EUROPEAN COMMISSION
ENTERPRISE and INDUSTRY DIRECTORATE-GENERAL

Consumer goods
Pharmaceuticals

GUIDANCE DOCUMENTS CONTAINING THE COMMON PROVISIONS ON THE CONDUCT OF GCP INSPECTIONS BY COMPETENT AUTHORITIES OF THE DIFFERENT MEMBER STATES

Annex III
TO GUIDANCE FOR THE CONDUCT OF GOOD CLINICAL PRACTICE INSPECTIONS
Computer Systems

Version: 28 May 2008

The EU GCP inspectors agreed to use as the reference for inspection of Computer Systems the published PIC/S Guidance on Good Practices for Computerised Systems in Regulated "GXP" Environments (PI 011-3). The hyperlink to the PIC/S site is http://www.picscheme.org/index.php

This document forms part of the guidance documents containing the common provisions on the conduct of GCP inspections . Please check for updates in the Volume 10 of the Rules Governing Medicinal Products in the European Union.
http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol10_en.htm