

数据完整性法规梳理

国内法规

NMPA

药品记录与数据管理要求（试行） - 2020/06/24

中国 GMP 附录 计算机化系统 - 2015/05

药品GMP指南 质量管理体系 > 3 产品质量实现的要素 > 3.7 确认与验证 > 3.7.5 验证

国外法规

FDA

FDA Guidance Data Integrity and Compliance With CGMP Q&A

FDA CFR PART 11 ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

FDA Data Integrity and Compliance With Drug CGMP Questions and Answers - 2018/12

FDA Application Integrity Policy

FDA Electronic Source Data in Clinical Investigations - 2013/09

FDA Guidance for Industry Blood Establishment Computer System Validation in the User's Facility - 2013/04

FDA Computerized Systems Used in Clinical Investigations - 2007/05

Guidance for Industry Part 11, Electronic Records; Electronic Signatures — Scope and Application

FDA General Principles of Software Validation; Final Guidance for Industry and FDA Staff - 2002/01

CPGM 7346.832 Pre-Approval Inspections-Investigations - 2019/08

WHO

WHO ECSPP TRS 996 Annex 5 Guidance on good data and record management practices

WHO QAS Guideline on data integrity - 2020/06

WHO ECSPP TRS 1019 Annex 3 Good manufacturing practices: guidelines on validation - 2019/05

WHO ECSPP TRS 996 Annex 5 Guidance on good data and record management practices - 2016/05

MHRA

MHRA GXP Data Integrity Guidance and Definitions

'GXP' Data Integrity Guidance and Definitions

EU

EU GMP Annex 11 Computerised Systems - 2011/06

EMA

EMA GMP Data Integrity Questions and Answers - 2016/08

PIC/S

PIC/S Good Practices For Data Management And Integrity In Regulated GMP/ GDP Environments - 2018/11

IQ

IQ Consortium Data Integrity Risk Assessment Tool

其他

India IPA Data Reliability Guideline - 2017/02

FDA 警告信 - KVK-Tech, Inc. - 2020/10/08

FDA 警告信 - Tender Corporation - 2020/07/23