

The 38th Japanese IVD Industries Meeting in China Minutes

A member of International Affairs Committee of JACRI joined the 38th Japanese IVD Industries Meeting in China Main Meeting to exchange information each other. The meeting was held at JC-NET seminar room in Shanghai city on January 8th, 2016.

China Food and Drug Administration (CFDA) will improve their approval system in the near future. A number of examiners will be increased by the improvement, so rapid approval will be expected. On the other hand, there will be an ability gap between new and current examiners.

Each committee in the IVD Committee introduced recent its activities. It seems that they do not have big problems.

JACRI announced followings;

- We do not have disorder in the Japanese market despite the amendment of Pharmaceutical and Medical Device Act.
- A position paper, regarding “Ideas for appropriate provision of IVDMD”, which was presented by AMDD, EBC and JACRI, was sent to MHLW and PMDA.
- Summaries of GDA activities and topics in the GDA meeting.

We had 2 lectures in the latter half of the IVD Committee meeting.

The first lecture was “the trend of standardization of standards (like GB standards) in China.” We have “more than hundred thousand” (this means no one knows actual number) standards in China. There is a contradiction between some standards, and there is a gap between standards and actual market. Chinese government would like to dissolve these problems.

The second lecture was “Cases we have to pay attention in China, cutting salary.” If we cleared some conditions (set company rule, which is agreed with labor union, etc.), we may cut salary. Though

we cleared these conditions, we should not consider that cutting salary can be implemented in every case.

