



Chapter 5

ISO vs QMS

ISO vs QMS under the PAL

1. Difference between ISO13485:2003 and QMS under the PAL
 - (1) ISO13485:2003 is the standard fixed by ISO and also applicable globally, but not legal requirement everywhere in the world
 - (2) The QMS standard under the PAL is a version combining the requirements of ISO13485:2003 and Japan's Good Manufacturing Practice (GMP)
 - (3) The QMS under the PAL shall satisfy the requirements in Manufacturing control and quality control as mandated by the Ministerial Notice No. 169
 - (4) GMP differs from country to country but not universally required

QMS system under the PAL

2. The QMS system required by the PAL means:

A part of Manufacturing Control under the Ministerial Ordinance No.63

+

Inclusion of most of the ISO13485:2003, and its partially modified version

||

The QMS Standard under the PAL, which is very unique and specific to Japan as shown in the Ministerial Ordinance No. 169

QMS system under the PAL

3. Ministerial Ordinance No.169 dated Dec. 17th, 2004
 - Japanese QMS Ordinance is almost equal to ISO13485: 2003
 - The major difference from ISO 13485 is that a manufacturer must prepare and maintain a Seihin Hyojun Sho (Japanese version of Device Master Record)
 - A Device Master Record specifies the specifications and QMS-related requirements of the MD. (QMS Art. 6-2)