

Regulations for CSV and Data Integrity

Regulation Authority	Reference Link
EU	<u>Annex 15: Qualification and Validation</u>
EU	<u>Annex 11: Computerised Systems</u>
EMA	<u>EMA's Guidance on Data Integrity</u>
EMA	<u>EU GMP guide annexes: Supplementary requirements: Annex 11: Computerized systems</u>
US FDA	<u>Data Integrity and Compliance With Drug CGMP Questions and Answers Guidance for Industry</u>
US FDA	<u>General Principles of Software Validation</u>
US FDA	<u>Guidance for Industry Part 11, Electronic Records; Electronic Signatures — Scope and Application</u>
US FDA	<u>21 CFR Part 11 Electronic Records; Electronic Signatures</u>
WHO	<u>Guidance on good data and record management practices</u>
MHRA	<u>GXP' Data Integrity Guidance and Definitions</u>
PIC/S	<u>Good practices for data management and integrity in regulated gmp/gdp Environments</u>
PIC/S	<u>Good practices for Computerised systems in regulated "gxp" environments</u>
EPA	<u>Guidance on Environmental Data Verification and Data Validation</u>
PDA	<u>Data Integrity</u>
OECD	<u>Application of GLP Principles to Computerised Systems</u>
TGA	<u>Data Management and Data Integrity (DMDI)</u>
TGA	<u>Computerised systems (Annex 11)</u>
GAMP	<u>GAMP Guide: Records & Data Integrity</u>
GAMP	<u>GAMP 5 Guide: Compliant GxP Computerized Systems</u>