal or administrative framework within which the programme operates and references to published acts, normative documents (e.g., regulations, codes of practice), inspection manuals, guidance notes, periodicity of inspections and/or criteria for inspection schedules, etc.,
- maintain records of test facilities inspected (and their GLP compliance status) and of studies audited for both national and international purposes.