Standards for better and safer medical devices

Standards play a crucial part in our lives. In healthcare, standards have an indispensable role for the proper functioning of medical devices, for correct transmission of information, for therapy, for monitoring and support in treatment, and much more. Thus, standards help manufacturers to produce safe medical devices with constant high quality and, as such, help competent authorities to ensure that medical devices in their country provide the performance they want for their citizens.

DITTA, the global voice of healthcare industry, has always been promoting the use of international standards as part of ensuring safe and effective medical equipment in the interest of patient safety. Key for DITTA is that these standards:

- benefit from competencies of the world's leading experts,
- are developed in a non-competitive process,
- reflect state of the art in continuity with an effective maintenance process,
- are effectively used to support product legislation

Very important is that all stakeholders are invited to participate in the drafting of international standards so that the requirements in these standards get the widest possible support. DITTA invited opinions about standards and the development process.

> Mr. **Satoshi Kimura** of Japan, DITTA chair from 2015-2016, said about the importance of standards: "*When in 2015 Japan chaired IMDRF, the International Medical Device Regulators Forum, DITTA organized a very successful workshop in Kyoto on the use of standards in regulatory environment. Speakers, both regulators and industry, emphasized the importance of standards. Also, they identified possibilities to improve the development process. Japan is very famous for quality improvement so the IMDRF regulators, inspired by the Japanese authorities, invited DITTA to make a project proposal. DITTA gladly did so and is proud that the proposal was adopted, early 2016. Regulators in IMDRF collaborate with industry to develop improvement proposals!*"

Who are the stakeholders, and under what settings do they collaborate to achieve the best possible technical specifications? DITTA approached IEC with this question.

> Mr. **Frans Vreeswijk**, secretary-general of IEC: "*The rules under which standards are developed in IEC –and it is not different in ISO- reflect the six principles considered important by WTO, the World Trade Organization: openness, transparency, impartiality and consensus, effectiveness and relevance, coherence, and development dimension. This is to make sure that the result reflects the state of the art, regardless whether the experts are from industry, medical practice, test institutes, or authorities. Of course, it is not possible to develop standards with thousands of experts. Therefore, organizations like IEC use the multi-layer scheme whereby National Committees, which are open to all relevant stakeholders in their country, delegate experts to a drafting group. This drafting group does not decide on the content of the individual standard: that decision comes through voting by the National Committees. Having multiple rounds of commenting, redrafting, and voting, the standards mature to a level that is relevant for all stakeholders.*"

So it is clear that all stakeholders can contribute to the development of international standards. DITTA asked the secretary of IEC/TC 62, the Technical Committee that develops the majority of the standards for medical electrical equipment for his views.

> Dr. **Nobert Bischof**, also secretary for two subcommittees in IEC/TC 62, is clear on the matter: "*The work of IEC/TC 62 focuses on safety, performance and a range of other aspects, including radiation protection. IEC/TC 62 and its subcommittees cover a vast field of product categories including diagnostic imaging, radiotherapy, nuclear medicine, electromedicine, anaesthesia, critical care, surgery, artificial respiration, and paediatrics. In all endeavours, the focus is exclusively on the safety and performance of electrical and electronic medical devices for patients, medical staff and accompanying persons. It is standing policy of IEC/TC 62 that all chairs, including those of the subcommittees, have a professional background in medical or biomedical functions.*"

As mentioned above, IMDRF has adopted the project to improve the process of standards development. Now the question remains: what can or should be improved in that process? DITTA asked the chair of ISO/TC 210, the Technical Committee in ISO for "horizontal" medical device standards: those that apply to (almost) all medical devices.

> Dr. **Peter Linders**: "*When speaking about possible process improvements, think first of better scrutiny for new work items: resources should be dedicated to those projects that matter the most for patient safety and clinical effectiveness. Secondly, it is important to have more involvement of regulators, especially in the early phases of standards projects. Therefore, we are proud that the Asian Harmonization Working Party, AHWP, is a liaison organization to our TC. AHWP represents 30 countries, mostly in Southeast Asia. We are also actively engaging with IMDRF. In ISO/TC 210, we aim for a balanced representation of stakeholders in the leadership of the projects.*"

For more information, please visit one of the below web sites, or send an e-mail to DITTA at secretariat@globalditta.org.

www.iec.ch
www.iso.ch
www.wto.org
www.imdrf.org
www.ahwp.info
www.globalditta.org