

Installation/setup and support services	
Instructions in case of unexpected events	
Sterilization procedures	Should be based on process validation results.
Quality agreement between MAH and manufacturer	Required even if your MAH is a subsidiary.
Quality specifications and testing methods, with their rationale	Only if you are using stricter quality specifications or more accurate testing methods than the standard Japanese tests for the product.
Any voluntarily established quality specifications and testing methods, with their rationale	Only if you are using quality specifications or testing methods <i>over and above</i> the standard Japanese tests.
Details of any testing conducted by contract laboratories, including test items, specifications, and testing methods	
Dates of completion and approval of product development	Any subsequent modifications or changes to the product should be listed with their dates, approval signatures, and rationales.

Please note that it is *extremely important* that the Seihin Hyojun Sho have no discrepancies with the equivalent documents that have *already* been submitted to the Japanese government as part of the product registration application. The PMDA will focus quickly on any discrepancies, including product or model names, facility addresses, and product data. Specifications, in particular, should be the same. For example, in providing product dimensions, having dimensions of a product measured by feet in one document and meters in the other (even if they are equivalent figures) can cause problems.

The Seihin Hyojun Sho does not need to be in a specific format, as long as each required item is easily identifiable.

**c. Determination of on-site vs. paper audit**

How does the PMDA determine whether to conduct an on-site audit or a paper audit on your manufacturing site?

The PMDA examines a number of risk criteria in order to determine the kind of audit it will apply. These criteria include: risk classification of the product itself; relative risk of different manufacturing processes; risk of the country of manufacture; and risk of the specific company applying.

The risk classification of the product is a major component of the PMDA's determination. The PMDA views classifications from least to most risky as follows:

*Least risky*  
↑  
-Class II medical devices  
-Class III and IV medical devices  
-New Class III and IV medical devices  
-Cell or tissue-based medical devices  
↓  
*Most risky*

With respect to manufacturing process risk, from least to most risky (as perceived, in general terms, by the PMDA) are: contract testing; contract design and development; sterilization and storage; contract sterilization; and critical processes.

With respect to country risk, the PMDA has more confidence in countries that are members of the Global Harmonization Task Force (GHTF). Besides Japan, these are the US, Canada, Australia, and the EU countries. If your manufacturing facility is not in one of these countries, it is much more likely to be audited. (In general, however, it is not common for high-risk medical devices made in non-GHTF countries to be introduced onto the Japanese market.)

Finally, there is corporate risk. The PMDA will look to see if your company has had incidents of recalls, defects, failed audits, etc., and be more wary if your record is problematic. Also, the PMDA usually perceives larger, public companies to have better regulatory, QA, and general management than smaller, private companies, and therefore to be less risky.

Out of all of these types of risk, product risk is generally seen as the most important factor by the PMDA. Therefore, Class IV medical devices, new devices, or cell/tissue-based devices are the most likely products to be subject to an on-site audit as of now.

It should be noted that due to limited manpower at the PMDA, to date, there have only been a few actual on-site audits of overseas medical device firms. In the 2007 fiscal year,