



Unidec Understands Regulatory Compliance

Unidec adheres to and helps our clients meet the following regulations:

FDA Code of Federal Regulations (CFR)

- 21 CFR Part 11 Computer Validation
- 21 CFR 58.61 Equipment Design
- 21 CFR 58.63 Maintenance and Calibration of Equipment
- 21 CFR Part 210 Good Manufacturing
- 21 CFR Part 211.68 Automatic, Mechanical and Electronic Equipment
- 21 CFR Part 820.70 Automated Processes

European Standards

- European Medicines Agency (EMA)
- EU GMP Annex 11

GAMP

- GAMP V Good Automated Manufacturing Practices

Compliance Policy Guidelines

- CPG 7132a.07 I/O Checking
- CPG 7132a.11 CGMP Applicability to Hardware and Software
- CPG 7132a.15 Source Code for Process Control Application Programs

ISO Standards

- ISO 13849-1 2006 Safety of Machinery
- ISO 13849-2 2012 Safety of Machinery Validation

We help pharmaceutical manufacturers extend end-of-life support on validated systems - allowing them to keep their older systems in place and avoid the long, costly process to validate a replacement system

Unidec

3603 Winding Way
Newtown Square, PA 19073
610-353-3221
www.unidec.com