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JP/dt

Progress with the implementation of the Final GHTF Guidance documents in Europe

The European Region is fully committed to actively participate in the development and in the implementation of guidance documents. These documents show that a common interpretation of different but basically equivalent regulatory systems can be established and help in the better understand each other's systems.

A. Three final documents have been elaborated by study Group 1.

1. Essential principles of safety and performance.
2. Labelling of Medical Devices :

Both documents have been studied carefully and it appears that the recommendation given in the documents have already been largely implemented by the directives that establish the European regulatory framework.

3. The role of standards in the Assessment of Medical Devices. The document describes an approach similar to the one followed in Europe.
 - The standards considered are harmonised European standards established by the European standardisation bodies;
 - The standards are for voluntary application;
 - If a standard is correctly applied, the technical solutions give presumption of compliance with the corresponding essential requirements. This means that the manufacture has not to demonstrate compliance with the essential requirements.

B. Study Group 2 has elaborated 6 documents that have been adopted as final documents. Four of them give guidance on adverse event reporting.

The European Community had developed a guidance document on the medical devices vigilance system, published under the reference MEDDEV 2.12.1.

Last year the European guidance document was reviewed and modified to take into account, where appropriate, the guidelines adopted by the Global Harmonisation Task Force.

The EU guidelines have been extended to include the reporting of incidents involving « in vitro » diagnostic medical devices.

These EU guidelines establish a uniform application of the relevant directive provisions:

1. Global Medical Device competent authority report;
2. Minimum data set for manufacturer's reports to the competent authority;
3. Guidance on how to handle information concerning vigilance reporting;
4. Adverse event reporting guidance for manufacturers.

The other 2 documents do not require any action from our side.

C. Study Group 3 – Three final documents have been adopted :

1. Guidance on Quality Systems;
2. Design control guidance;
3. Process validation guidance.

With respect to certification of medical devices the European directives allow in parallel with Type examination procedures, the application by the manufacturer of an approved Quality Assurance System.

The directives recognise that device specific standards based upon the ISO 9000 series are appropriate for the development of Quality Systems, the application of which ensures that the devices conform to the requirements of the directives.

It was considered necessary to elaborate guidance documents to ensure a coherent application of these standards.

Manufacturers and certification bodies have reviewed these European documents to ensure a common interpretation and application.

The 3 documents established by Study Group 3 have been used as references within these guidance documents and the result are, as far as possible, coherent with GHTF documents.

D. Study Group 4 – four final documents have been adopted.

For obvious reasons, the document on audit language requirements is of no interest to Europe.

The other final documents give guidance for regulatory auditing of Quality Systems. Guidelines for Regulatory Auditing of quality systems ;

- a) general requirements,
- b) observed audits of conformity assessment bodies,
- c) training requirements for Q.A. Auditors.

A EU working group, set up to ensure coherent work procedures for notified bodies, has established an EU guidance on the designation and monitoring of the notified bodies, in particular when they have to evaluate quality systems (MEDDEV 2.10.2). This EU guidance (§ 4.C) requires application of the GHTF guidelines for Regulatory Auditing of the quality systems with respect to the assessment procedures and the competence, qualifications and training of Auditors.

Furthermore it has been agreed to apply these documents under the MRA-agreements.

E. A few comments on the ongoing work in Europe.

The Commission has elaborated, in co-operation with Member States and Industry, a report on the functioning of the European regulatory system for medical devices.

This evaluation has made us aware of the need to be very careful in order to ensure the compatibility and coherence between the different elements of the systems.

This applies in particular between the regulatory parts and the corresponding guidance.

Guidance shall never contradict nor complement the regulation. It is therefore necessary to verify carefully coherence of the overall system before modifications are adopted.

A system composed out of regulations, standards and guidance shall be coherent and ensure legal certainty. In the context of this comment and in reference to the many GHTF documents available I think it would be appropriate to develop a consistent Global Model for medical devices.