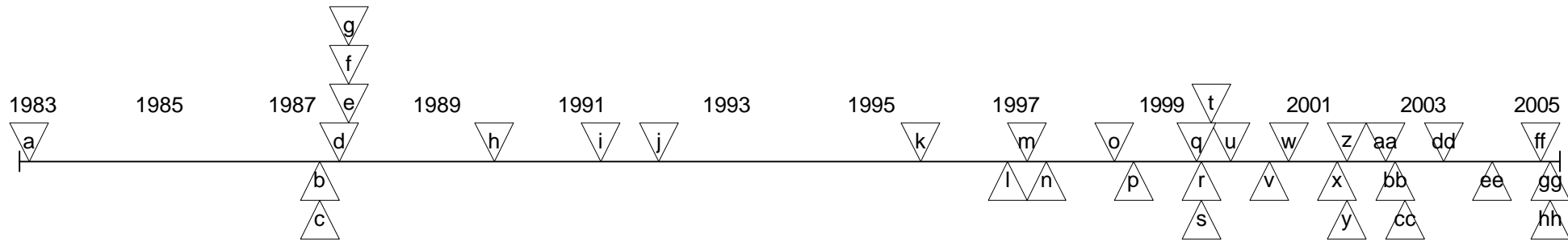


SoftwareCPR - FDA Software Regulation Timeline - Partial list of key documents

(Click on links to actual documents)



- a. [CDER 02/01/83 Guide To Inspection Of Computerized Systems In Drug Processing](#) - 2/1/83
- b. [Sec. 425.300 Computerized Drug Processing; Source Code for Process Control Application Programs \(CPG 7132a.15\)](#) - 4/16/87
- c. [Sec. 425.500 Computerized Drug Processing; Identification of "Persons" on Batch Production and Control Records \(CPG 7132a.08\)](#)-4/16/87
- d. [Technical Reference On Software Development Activities](#) - 7/1/87
- e. [Computerized Drug Processing; Vender Responsibility \(CPG 7132a.12\)](#) - 9/4/87
- f. [Computerized Drug Processing; CGMP Applicability to Hardware and Software \(CPG 7132a.11\)](#) - 9/4/87
- g. [Computerized Drug Processing; Input/Output Checking \(CPG 7132a.07\)](#) - 9/4/87
- h. [FDA's policy for the Regulation of Computer Products - Draft](#) - 11/13/89
- i. Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review - 1991 (obsolete)
- j. CDRH's "Application of the medical device GMP to computerized Devices..." 5/1/92 (obsolete)
- k. [ORA Glossary Of Computerized System And Software Development Terminology](#) - 8/1/95
- l. [Do It By Design: An Introduction To Human Factors In Medical Devices](#) - 12/1/96
- m. Reviewer Guidance For A Premarket Notification Submission For Blood Establishment Computer Software - 1/13/97 (obsolete)
- n. [21 CFR Part 11 Electronic Records; Electronic Signatures](#) - 3/20/97
- o. Guidance for the Content of Premarket Submissions for Software Contained In Medical Devices(supercedes 1991 version)-5/29/98 (obsolete)
- p. [FDA Standards Recognition Statement for ISO/IEC 12207 Information Technology - Software Lifecycle Processes](#) - 8/14/98
- q. [Guidance for Industry: Computerized Systems Used in Clinical Trials](#) - 4/1/99
- r. [FDA Standards Recognition Statement for IEEE/EIA 12207.0-1996 - Software Life Cycle Processes](#) - 5/3/99
- s. [FDA Standards Recognition Statement for IEEE 1074:1997 Standard for developing the software life cycle processes](#) - 5/3/99
- t. Enforcement Policy: 21 CFR Part 11; Electronic Records; Electronic Signatures (CPG 7153.17) - 5/13/99 (obsolete)
- u. [Guidance on Off-the-Shelf Software Use in Medical Devices](#) - 9/9/99
- v. [Medical Device Use--Safety: Incorporating Human Factors Engineering into Risk Management](#) - 7/18/00
- w. [FDA Standards Recognition Statement ANSI/UL 1998 Software in Programmable Components](#) - 11/19/00
- x. [Good Laboratory Practice Compliance Program 7348.808 \(BIMO\) Attachment A Computer Systems](#) - 2/21/01
- y. [FDA Standard Recognition Statement for ISO 14971:2000, Medical devices - Application of risk management to medical devices](#) - 7/23/01
- z. FDA's Inspections Operations Manual (Section 527 Electronic Copies) - 7/27/01 (Obsolete)
- aa. [Final General Principles of Software Validation Guidance](#) - 1/11/02
- bb. [FDA Standards Recognition Statement AAMI SW68 Medical Device Software Life Cycle Processes](#) - 1/14/02
- cc.ORA Updated Inspections Operations Manual with additional computer system guidance including for complaint systems-May 2002 (obsolete)
- dd. [Part 11, Electronic Records; Electronic Signatures — Scope and Application](#) - August 2003
- ee. [Guidance for Industry: Computerized Systems Used in Clinical Trials Draft Revision #1 - September 2004](#)
- ff. AAMI TIR32: 2004 Medical Device Software Risk Management - Feb 2005
- gg. [FDA CDRH/CBER Guidance for Content of Premarket Submissions for Software Contained in Medical Devices](#) - May 2005
- hh. [FDA's Inspections Operations Manual \(Section 527 Electronic Copies\)](#) - May 2005