

ID: R-PP-01**How to deal with Regulatory Requirements – Standards and other Friends**

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The way of a new in-vitro diagnostic (IVD) medical device into the market may end in the valley of death of regulatory requirements. These requirements are regarded as considerable challenges especially for small and medium-sized enterprises (SME) with limited financial and human resources. Consequently, the development process results in innovative products often neglecting the consideration of the regulatory requirements. The conformity of a product may be demonstrated by the application of harmonised standards leading to the presumption of conformity. Among the large number of standards even for the manufacturers of IVD medical devices, it is sometimes difficult to identify those which are relevant for a particular requirement. Furthermore, the question arises, what additional sources can be used when there no harmonized standard is available. The VDE published this year the first guideline on the development and manufacture of IVD medical devices concentrating on the application of standards. In this presentation, an overview of the development process in the light of the legal framework and the respective standards for IVD medical devices will be given.

ID: R-PP-03**A Case Study on Performance Reliability of Infusion Pump Devices**

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Nowadays, more than 10,000 different types of medical devices can be found in hospitals. In this regard, medical Electrical equipment are being employed in a wide variety of fields in medical sciences with different physiological effects and measurements. By the way, hospitals and medical centers must ensure that their critical medical devices are safe, accurate, reliable and operating at the required level of performance.

Infusion devices are used extensively in clinical settings and patients' homes as an essential tool for providing critical care, perioperative care and pain management. Because infusion pumps are frequently used to administer critical fluids, including high-risk medications, pump failures can have significant implications for patient safety. So, the reliability of infusion pumps is extremely important. Moreover, the safety incidents associated with infusion devices demonstrate that there is a need to adequately validate the accuracy and performance of these devices. The metrological reliability of fifty (50), infusion pump in use ten hospitals (4 privates and 6 publics) in one of the province according to international and national standards was evaluated.

Quantitative analysis of flow rate accuracy measurements, showed the amount of the obtained results in many units are critical and have less value over the standard limitations, especially in devices with inappropriate IV set. For example, it has been seen, the usage of a wrong or nonstandard syringe or tubing set, which is not made based on the approved technical specifications, increases the occurred error percent and the inaccuracy 10 to 20 percent. It has been seen that the low quality batteries and the batteries which are sensitive to the improper voltage could reduce the outflow rate between 10 to 30 percent. This could be occurring on the condition that the battery power reaches to 25% under the full power limit.

Acquiring results indicate a need for new and severe regulations on periodic performance verifications and medical equipment quality control program especially in high risk instruments. It is also necessary provide training courses on the fundamental of operation and performane parameters for medical staff in the field of meterology in medicine and how can get good accuracy results especially in high risk medical devices.

ID: R-PP-04**Building medical device ontologies for cross device group risk profiles**

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As innovation is constantly driving medical device manufacturers to provide technical solutions for nowadays medical problems inevitably also new types of risks occur and need to be identified as early and reliably as possible to assure patient safety. In Germany the Federal Institute for Drugs and Medical Devices (BfArM) is the competent authority in charge for scientific risk assessment of most of the critical incidents that occur with medical devices. In addition to assessing each incident individually a new type of assessment by profiling risks patterns needs to be developed to allow for improved, software-based identification of common failure modes across device groups.

Over the past eight years electrical failures have been identified by BfArM in about 15% of all determined failure modes per year and thereby rank number three behind the categories mechanical issues (~40%) and dysfunctional device (~25%). A disruption in power supply or early battery depletion accounts for more than a third of the electrical failures. In addition to this substantial amount of incidents received regarding power supply issues the spectrum of devices makes this group particularly interesting for building up a systematic ontology. Apart from power supply issues in many active implants such as cardiac pacemakers, implantable defibrillators, artificial hearts, and devices for neuromodulation, these types of issues also occur in devices for electrotherapy, infusion pumps as well as heart-lung machines.

Evaluating different methods to transfer the domain specialist's knowledge to such ontology for monitoring this specific risk profile as well as evaluating the resulting benefits is part of the recently started OntoPMS project and background, current approaches as well as first results will be presented. OntoPMS is a collaborative effort by medical device manufacturers and BfArM together with ontology and search specialists.

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ID: R-PP-07**High throughput model building workflow for generating personalized models of whole heart anatomy and electromechanical function**

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Introduction. Computational models of cardiac electromechanics are increasingly being applied to clinical problems, with patient-specific models being generated from high fidelity imaging and used to simulate patient physiology, pathophysiology and response to treatment. Advances in medical imaging technology provide data on cardiac anatomy at an ever increasing level of detail, facilitating the representation of all four chambers of a given patient's heart with high geometric fidelity. In this study we report on recent methodological developments which facilitate the efficient generation of patient specific whole heart anatomy models from clinical image data. A set of 9 personalized anatomical models were generated for both healthy patients as well as various pathologies (DCM,...). A simplified representation of the cardiac conduction system was incorporated to compute activation and repolarization sequences as well as the body surface ECG using a monodomain model.

Methods. MRI scans of human hearts were semi-automatically segmented and classified. Variational smoothing was applied to mitigate surface artifacts originating from insufficient scan resolution. The smoothed geometry was then rendered at a higher resolution and output as a labelled image dataset. Unstructured and locally refined tetrahedral meshes of the cardiac geometry were generated at different resolutions. Label information from the image processing step was incorporated into the generated mesh and used for local mesh refinement and later application for model boundary conditions. In absence of diffusion tensor imaging data, a Laplace-Dirichlet rule-based algorithm was employed to assign fiber and sheet information in both ventricles. Using *a priori* knowledge, the anatomical locations of fascicles were iteratively adjusted to obtain realistic QRS morphologies.

Results and Conclusions. The methodology has been applied to nine patient cases, generating a set of personalized, highly detailed cardiac computer models. The model building workflow has been efficiently streamlined and makes patient specific modeling feasible with relatively fast turnaround times.