

## **1 Purpose**

To provide the minimum mandatory requirements for notification, conduct, reporting and follow-up action associated with inspections by regulatory authorities and also to outline recommendations on how to achieve compliance.

## **2 Scope and Applicability**

This guideline covers GLP, GCP and GMP inspections of a manufacturing functions, departments, clinical investigation facilities, Pharmacovigilance programs, and R&D or manufacturing sites by Regulatory Authorities including 'Notified Bodies' in the case of medical devices and diagnostics. It also includes Information Services (and any associated third party providers) in support of the GXP regulated computerized systems.

## **3 Definition**

None

## **4. Responsibilities**

The Quality Assurance/Compliance/Qualified Person (QP) in EU and functional management at the site inspected are responsible for the preparation, conduct and follow-up of inspections.

Clinical Quality Management will provide the key contact for regulatory inspections of clinical studies or of Clinical Development systems.

For inspections that involve Information Services (and any associated 3rd party providers) there may be a need to also involve IS Compliance group.

The Out Sourcing and Procurement Group play a significant role in inspections at contract facilities.

## **5 Guideline**

### **5.1 Minimum Mandatory Requirements**

**5.1.1** It is essential that management develop, document and implement procedure(s) for managing inspections by Regulatory Authorities in order to protect the legal rights of the business (and the Regulatory Authorities to perform repeated inspections) and, at the same time, to maintain a professional relationship with the regulatory authority conducting the inspection.

**5.1.2** Senior Management at a site or function must be present during key parts of an inspection.

**5.1.3** Inspection notification, ongoing highlights of the inspection, and the final results of an inspection must be communicated to relevant Senior Management in a timely

### **5.2.2 Senior Management Presence and Support**

The most senior management of the department, function or site should be present during at least the opening and closing of a Regulatory Authority Inspection. For inspections of clinical investigator facilities, this is the Principal Investigator.

It is customary for Senior Management to give a brief introductory presentation covering the department, function or site.

The Qualified Person (QP) in the EU should participate for the entire inspection.

### **5.2.3 Communication**

Senior Management and all relevant Corporate Quality functions should be notified as soon as an inspection has been scheduled or announced.

A short summary, phone call or e-mail should be prepared daily during the inspection highlighting any significant issues or concerns raised. This summary should be sent to appropriate Senior Management..

On the day the inspection concludes, appropriate Senior Management should be notified when the inspector departs. A brief, immediate summary of events should be provided and, if observations were issued, a copy should be immediately sent to Senior Management of the department, function or site inspected.

### **5.2.4 Photographs, Tape Recordings, Affidavits, Internal Audit Reports**

The taking of photographs; the use of tape recorders or other electronic equipment; the listening to, reading and signing of affidavits (sworn statements) by company personnel; the review of internal audit reports and allowing access to computer databases should all be subject to a policy that meets local legal requirements.

In general, it is usually best to remain silent on these issues until it becomes apparent that the inspector intends to invoke these tools during the inspection process.

If local requirements allow flexibility, then the initial position should be not to permit any of these activities.

Senior Management should approve any deviation from local legal requirements and this must be documented. Duplicate records of any pictures, recordings, etc. are to be retained.

### **5.2.5 Accurate Record of the Inspection Proceedings**

The inspection escort team should keep accurate, detailed notes documenting those issues, products, operations, studies (pre-clinical and clinical), and other areas covered during the inspection.

All comments or observations made by the inspector and a listing of all documents reviewed or supplied should be documented. It is essential that those responsible for