

Regulatory System of Medical Devices in Japan - From the Standpoint of a Physician

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In Japan, not only medical devices but also pharmaceuticals are evaluated by two authorized regulatory bodies, Pharmaceutical and Medical Device Agency (PMDA) and Ministry of Health, Labour and Welfare (MHLW) before getting approval. Medical devices have been classified. Class III or novel device should be approved by MHLW. Applicant submits the application form (Form 22-3) with summary of data set and data set to PMDA. The submitted documents are evaluated by a review team in PMDA. The review team interviews with the applicant and consults with several external experts such as basic medical scientists and physicians regarding with teratogenesis, carcinogenesis, clinical significance and so on. Physicians who are expertise in submitted device review and asses the clinical data set and submit assessment comments. Then PMDA assessment outcome is sent to MHLW. MHLW organizes Panel Board. In terms of medical devices, the Board members are fixed and comprised of physicians from several fields such as cardiovascularology, ophthalmology, neurosurgery and other medical field.

In the symposium, I will talk about those approval systems including my personal participation as a physician