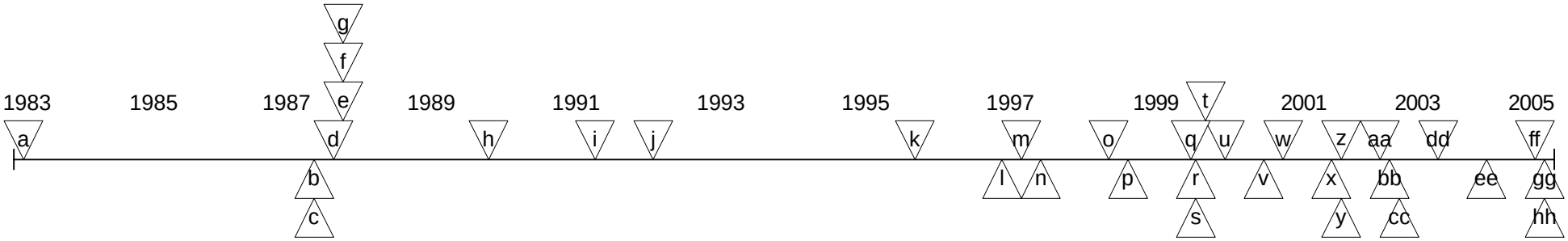
SoftwareCPR - FDA Software Regulation Timeline - Partial list of key documents

(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 addtional computer system guidance including for complaint systems-May 2002 (obslolete)
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**