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THE DEVELOPMENT OF PRODUCTS IN A HIGHLY REGULATED ENVIRONMENT: THE AEROSPACE VERSUS MEDICAL DEVICE INDUSTRIES

Abstract

The aerospace and medical device industries are highly-regulated whereas safety, quality and reliability play an important role in the development of products. The National Aeronautics and Space Administration (NASA) is a leader in technology innovations developed for aerospace applications with a promising history of successful technology transfer to the medical device industry. Examples of medical device developments where NASA has been involved include: an IntraVenous Fluid Generation (IVGEN) water filter system to help sick astronauts in space, and devices to treat balance disorders for astronauts returning from space. Further, NASA's efforts include creating partnerships with the medical device industry for the development of technologies that would contribute with NASA's missions and lead to the creation of new medical devices.

Motivated by the current collaborations between the aerospace and medical device industries, this paper compares both industries in terms of the development process and regulatory compliance requirements. The literature to date has only reported one study with a comparison between these industries; with a study that looked at the reliability of medical devices though a comparison with the aerospace industry, and defined some of the factors impacting the product reliability. To attend this gap, this paper advances the existing literature with a comparison of the development considerations for both industries. The results include a comparison on important issues such as: 1) the application of Design for X (DfX) methods to facilitate the development, 2) the importance of human factors, and 3) and the compliance with government regulations. For instance, in the Unites States both industries have to comply with different parts of the Code of Federal Regulations (CFR). Medical devices are regulated by the CFR Title 21 Food and Drugs, and aerospace products regulations include the CFR Title 14 Aeronautics and Space, CFR Title 32 National Defense and CFR Title 49 Transportation. Overall, this study is intended to enhance the collaborations between the aerospace and medical device industries and to identify tools that would benefit the development of highly-regulated products in general.