DuPont™ Tyvek® Transition Project

Japan Regulatory Guidance

Three-party meeting was held on September 25, 2013

Participants included: Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceutical and Medical Device Agency (PMDA), Association of Registered Certification Bodies (ARCB) under PAL, and Japan Federation of Medical Device Association (JFMDA).

Specification and miscellaneous properties of Transition Protocol materials were reviewed during the meeting.

The recommendation from the three-party committee for Class II, III and IV medical devices is:

- Medical device manufacturers (MDMs) should review their entries of record and assess if any information needs to be updated.
- If updates are required, MDMs simply need to submit a minor change notification (Keibi Henkou Todoke); there is no need to wait for response.

The official Japanese guidance (Yakushokuki) describes the process of reporting partial changes made to medical devices under a minor change notification.

Example of Japanese Minor Change Notification Form (Keibi Henkou Todoke)

原材料又は構成部品
Raw material or component parts

番号 Number	名称 Name		原材料名 Raw material name	規格 Specification	概要 Brief summary
1)	構成部品 Component parts	①タイプ１ Type 1		ASTM ○○○ Type ○○○	
		②タイプ２ Type 2		ASTM ○○○ Type ○○○	
2)	滅菌包装材料 Sterile packaging material				

NOTE: English translation in blue

【滅菌包装材料の留意点】

EOG 滅菌の場合には、厚さ等を記載すること

[Note for sterile packaging material]
Record the value such as thickness in case of EOG sterilization