

## Guidelines for Regulatory Inspections

escorting the inspector clearly understand any concerns raised during the inspection and that these be discussed with Senior Management if appropriate.

Any documents provided to the inspector should be stamped CONFIDENTIAL, the only exceptions being those documents publicly available.

The purpose of any samples requested by the inspector should be determined. The inspection team should ensure that sufficient duplicate samples remain for in-house use.

### 5.2.6 Inspection Conclusion and Follow-up

Written responses to inspection observations should be submitted to the Authority within 30 calendar days maximum.

The inspector should be asked to clarify for which observations a written response is expected.

Any proposed written responses to be submitted to the Regulatory Authorities should be agreed by the relevant Senior Management and. It may be appropriate to provide evidence of the corrective action taken, for example a copy of a revised SOP, with the written responses.

After the close of an inspection, it is suggested that the personnel involved should prepare a detailed report to be sent to functional Senior Management. The report should minimally include:

Site, inspecting authority/inspector(s)/details/ duration/dates, hosts, reason/type of inspection/ scope, areas covered, inspector's recommendations, official observations, responses/outcome, learning points, issues, listing of any samples and documents given to inspector, report author.