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Comparison of guidelines of Indian GMP with WHO GMP

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Good Manufacturing Practice is a set of principles and procedures for ensuring that pharmaceutical products are consistently produced under controlled conditions to achieve quality standards appropriate to their intended use. India and many countries have formulated guidelines corresponding to their legislative requirements which are governed by regulatory bodies. World Health Organization Good Manufacturing Practices certification is a necessary condition to participate in the international commerce for market authorization. A comparison of guidelines of Indian Good Manufacturing Practices with World Health Organization Good Manufacturing Practices for pharmaceutical products was done. In India, under the Drugs and Cosmetics Act, 1940 and Rules 1945, there under prescribes Good Manufacturing Practices under Schedule M and they are to be interpreted with many other conditions laid down under various rules. An elaborate explanation on Schedule M was given which are relevant in the Indian context. Schedule M covers all aspects of production from the raw materials, premises and equipment to the training and personal hygiene of staff. Quality is to be built into each batch of product during all stages of the manufacturing process. Every time a product is made there must be a written procedure and documented proof is essential for each process that could affect the quality of the finished product. On comparison of regulations of Indian Good Manufacturing Practices under the Schedule M and World Health Organization Good Manufacturing Practices it was noticed that Indian Good Manufacturing Practices is found to be more stringent than the World Health Organization Good Manufacturing Practices Guidelines. Compliance and updating of Indian Good Manufacturing Practices will encourage in boosting exports of Indian pharmaceutical Industry by keeping the spirit of 'Make in India'.

Biography

Uma Vasireddy has completed her MPharm from UCPS, Kakatiya University campus and PhD from JNTU Hyderabad in Pharmaceutical Sciences. She is the Principal of Kakatiya Institute of Pharmaceutical Sciences, Kakatiya University and also Honorary Coordinator for Pharmaceuticals Export Promotion Council of India (PHARMEXCIL). She has 30 years of experience in Manufacturing, Clinical Research and also grew to the heights of Vice President in the Abdul Kalam Raju Heart Stent Manufacturing Division. The highest position held was Dean in Academia and closely associated with several academic institutions as a guide for student research projects. She presented and attended several national and international conferences. One of her scholastic achievements as a Professor of an academic institute is setting up of an Industry Institution Innovation (III) Cell, under, DST, Government of India. To her credit, she has more than 50 publications in reputed national and international journals.

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