

STANDARDIZATION & BIOMEDICAL TECHNOLOGIES

«Standards to support an innovative sector»

In order to meet the demand for a more personalized and patient-centered medicine and also to find solutions to reduce health expenditures, innovation in the biomedical technologies sector has been encouraged both at European and International level.

The World Health Organization announced recently that 36% of 170 countries have a national health technology policy that is part of their national health program. This sector is considered by the Government of Luxembourg as a significant economical motor in constant progress. The development of the eHealth technologies and telemedicine devices are key examples of this trend. In this context, standardization work is of crucial importance to go with the development of the biomedical technologies as standards help in guaranteeing the safety, effectiveness and compatibility of health products, software or services.



What are the main fields of international standardization activity in the biomedical technologies sector?

Various standardization works are in development and cover several fields of the biomedical technologies including:

- Medical devices, encompassing medical instruments and implantable medical devices
- Medical equipment, such as medical lasers
- Services dedicated to health
- eHealth, Telemedicine
- Diagnostics sector, e.g. molecular diagnosis

The Normative Analysis in the biomedical technologies developed in Luxembourg

Biomedical technologies have been identified by the Minister of the Economy and Foreign Trade as a promising sector for the national economic market. Thus, a normative analysis dedicated to this sector was launched in December 2011 in order to highlight potential interests for the national stakeholders as well as opportunities for the national market.

The main objectives of this normative analysis are to:

- **Inform** the national players about standardization developments in their sector
- **Identify** potential interests for the national players and opportunities for the national market
- **Encourage** all players of a sector to have reflex for standardization
- **Develop** "standards-related" skills and collaboration between players of a sector

Expected results:

- A normative analysis report presenting the standardization technical committees of strategic importance in the biomedical technologies sector
- Potential interests of the national stakeholders based on the standards watch results
- Opportunities for the national market and potential benefits for its stakeholders
- Development of awareness and training material dedicated to the biomedical technologies sector



APPLICATIONS WANTED: SEEKING EXPERTS IN THE BIOMEDICAL TECHNOLOGIES!

Do you have skills and experience in the field of biomedical technologies?
Do you want to anticipate future requirements and influence the market?

JOIN THE STANDARDIZATION PROCESS NOW! BECOME A COMMITTEE MEMBER!

SETTING STANDARDS MEANS SETTING THE MARKET



STANDARDIZATION

An essential tool to boost competitiveness

What is standardization?

Standardization is a VOLUNTARY, CONSENSUS-driven activity, carried out by and for the interested parties themselves, based on openness and transparency, within independent and recognized standards organizations, leading to the adoption of standards compliance with which is voluntary.

[Source: Official Journal of the European Communities 2000/C141/01]



How is standardization organized in Luxembourg?

The Luxembourg system of standardization is based on a network of experts coming from all sectors enrolled in standardization technical committees at national, european and international level. Their role is to bring their expertise and knowledge to bear on guaranteeing quality of standards. They also take part in voting and can thus guide future market demand. The Luxembourg national standards body ensures coordination among the different committees at national level.

A new momentum for standardization in Luxembourg

To promote standardization in Luxembourg, ILNAS (Institut luxembourgeois de la normalisation, de l'accréditation, de la sécurité et qualité des produits et services) has drawn up the Luxembourg Standardization Strategy 2010-2020¹ based on a sectorial economic approach and in accordance with market needs. Since October 2010, ILNAS has been supported by ANEC (Agence pour la Normalisation et l'Economie de la Connaissance) in implementing this strategy. The purpose is raising awareness, training and monitoring in the field of standardization and applied research.

¹<http://www.ilnas.public.lu/fr/publications/normalisation/etudes-nationales/ilnas-strategie-normalisation-2010-2020.pdf>