News story: MHRA GxP Data Integrity Definitions and Guidance for Industry

Updated: Updated to link to the final guidance on GxP data integrity

View the final Guidance on GxP data integrity.

This
consultation document
(PDF, 599KB, 14 pages)

provides guidance on the data integrity expectations that should be considered by organisations involved in any aspect of the pharmaceutical lifecycle or GLP studies regulated by MHRA.

The guidance is intended to be a useful resource on the core elements of a compliant data governance system across all GxP sectors (good laboratory practice, good clinical practice, good manufacturing practice, good distribution practice and good pharmacovigilance practice).

It addresses fundamental failures identified by MHRA and international regulatory partners during GLP, GCP, GMP and GDP inspections; many of which have resulted in regulatory action.

The document should be read in conjunction with the applicable regulations and the general guidance specific to each GxP.

We welcome your comments via the
comment sheet
(MS Word Document, 224KB)

which can be emailed to inspectorate@mhra.gov.uk

Deadline for comments: 31 October 2016