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The impact of medical devices post-market regulatory activities in the clinical research and clinical trials

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Medical devices are used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used either alone or in combination with any accessory, consumable or other piece. The evolution in medical technologies increases yearly. According to the United States patent and trademark office and the European patent office, the total number of granted patents for medical devices technologies in 2015 is 30,000 applications. These huge patents and other inventions in medical devices are required to have a regulatory framework in order to set regulations, standards and guidelines controlling the product's life cycle (premarket, on-market and postmarket). Post market surveillance is the important phase in the devices life cycle. Series of different reactive and proactive activities are performed in addition to continuous ongoing assessment of safety information to ensure long terms safety, efficacy and performance of the device. Moreover, the mining approach of postmarket data provide a scientific based evidence which may be used by regulators, governments to update guidelines, regulation or even can be used by manufacturers to improve the product's quality. This paper will address the importance of post-market surveillance activities (proactive and reactive) in terms of clinical research, whereas clinical evaluation and risk assessment measurement of the received/gathered safety signals will be supporting clinical trials.

Biography

Mohammed Majrashi has more than 12 years of experience in medical devices regulations and healthcare technologies. He is currently the Project Manager of post-market clinical follow up studies (evaluation and investigation). He has been very active in the area of safety reporting and data analysis. He is an active member in many organizations and committees, among which are the Asian Harmonization Working Party (AHWP), the International Organization for Standardization (ISO), Cardiothoracic Surgeons and Artificial Organs. He has completed his BSc in Medical Instruments Technology, minor in Instrumentation from the King Saud University, 2005; Graduate Diploma in regulatory affairs from the Academy of Applied Pharmaceutical Science, Toronto, Canada, 2006; MSc in Bioengineering, minor in Biomaterials from the University of Strathclyde, Glasgow, United Kingdom, 2008 and; PhD in Biomedical Engineering, in the field of diagnostics in cardiovascular surgery from the University of Strathclyde, Glasgow, 2016. His research interests include: point of care medical diagnostic and therapeutic devices; biosensors and wireless applications in the medical field; 3D printing applications in the medical engineering; medical devices regulation and; medical devices post-market clinical studies.

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