

## ***Abbreviations***

<b>Abbreviation</b>	<b>Meaning</b>
ANSI	American National Standards Institute
API	Active Pharmaceutical Ingredient
ASTM	American Society for Testing and Materials
CANDA	Computer Assisted New Drug Application
CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
CDS	Chromatography Data System
CFR	Code of Federal Regulations ( <i>e.g.</i> 21 CFR 11)
CPG	Compliance Policy Guide
CRO	Contract Research Organization
cGMP	Current Good Manufacturing Practice
COA	Certificate of Analysis
COTS	Commercial Off The Shelf
CSV	Computer System Validation
DHHS	Department of Health and Human Services (US)
DQ	Design Qualification
DS	Design Specification
EC	European Community
EDMS	Electronic Document Management System
EIR	Establishment Inspection Report
EMA	European Agency for the Evaluation of Medical Products
EP	European Pharmacopoeia (Ph.Eur.)
EU	European Union
FDA	Food and Drug Administration
FMEA	Failure Mode and Effects Analysis
FOI (A)	Freedom of Information (Act)
FR	Federal Register
F(D)S	Functional (Design) Specifications
GAMP	Good Automated Manufacturing Practice guidelines
GC	Gas Chromatography
GERM	Good Electronic Record Management