

The New Pharmaceutical Affairs Law

Sample

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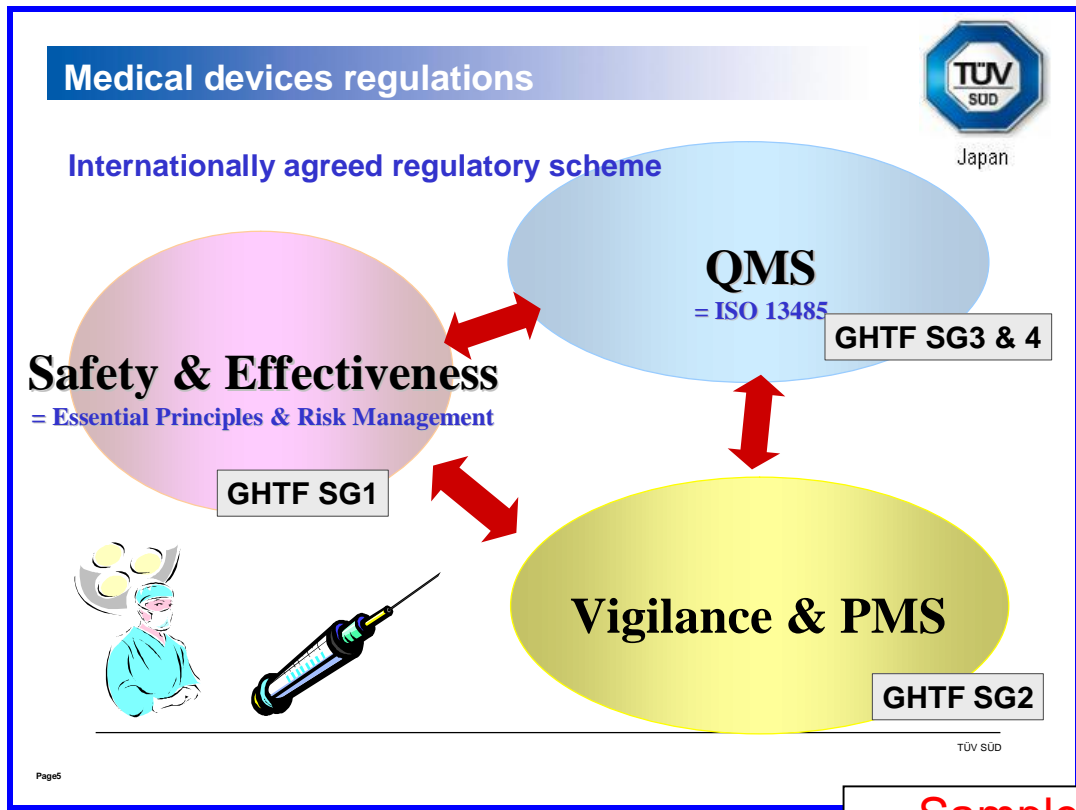
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1.1 Comparison with International Model (GHTF)

This is a picture to show the concept of the regulations for medical devices of the members of the Global Harmonization Task Force (GHTF), *i.e.* EU, USA, Canada, Australia and Japan. This picture shows that there are three major aspects of the requirements with the regulations for medical devices.

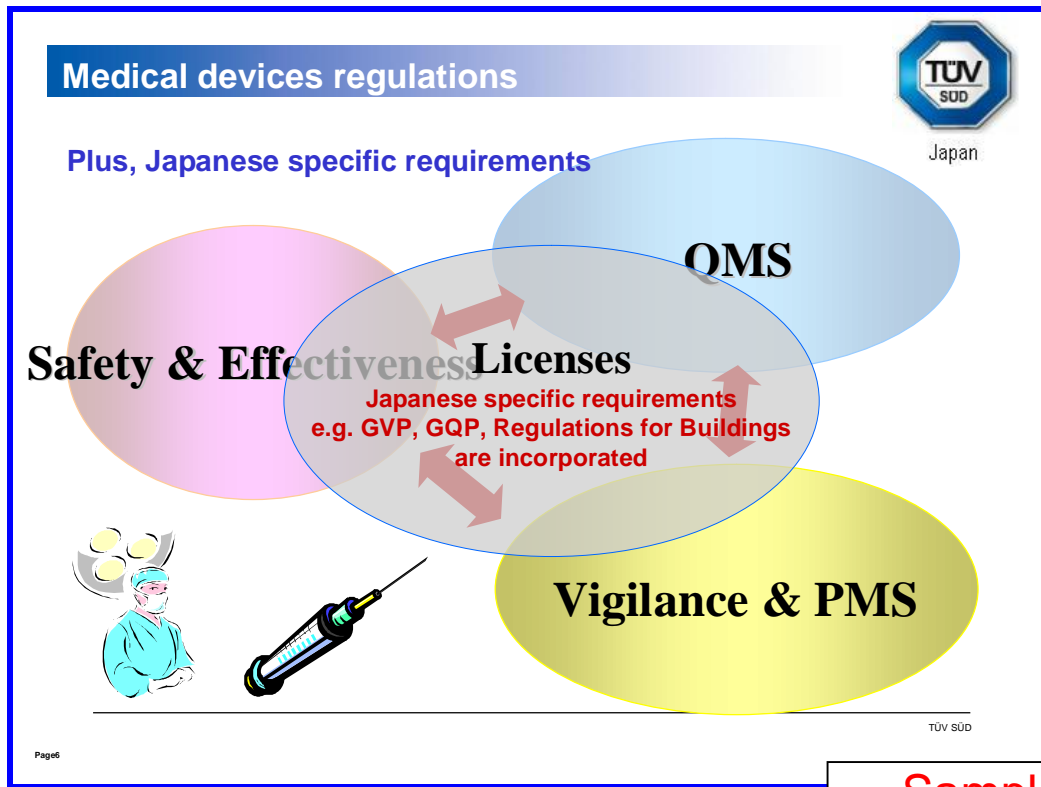
1. Requirements for Safety & effectiveness of medical devices
2. QMS Requirements
3. Requirements for Vigilance and PMS system

There are several SG's (Study Groups) established in the GHTF to discuss about the harmonization of the requirements by experts in detail.

SG1 is in charge for the harmonization of the requirements related to the safety and effectiveness of medical devices, and it recommends adopting the concepts of "Essential Principles" as safety and effectiveness requirements for medical devices. SG2 is discussing about the vigilance and post-market surveillance of medical devices and issued several documents for that. QMS requirements and auditing of QMS are discussed by SG3 and SG4. As a result, it is recommended that ISO 13485 be adopted as the regulatory QMS requirements by the GHTF.

Based on the discussion of relevant SG's the GHTF issued various documents in light of the harmonization of the regulatory requirements for medical devices.

The new PAL in Japan incorporated the concept of the GHTF documents, for example, the concept of "Essential Principles" is incorporated in the revised new PAL as safety and effectiveness requirements, and the requirements of ISO13485:2003 are used as well.



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However, there is Japanese specific aspect in the PAL, which is the license system for medical device manufacturers.

To be a medical device manufacturer in Japan, and manufacture and market medical devices in Japanese market, the PAL requires that at least two licenses be obtained. The most important one is a license given to a "MAH" (Marketing Approval Holder). Having this license, the organization must be fully responsible for the safe and effectiveness of the medical device. The other one is a license for manufacturing. This license is necessary to physically manufacture medical devices.

There are some related requirements for the licenses, which are not harmonized with other countries regulations.

For example, there are requirements called as GVP and GQP, or Regulations for Buildings and so on. These are Japanese specific concepts, and therefore they are making difficulty to understand the PAL for foreigners.

As the summary, the PAL has three major aspects of the requirements;

- Safety and Effectiveness
- Vigilance and PMS
- QMS

And, these are the requirements which are more or less harmonized with the model recommended by the GHTF. However, there is a Japanese specific concept of license requirements to cover these three aspects, and also there are several important requirements linked directly with licenses.