

1 Purpose

The purpose of this document is to provide some requirements as well as some recommendations for the development, content and management of Compliance Improvement Plans (CIPs).

2 Scope and Applicability

This guideline is applicable to all manufacturing functions, departments, or marketing companies undertaking work, or providing support services, required to meet Good Laboratory Practice (GLP), Good Clinical Practice (GCP), Good Manufacturing Practice (GMP) and/or International Organization for Standardization (ISO) standards.

3 Responsibilities

3.1 Management

It is the responsibility of the management of each function, department, manufacturing site or marketing company to regularly monitor the compliance status of their operations. Management should generate a Compliance Improvement Plan (CIP) as a result of their review. Quality Risk Management should be applied to priorities any improvement areas identified.

3.2 QA Managers

QA Managers, IS Quality Managers shall ensure that the CIP is generated, maintained and regularly reviewed.

3.3 Individuals

The individual responsible for completion of each issue should be identified within the plan.

4 Guideline

4.1 Establishment of Compliance Improvement Plan

A CIP must be established and maintained as an outcome of the management review process of compliance issues and status. It is recommended that the CIP be a separate document, however, there may be alternate ways to capture and manage the necessary information.

4.2 Areas to Review for Compliance Improvement