Role of Good Manufacturing Practices Compliance in Pharmaceutical Industry

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ABSTRACT
Pharmaceutical products are prepared to be used for treatment and improving the health status so they must meet the quality and safety standards. For pharmaceuticals key to produce quality products is to follow Good Manufacturing Practices (GMP) governed by ICH and other stringent drug regulatory authorities. In this research study we assessed the role of GMP compliance on quality of pharmaceutical products. Top 25 pharmaceutical companies as per IMS ranking of quarter I 2015 are selected being the representative of whole pharmaceutical industry. The sample size is 200 and 100 responses were collected each from the national and multinational companies. Employees having work experience of 3yrs or more and designated as executive or above, working in technical function departments like quality control and assurance, production, research & development, technical services, GMP, regulatory, compliance and other relevant departments were made part of this research. Duration of study is 4 months & data is collected by self-designed and self-administered questionnaire. Analysis is done on SPSS 20 and revealed that there is no significant difference in GMP understanding i-e national companies have 97% high and 3% moderate, while multinational companies have 100% high. However, there is significant difference in GMP performance levels i-e national companies have 36% high, 61% moderate & 3% low, while multinational companies have 88% high and 12% low. Results conclude that there is role of GMP compliance on the quality of pharmaceutical products and national companies needs to follow GMP parameters to improve their GMP performance level.

Keywords: Good Manufacturing practices (GMP), compliance, pharmaceuticals, International Marketing services (IMS), quality.