Conformity Assessment and Notified Bodies

Role of Accredited Persons/Conformity Assessment Bodies in the Regulatory Process

Laurent SELLES
Deputy Head of Unit « Cosmetics and Medical Devices »

Regulatory Framework: Two sides of the same coin

Internal Market

EU Directives

International Harmonisation

GHTF Guidance

Type of Control

- Pre Marketing phase
  - Authorisation from Notified Bodies
  - Certification
- Post Marketing phase
  - requirements monitoring,
  - adverse reporting
  - corrective measures (recall or withdrawal).

In the EU (I)

Pre-marketing phase

The manufacturer affixes the CE-marking after the intervention of a NB who assesses :

- the manufacturer according to the conformity assessment procedure for the chosen devices of Class III, Class IIb, Class IIa, Class I “sterile”+“measuring”;

- and the design of the product for Class III devices.

Other medical devices of class I and “custom made” are exempt from the assessment by notified body, but must follow the essential principles of safety and performance in their design, construction and labelling requirements.

In the EU (II)

Post-marketing phase

i.e. monitoring requirements, adverse reporting and corrective measures (recall or withdrawal).

In the EU, post-market surveillance falls within the competence of the Member States.

(Local control with EU-wide coordination + alert system)

In the USA (I)

Pre-marketing phase

The manufacturer of the device receives a marketing clearance (pre-market entry notification, termed 510k) or an Approval Letter (PMA) from the US FDA

- **Most class II and some class I devices require the 510k, an information package for the FDA (less stringent review than the PMA process).**
- **The 510k submission must demonstrate how the proposed medical device is substantially equivalent to a medical device that is already on the US market. Most class I and some class II (low-risk) devices are exempt from 510k submission before sale, but are still subject to general control requirements.**
- **Most Class III and new devices that are not substantially equivalent to a legally marketed product do require a marketing clearance or a pre-market approval.**

In the USA (II)

Post-marketing phase

i.e. monitoring requirements, adverse reporting and corrective measures (recall or withdrawal).

- **Food and Drug Administration deals with these issues centrally**

Message: The EU is looking for convergence with the US system…

Conformity Assessment Bodies (CABs) and Notified Bodies

- **Notified bodies are independent testing houses or laboratories authorized by EU member states to perform conformity assessment tasks.**

- **They may be private organizations or public entities.**

- **A notified body is responsible for determining and certifying that a firm has met the minimum technical requirements established by customers or other interested parties, including government regulators.**

- **It conducts inspections, performs tests, and certifies whether firms meet the minimum regulatory requirements for the CE marked medical devices.**

Global Harmonisation Task Force

The Global Harmonization Task Force (GHTF) was conceived in 1992 in an effort to respond to the growing need for international harmonization in the regulation of medical devices.
GHTF Chairmanship is rotated amongst the regulatory representatives of

Purpose of the task force is to encourage convergence in regulatory practices related to ensuring the safety, effectiveness, performance adequacy, and quality of devices and thus to promote technological innovation and facilitate international trade. The primary way is through publication and dissemination of harmonized guidance documents on basic regulatory practices. These documents, which are developed by four GHTF study groups, are intended for adoption and implementation by national regulatory authorities.

Thank you again…

Laurent Sellès
phone: +32 (0)2 296 34 20
fax: +32 (0)2 296 64 67
Laurent.selles@ec.europa.eu

Cosmetics:
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