Biol Med 2018, Volume 10
DOI: 10.4172/0974-8369-C1-006

Medical device single audit program and European medical device regulation: A tighten approach to control the health industry-benefits and disadvantages: Critical review

Ramiro Fabian Casas
Huasi Biomedical, Argentina

The medical device industry is facing a new challenge regarding regulations since the Medical Device Single Audit Program (MDSAP) and Medical Devices Regulation (MDR) have been launched into the big economic players. These new approaches tighten manufacturers, importers and distributors in order to have more documented information about their processes and devices released for consumption. The rationale of this huge modification comes from fraudulent products produced by the biggest companies and put into the market around 2012 that derive into world-wide scandals. However, this approach creates higher burden to small and medium size companies (SME's) which produce around 80% of innovation while having outstanding technical and clinical performance in the medical sector. The estimated economic investment increase of more than 400% for SME's compliance to new regulations, represent for them an over-effort without necessary bringing added value to their qualified processes or products. In contrast, more prescriptive requirements do not cause larger effects over big companies, mainly due that their administrative or IT processes have them already implemented. Changes in regulations that have the most impact on prescription and do not add new processes to implement and neither offer a specific market oversight based on production volume and number of incidents, do not guarantee new safety measures to avoid further fraudulent actions as it has happened in the recent past. Instead, these changes also induce the market to harden access for SME's, the only producers who have a historical record of outstanding performance and who indeed introduce the biggest innovation to the industry.

huasi.biomedical@gmail.com