

Industry view point on Software

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1. Introduction

- Key elements of medical device regulation to protect public health are safety, effectiveness and quality of a product. Safety is the first.
- The preamble of the FDA Quality System Regulation (QSR, issued in 1996) indicates that a significant proportion of device recalls were attributed to faulty design of product including software.
- From 2004 to 2006, main themes of GHTF chaired by EU were 1)Design for patient safety, 2)Medical device software, 3)Emerging technology. Software is the hot topic of GHTF now.
- In March 2005, FDA proposed starting investigation on software regulation at the Steering Committee (SC) meeting.
- In November 2005, it was decided to organize the software ad hoc group at the SC meeting in London.
- In June 2006, the ad hoc group proposed 11 activities at the Luebeck SC meeting. SC selected 3 major items among them, i.e. GHTF guidance documents on software for 1)Premarket review, 2)Regulatory audit and 3)Qualification of an auditor.



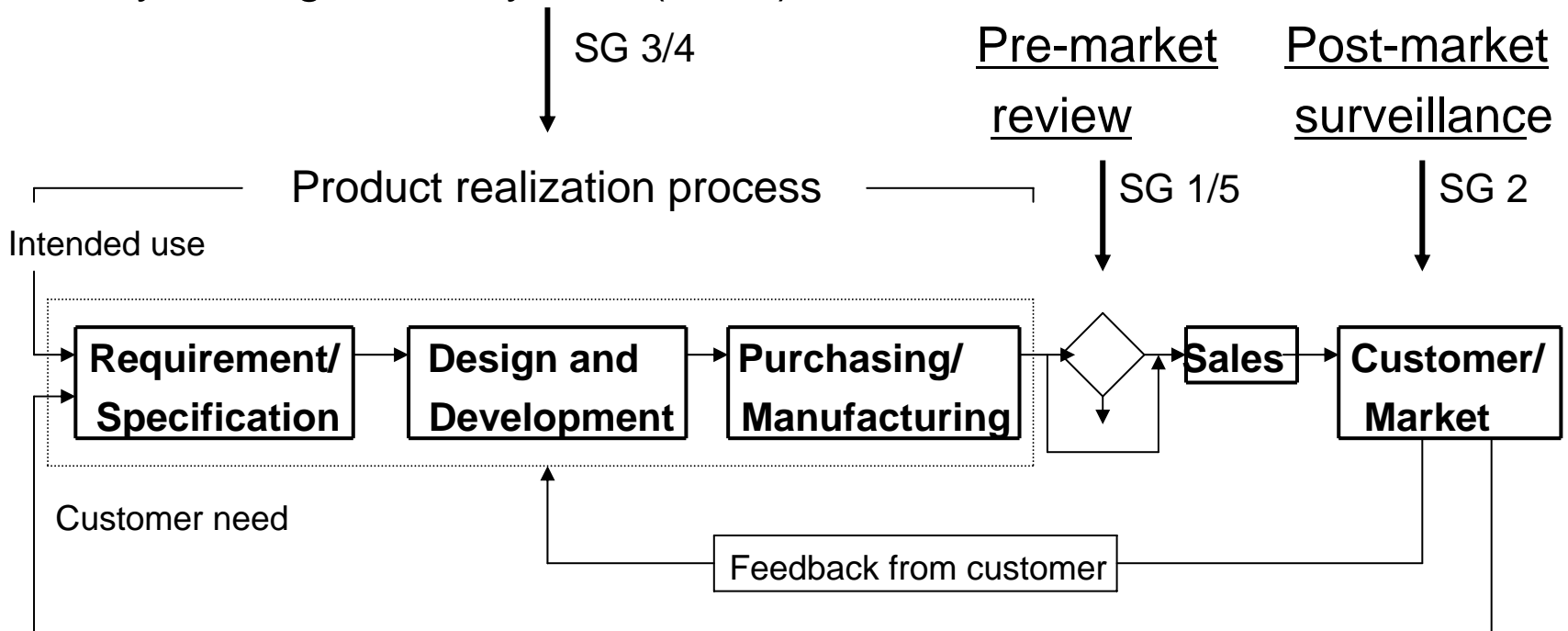
2. Medical device regulation and GHTF

Medical device regulation

SG: Study Group (GHTF)

1)Pre-market review, 2)Post-market surveillance, 3)QMS

Quality Management System (QMS)



3.Regulation vs. Standard (1)

1.Standard

- Voluntary
- Provide sufficient information including state of art technology
- For some standards, certification is issued based on the result of audit

2.Regulation

- Mandatory
- Minimum requirements based on established technology
- Efficiency is one of key elements
- Nonconformity against regulation is violation
- Regulatory Authority may order recall, stop shipment, facility close, fine payment etc. In the worst case, you have to go to jail



3. Regulation vs. Standard (2)

1. Standard

- A standard is developed for voluntary use. A standard, especially horizontal standard should not be used as regulatory requirements.
- ISO 13485:2003 is an exception. It was developed by ISO/TC 210 WG 1 and GHTF/SG 3 for “regulatory purpose”.
- Requirements of “Design and development” in ISO 13485:2003 includes 7 clauses, i.e. 1)Design and development planning, 2)Design and development inputs, 3)Design and development outputs, 4)Desing and development review, 5)Design and development verification, 6)Design and development validation, 7)Control of design and development changes. The total number of words of 7 clauses is only 750 (4 pages). Requirements for software development should be a part of them.

2. Regulation

Development of a regulation is more difficult than that of a standard.



4. Role of standards (GHTF SG 1/N12R10)

- International standards (ISs) are a building block for harmonized regulatory process.
- The GHTF guidance document “Role of standards” recommends:
 - 1)Regulatory Authorities (AR) and industry should encourage and support the development of ISs for medical device to demonstrate compliance with “the Essential Principle of Safety and Performance of medical device”.
 - 2)RAs developing new medical device regulations should encourage the use of ISs.
 - 3)RA should provide a mechanism for recognizing ISs.
 - 4)Standard Bodies developing or revising standards for use with medical devices should consider the suitability of such standards for demonstrating compliance with the Essential Principle.
- The use of standards is voluntary except in particular cases the RA deems mandatory. Manufactures should be free to select alternative solutions.



5. Standard on medical device software

- IEC 62304 is the only one specific standard for medical device software. It was developed during 2002 – 2006 by the joint working group (JWG) between ISO/TC 210 and IEC 62A.
- As medical device sector is regulated, any standard may be used to support regulation. Standard Bodies and experts developing standards for use with medical devices should recognize the fact.
- JFMDA (Japanese industry) proposed the group to simplify IEC 62304 and to make it easy to understand.
- However, IEC 62304 is too aggressive and complicated to be regulatory requirements. Its enforcement will be huge burden for a manufacture, especially for small one.
- IEC 62304 is not suitable for the regulatory audit criteria.



6. Risk management

1) Key points of risk management

Risk management is a kind of “preventive action”. It is the requirement of preventive to eliminate the cause of potential nonconformities. On the other hand, as hazard (potential cause of harm) in risk management can not be separated from benefit/effectiveness of the device, it is difficult or impossible to eliminate the cause. It is the major reason why the concept of risk is introduced. Risk is combination of the probability and the severity.

2) Key elements of risk management

a) Risk analysis (including hazard identification), b) Risk evaluation, c) Risk control, d) Residual risk control, e) Post-market information.

3) ISO 14971 is the standard for “Risk management of medical device”. It is informative reference of ISO 13485:2003 (not normative).

4) Risk management and its related requirements should be based on the facts (adverse events) not to repeat them.



7. Software vs. Hardware

Comparison between software and hardware on risk management

	<u>Software aspect</u>	<u>Hardware aspect</u>
1) Major common hazard	Error (Bug)	No common hazard
2) Location of the hazard	Unknown	Known
3) Risk assessment	Difficult	Not difficult
4) Drastic risk control	Eliminate error	Reduce risk for each hazard
5) Risk control timing	All stages	Early stage
6) ISO 14971	Difficult to apply as it is	Should be applied

As software can be an integral part of a medical device, software risk management should not be isolated from that of hardware and from overall medical device risk management.

8. Key points of software development

- Product realization of software does not include manufacturing process.
- Safety, effectiveness and quality of software are established during design and development process.
- Hazard identification is the start point of risk management. Common hazards of software are errors (bugs). It is difficult to identify software errors. ISO 14971 can not be applied for software as it is. Special interpretation of ISO 14971 is necessary for software.
- There is no correlation between nature of an error (bug) and its result. Software behaves in a non-linear way. Even a trivial error such as coding mistake may cause serious accident.
- Software is easy to change and a minor change may cause failure.
- No software expert dose not make mistake.
- Effective test to detect an error is key for assurance of safety and quality of software.



9. Industry view points on software regulation

- Standards should provide useful and effective information and should not be regulatory requirements except special cases.
- Vital few, trivial many. Regulations should focus on vital issues. They should be minimum requirements (simple and short). For example, “Design and development of ISO 13485:2003” is only 750 words (4 pages). Software development should be a part of it.
- Regulations should be condensed essence, the best and the most effective way to assure safety, effectiveness and quality.
- There is no big difference between pre-market review for a medical device with embedded software and without it. Existing guidance documents can be applied.
- 1) New guidance document for pre-market review of standalone software and 2) Regulatory audit criteria for software as a part of QMS are essential.



10. Summary

- It is an urgent issues for GHTF to develop a guidance document for pre-market review of standalone software and regulatory QMS audit criteria for software to harmonize them.
- Because of resource limitation, it is impossible for RAs to separate audit for software and hardware. An audit criteria should be single.
- It will be the best solution for medical device sector to revise ISO 13485:2003 and to incorporate key elements of risk management and requirements for software development.
- Elimination/reduction of software errors through verification and validation is important. Test is key for them.
- It is the most important for software risk management not to repeat the same/similar adverse event. Analysis of adverse events report is essential.

