Medical Devices
WG4 - Regulatory Convergence and Communication

Introduction
Working Group 4 was commissioned by the HBD steering committee to promote improvements in "regulatory convergence and communication." This concept paper provides information on the WG4 mission and activities as envisioned by its members in response to the HBD steering committee's direction and guidance to the working group.

Background
The differences in medical device regulations between the US and Japan provide an opportunity to improve the timely availability of innovative medical devices to patients who would be most benefit from them in the course of their medical treatment. Whereas the GHTF (Global Harmonization Task Force) focuses its activities on the development of harmonized regulatory guidance and broader global harmonization of medical device regulations, more specific and experience-based studies need to be conducted to find solutions to the real problems that the US and Japan specifically share in providing timely approvals of medical devices. The fundamental purpose of HBD is to seek convergence of regulatory requirements and practices through concrete experience "by doing" rather than through theory. HBD is intended to offer a suitable venue for such studies. Under the direction of the HBD steering committee, "regulatory convergence and communication" was identified as critical to the implementation of harmonization initiatives and was assigned to WG4. Issues associated with regulatory convergence and communication will likely be identified within other HBD working groups as well. The steering committee will therefore coordinate work between the groups on common issues. The HBD working groups will work jointly and collaborate to find solutions to the shared issues. The concepts and planning of WG4 as described above are subject to change by the steering committee and by input from WG4, other HBD working groups and stakeholders.

Mission
The mission of WG4 is to facilitate the timely global introduction of new medical technologies by identifying and addressing specific regulatory barriers through proof-of-concept projects. The scope of WG4 is to improve administrative practices within the context of existing regulations with the goal of convergence between Japanese and US practices and improved communication between

stakeholders.
WG4 will also look for opportunities for possible future revisions of those existing regulations where changes in administrative practices are insufficient to promote regulatory convergence.

Specific Aims

The specific aims are:
a. To facilitate dialogue and provide suggestions, or points-to-consider intended for US FDA (Food and Drug Administration) and/or Japan MHLW/PMDA (Ministry of Health, Labour, and Welfare / Pharmaceuticals and Medical Devices Agency) as well as those regulated parties (e.g. investigators conducting clinical trials, medical device manufacturers submitting applications ("sponsors")), to resolve the difficulties found; and

b. To identify regulatory-related obstacles, to serve as a catalyst for resolution, in conducting clinical trials, filing and reviewing applications for clinical trials and marketing approval of medical devices including post approval processes in the US and Japan, especially those resulting from the difference between the two countries' regulations, interpretations, and practices; and

c. To report findings to the HBD steering committee, other HBD working groups and all stakeholders; and

d. To share information publicly (e.g. at the HBD meetings, on the HBD website, at the professional society meetings, or congresses), on important similarities and differences in laws, regulations and regulatory practices related to medical devices in the US and Japan.

Deliverables

The expected deliverables include:
a. Summary of key similarities and differences between FDA and MHLW laws, regulations, and regulatory practices as related to medical devices;

b. Delineation of the issues related to current regulatory practice; and

c. Prioritized identifying issues that may significantly affect the progress of the HBD effort; and

d. Identification, implementation and analysis of proof-of-concept projects; and

e. Proposed solutions (recommendations, suggestions, or points-to-consider); and

f. Follow-up on implementation of the proposed solutions.

Membership

Membership selection will consider the general principles of HBD for symmetry and balance between the US and Japan, among government, academia and industry, and among all stakeholders and constituencies.
The chairmanship of WG4 will be held jointly by designated representatives of FDA and MHLW. Chairmanship by regulators is justified because the issues discussed in WG4 are primarily related to the regulatory approach by authorities. Moreover, regulators are more aware of agency policies and procedures, therefore any recommendations from WG4 will be more conducive to implementation in both agencies.

Possible Regulatory Target Areas

Possible target areas for examination include:
a. Regulations on clinical trials and medical device GCP (good clinical practices), including pre-authorization, medical device implementation issues, documentation requirements, comparison of standards, and agency recognition of medical device GCP standards and bioresearch inspection/audit practices; and

b. Regulatory practices of FDA and MHLW/PMDA, including modes of review (simultaneous review, modular review, whole-dossier approach) of applications for marketing authorization/premarket approval/notification, including GHTF's STED (Summary Technical Documentation) format and content differences between GHTF countries, ways to improve speed and quality of reviews; and

c. Regulator/applicant and regulator/regulator communication; and

d. Reporting requirements for adverse events occurring during clinical trials, post market surveillance studies as a condition of approval; and

e. Reduction of pre-approval clinical trial sample size based on post approval PMS requirement

Deliverables / Milestones

Deliverables / milestones for 2009 - 2011 include:
a. Annual update of the WG4 concept paper and

b. Publish Good Clinical Practices (GCP) manuscript and

c.Initiate and conduct STED POCs; and

d. Proof of concept projects pertaining to medical devices GCP and STED as well as initiation of new topics (HBD Think Tank West/East Meetings).

In summary, this concept paper will guide WG4 mission and activities to promote improvements in “regulatory convergence and communication”.

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