



London, 28 November 2007
EMA/INS/GCP/444656/2007

Procedure no: INS/GCP/3/III-Rev 1

ANNEX III
TO PROCEDURE FOR CONDUCTING GCP INSPECTIONS
REQUESTED BY THE EMEA:
COMPUTER SYSTEMS

GCP Inspectors Working Group

Applies to: EMEA, EU/EEA Inspectorates	
Summary of scope: This procedure compiles the main aspects that are to be verified at a clinical laboratory during a GCP inspection requested by the EMEA	
Keywords: GCP Inspection, Computer systems	Public
Supersedes: version dated 20 September 2007 (updated in this Rev 1 version the reference to the PIC/S Guidance)	

Finalisation	Date
Adoption by GCP Inspectors Working Group	5 September 2007
Revision 1 adopted by GCP Inspectors Working Group	28 November 2007

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>