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JAPAN REGULATORY REQUIREMENTS FOR VARIATION PROCEDURES AND GMP INSPECTION

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ABSTRACT

The Japanese pharmaceutical market in the year 2009 is the second largest individual market commanding annual sales of approximately 7.16 trillion yen (71.6 billion US $) constitutes approximately 11% of the world market. It is forecasted that market increases to 79 billion US$ within the five years and nearly double to 105 billion US $ by 2023. Due to its commercial size, Japan is the one major market that all pharmaceutical companies are keen to increase their share in. The laws and regulations governing the pharmaceutical industry were adopted to protect the consuming public by attempting to provide the drugs of consistent quality, purity and efficacy. The legal process of regulation and legislation of variations to approved products and GMP inspection requirements changes from country to country. GMP and good quality practices (GQP) are crucial regulations for assuring the quality, efficacy and safety of pharmaceutical products. It is always necessary, whenever the changes are done to the already approved products then the concerned regulatory agency of the nation should be informed in order to prevent ill effects which may arise when they are directly introduced into the market[1]. Historically, the Japanese pharmaceutical market has been one of the less penetrable foreign companies. The study describes classification of variations, requirements for each type of variation, fee requirements, time period for approval of variations. It also describes about classification of GMP inspections, fee requirements, the requirements needed by PMDA for domestic and foreign manufactures for GMP compliance inspection, the foreign manufactures accreditation process by PMDA. An attempt was made to study the limitations of present regulations and suggest measures to overcome the regulations.