



## An Indispensible Role of Regulatory Affairs

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**ABSTRACT:** The massive growth in the global medical needs has led to the expansion of healthcare industry. Regulatory affairs scientifically directs the industry in making safe and effective healthcare products that are available in a wide range including pharmaceuticals, medical devices, in vitro diagnostics, biologics & biotechnology, nutritional products, cosmetics and veterinary products. Amongst the healthcare products mentioned above, in-vitro diagnostic tests help in personalizing medicine based on the test results as they aid in the type of medication & dose required for the treatment of the detected illness. Because of such uses, lot of research advancements & innovation is taking place in the IVD sector, for example the development of continuous glucose monitoring system based on sensing technology and the development blood screening techniques against dreadful viruses like Zika. Regulatory affairs acts as a “glue” between regulatory principles and every stage of development (for the new and existing medical products including IVDs). The role of regulatory affairs often begins in the research and development phases, moving into clinical trials and extends through obtaining premarket approvals, manufacturing, labeling & advertising, and post-market surveillance. Along with these, it is also required to keep track of the legislations in all the regions in which a company wishes to distribute its products and stay current with them. The region specific legislations/regulations provide advice on the legal and scientific restraints and requirements, and collect, collate and evaluate scientific data. For the same reason, it can be said that Regulatory affairs and Intellectual Property rights go hand in hand for the development and distribution of all the health care products including IVDs and help in making the vital strategic and technical advancements at the highest level in healthcare companies. Thus, it can be said that, regulatory affairs plays a decisive role in making safe, effective and good quality health care products. In this paper, the specific role of regulatory affairs with respect to in-vitro diagnostic devices will be discussed along with the impact of global regulations in the IVD distribution. © 2016 iGlobal Research and Publishing Foundation. All rights reserved.

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