

Software Ad Hoc Mission

Workshop Oct 4, 2007



Activity (1); Guidance for the assessment of premarket submissions containing software.

Basis: SG1 STED, FDA reviewer guidance.

Rationale: Evaluating the engineering methodology used by the manufacturer during software design and the design history documentation, provides visibility into the safety related controls employed to reduce risk. This evaluation should be made prior to market placement and under common criteria. This issue is particular to software and programmable systems since the essential principle which deals with programmable systems only cites "...repeatable, reliable, and performs as intended" SG1N41R9 15.12.1. Exactly how these properties, and others such as product surveillance, are evaluated will be the subject of these proposed activities.

Activity (6); Guidance for the regulatory assessment of software used in medical device process software.

Basis: FDA software validation guidance, industry documents, literature, existing standards.

Rationale: A common approach to the regulatory evaluation of a manufacturer's software (validation of its fitness for use) used throughout the development cycle of devices and its documentation is preferred.

Activity (10); Guidance for the auditing of software processes and the qualification of auditors.

Basis: supplement to SG4 existing documents.

Rationale: Auditing practices and qualification employed during the software development lifecycle processes (risk management and quality management) is a highly specialized activity and should supplement the existing SG4 guidance. A liaison activity is preferred over a task delegation.



Rationale why software might be treated differently from other technological domains

- Easily modified, both pre and post market
- Remote assembly, operation and display readily possible
- Not easily verified
- Essential Performance envelope of device may be radically altered by minute software changes
- The regulatory QA is compressed into the design cycle
- Notions of reliability are not well developed
- Risk estimation is problematic
- More possible interactions in use environment.

Draft recommendation #1

- Related to activity 1
- Toward study group 1 activities; The software Ad Hoc should perform appropriate liaison to determine whether to provide an analog to [EP 5.12](#) which relates to standalone software since standalone software is not covered because there is no energy transfer.
- Rational: the definition of device contemplates standalone software

Draft recommendation #2

- Related to activity 1
- Toward study group 1 activities; The software Ad Hoc should perform appropriate liaison activities with SG1 to determine whether to replace the language used in EP 5.12.1 with suitable language found in the new MDD and AIMDD, as appropriate, supplement it.
- Rational: the new language relates well to the standards available.



Draft recommendation #3

- Related to activity 1
- Toward study group 1 activities; The software Ad Hoc should perform appropriate liaison to clarify the definition of 'software' by defining it and several related terms (embedded, standalone, installable, programmable, configurable, system, accessory, etc.).
- Rational: the way the EP and other related guidance applies relates to the context of the software's use, and therefore the definition needs to be clearer.

Draft recommendation #4

- Related to activity 1
- Toward study group 1 activities; The software Ad Hoc should perform appropriate liaison to examine whether the STED guidance clause 7.2.4 should include a reference to software and it should refer to EP 5.9.1 and 5.9.2 which highlight the need for documentation and assessment relating to the possible negative interactions between software and other influences in its use environment .
- Rational: critical for the proper use of standalone software, vis a vis the hardware it runs on.

Draft recommendation #5

- Related to activity 1
- Toward study group 2 activities; The software Ad Hoc should perform appropriate liaison to evaluate and update the examples given to highlight the complexity of who reports what, and to whom in NCAR containing networking scenarios .
- Rational: The device may be working as intended and the system in which it is used may cause the fault (example; timing synch).

Draft recommendation #6

- Related to all activities
- Recommend that a task group be assembled under study group 3 which can freely move between and assist other study groups to attend to software and IT related issues, as needed . This task group would implement the current recommendation which may be accepted by the Steering Committee.
- Rational: These activities are cross-cutting through many technical domains and study groups and it is important to maintain consistency

Draft recommendation #7

- Related to activity 1 and 6
- Toward study group 3 activities; The software Ad Hoc should perform appropriate liaison to evaluate and determine whether to recommend that SG3/N17R3 now make reference to procurement of software and outsourcing of software.
- Rational: critical for the proper inclusion of outsourced development and the use environment of standalone software.

Draft recommendation #8

- Related to activity 6
- Toward study group 3 activities; The software Ad Hoc should perform appropriate liaison to evaluate whether reference be made to software controlled manufacturing and measuring processes in SG3/N99-10 and remove the software exception, and whether to clarify, that process validation also applies to SW design activities, through general principles of software validation.
- Rational: Software validation is critical for the proper design-side process validation of such software and the extent of that software validation should to be defined.

Draft recommendation #9

- Related to activity 11
- Toward study group 4 activities; The software Ad Hoc should perform appropriate liaison to evaluate whether a software quality/regulatory audit document be developed. The scope of the software audit process should be focused on both design side QMS process aspects and software development process aspects which support safety and effectiveness in software.
- Rational: the current documents cannot be easily ‘scaled’ to software audits and the Industry Standard QA processes for Software Quality Assurance (SQA) can only rely on a discrete subset of the elements covered by the current document, (e.g SQA activities place less reliance on verification).

Draft recommendation #10

- Related to activity 1
- Toward study group 5 activities; The software Ad Hoc should perform appropriate liaison to recommend that the software which controls therapy or performs diagnosis may require clinical evidence to perform its validation.
- Rational: when sw is a medical device it may require clinical evaluation to validate it.

Draft recommendation #11

- Related to all activities
- The software Ad Hoc should perform appropriate liaison to evaluate and provide definitions, boundaries and use cases for 'medical software' and general use software that is not a device
- Rational: some medical software may not be a device but may be an accessory to a device or may manage devices through clinical workflow management.



Draft recommendation #12

- Related to activity 11
- The software Ad Hoc should perform appropriate liaison to evaluate whether a criteria guidance should be developed to complement any new SW audit document (see recommendation #9)
- Request the steering committee to ask SG3 and SG4 to jointly decide whether GHTF should develop a guidance for regulatory criteria for software audit, complementary to the requested SW quality audit document, or refer it to ISO/IEC for TC210 action.
- Rational: This would be complementary criteria to the audit methodology.

