

Session D:
Critical Thinking and Decision Making
Medical Devices

2012/NOV/08 08:30-11:30

Philosophy of PMDA

PMDA continues to improve the public health and safety of our nation by reviewing applications for marketing approval of pharmaceuticals and medical devices, conducting safety measures, and providing relief to people who have suffered from adverse drug reactions.

We conduct our mission in accordance with the following principles:

- We pursue the development of medical science while performing our duty with greater transparency based on our mission to protect public health and the lives of our citizens.
- We will be the bridge between the patients and their wishes for faster access to safer and more effective drugs and medical devices.
- We make science-based judgments on quality, safety, and efficacy of medical products by training personnel to have the latest technical knowledge and wisdom in their field of expertise.
- We play an active role within the international community by promoting international harmonization.
- We conduct services in a way that is trusted by the public based on our experiences from the past.

Conclusions

- The key step for decision making is to identify questions and to define if a question is critical or non-critical.
- Not all economies have a medical device regulatory section.
- it is common to adopt the concepts and approaches from the pharmaceuticals
- the differences between the pharmaceutical measures and medical devices measures shall be understood and well-noticed by the authorities/review parties, law-makers, and the public.