ABSTRACT

Pre-screening solutions for disease prediction fall under medical device regulations because of the intended purpose of diagnosis. The chapter begins with an overview of the medical device regulations focusing on the two major regulations. The definition of a medical device to the guideline of how a medical device is classified is then discussed. The later part of the chapter covers the design control process with stages of user needs translating to requirements, the design process with the design outputs, design verification conforming that the design is right, followed by design validation that proves that a right medical device is made. The risk management, usability engineering, and security and privacy risk management are part of the product realization process. Having a clear regulatory strategy and plan beginning with the list of target countries and intended use followed by identification of all the applicable product standards is vital. The process thus culminates in the design and development file which is a formal document that describes the design history of the medical device.
INTRODUCTION

The healthcare delivery models in modern medicine have evolved a lot from the conventional physician auscultating and making clinical judgement to the current practices of evidence based medicine with heavy dependence on medical devices and healthcare solutions. One cannot imagine any segment of the healthcare continuum be it prevention, diagnosis, treatment or rehabilitation without the assistance of devices and solutions. Imagine yourself lying on a surgical table in front of tools of dubious origin; would you feel safe? Let us envisage the scenario of a pacemaker being implanted on our dear one. Do you feel confident that the pacemaker will effectively perform its intended function?

It is clear that as a consumer of devices and solutions used in healthcare practice, we need them to be safe and effective. But, how does one ensure that the systems used in healthcare are safe and effective. How does the user report if he notices, issues related to safety or effectiveness. It is hence essential to have a mechanism by which the devices and solutions for healthcare are controlled and monitored for its safety and effectiveness.

The mechanism of such a system that controls the use of devices and solutions for medical purpose is called Medical Regulatory body. The Food and Drug Administration (FDA) in the United States of America is one such regulatory body. Similarly, European Commission, Health Canada, Pharmaceuticals and Medical Devices Agency (PMDA), China Food and Drug Administration (CFDA) and other agencies have responsibility to ensure that the medical devices are safe for potential users before manufacturers start to market the devices in their respective geographies (eInfochips, 2017). The whole mechanism of the regulation is like a gatekeeper who first ensures that only appropriate devices that show evidences of the product being safe and effective are allowed inside and further continues to keep a watch on the safety and effectiveness of the medical devices.

In order to get into the market, the medical device must comply with regulatory compliances defined by the medical regulatory body, subject to both regional and international standards. Medical device standards are thus helpful and also enforced by law in specifying and evaluating the requirement for design and performance parameters for biomedical materials, tools, and equipment (eInfochips, 2017).

The focus of screening test is mainly to detect the cause of certain symptoms and help in confirmation of presence or absence of the disease. The goal of disease pre-screening however is to detect potential health disorders or diseases in people who do not have clear visible symptoms of disease. This gives an advantage in treating the diseases much earlier which also results in a better health outcome. Non-invasive biomedical sensing devices offer benefits such as early detection and thus prevention of the risk of infection, ease of use and suitability for long-term monitoring. The
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