Journal of Material Sciences & Engineering
ISSN 2169-0022
2020
Vol.09 No.6

Development of New Medical Technologies: from Biomaterials to Medical Device — The Regulatory Considerations and Compliance.

Gabriel O Adusei

Triune Technologies Ltd, UK

Abstract

The new medical technologies are transforming the delivery and management of health care. The investment and interest in research, design and development of new medical technologies are growing and making their way into the healthcare systems at a faster rate than ever. Whilst the scientists, engineers and clinicians collaborate in the bringing of new medical technologies to the commercial stage, there are three main factors to ensure their approval, namely quality, efficacy (performance) and safety. These aspects of the technology are subjected to regulatory scrutiny and approval process by Regulatory Agencies or Authorities.

Typical responsibilities of a Regulatory Agency or Authority (e.g. US FDA, UK MHRA, Germany ZLG, Netherlands IGZ, and Ireland HPRA) are protecting the public health by ensuring the quality, safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and the scope may be extended to cover ensuring the safety of food supply, cosmetics, and products. Some agencies are responsible for advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health.

The regulatory approval processes are based on scientific, technical and clinical evidence that the appropriate tests, verifications and validations have been conducted to support the clinical claims as per the approved indication(s) for use with adequate information to ensure the medical device can be used as intended. No biomaterial progresses to be considered as medical device for use without being subjected to some regulatory scrutiny.IMDRF has been working on the harmonisation of regulations at the global level to help facilitate the process of meeting the regulatory requirements and bringing new technologies to the end-users. This promotes Mutual Recognition Agreement (MRA) to allow inspectors to rely upon information from inspections conducted within each other's borders.

Biography:

Dr Gabriel Adusei has nearly 30 years of experience in the medical device industry. In recent years as a medtech Regulatory Affairs and Quality Assurance consultant, he has served a number of medtech companies and has worked with a number of consulting firms developing and delivering many professional short courses for industries and academic institutions. Earlier in his career, he was a Biomaterials Science Researcher and Lecturer at Cardiff University for over 5 years with focused research interest in Dental and Orthopaedic restorative devices. He worked with the BSI and Intertek as a Medical Device Technical Reviewer and Lead Auditor as the Dental and Orthopaedic Expert and a representative at ISO Dental Technical Committee. With active interest in biomaterials science research, he is a research grant reviewer of EPSRC. He has an MSc in Pharmaceutical Science from the University of Greenwich and a PhD in Biomaterials from King's College, London.

Speaker Publications:

https://www.fda.gov/

https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency