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Regulatory perspective of transdermal drug delivery systems

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The Regulatory Affairs is a part of the Food and Drug Administration (FDA) that enforces the laws governing biologic, drugs, medical devices, etc. which may have potential side effects for the consumers. Transdermal delivery is used to administer drugs via the skin, for systemic or local use. Transdermal drug delivery represents a promising alternative to oral, intravascular and subcutaneous routes. The first US transdermal drug delivery system (TDDS) was approved by the FDA more than 30 years ago. Despite this length of time and the advancement of science in many other pharmaceutical fields, little has changed or evolved in the development and control of these products. Over the years, various product quality problems have been reported by patients and practitioners. Some of these quality problems have a safety and efficacy implications that have led to the recall of numerous batches of products and, in some cases, the temporary or permanent removal of the product from the market. Regulatory agencies worldwide is constantly raising the bar with more stringent interpretation of existing and new regulations with government increasing focus and attention towards patient safety and costs of health care. The worldwide transdermal delivery market is growing at about $2 billion per year. The yearly U.S. market for transdermal patches is projected to exceed $3-plus billion. Industry analysts predict that the transdermal delivery market will rise from $21.5 billion during 2010 to $31.5 billion in 2015. The present review focuses on different approved polymers, Chronological Events in Transdermal Drug Delivery System and FDA Approvals and more importance is given to Regulatory Requirements for TDDS in U.S U.K, Japan and Asian countries.

Biography

C. Kishore completed Bachelors in Pharmacy from Sri Venkateshwara College of Pharmacy affiliated to Osmania University , Hyderabad and now pursuing a Masters in Pharmacy (second semester) from Department of Pharmaceutics, G. Pulla Reddy college of Pharmacy.

ERP- A tool for uninterrupted supplies in pharmaceutical supply chain

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ERP (Enterprise Resource Planning) links all areas of a company including order management, manufacturing, human resources, financial systems, and distribution with external suppliers and customers with a tightly integrated system with shared data and visibility.

The ERP and Supply Chain Management (SCM) are rapidly growing in the various industries. There is however, a growing need for the incorporation of the applied planning in the business which seems to be an inevitable part of this sector. This technology helps to establish a chain of suppliers/producers, and customers; the management chain can coordinate and facilitate the relations between the suppliers and customers through the information sharing program along this chain through which the efficiency and effectiveness of the organization can be increased considerably.

ERP system in pharmaceutical companies helps to

1. Source the raw material/packaging material
2. Manage the inventory
3. Maintain the database of approved vendor
4. Continuing of supply with prior planning.

Thus, we need to understand it and use the specific advantages of this technological phenomenon in the management of the modern companies.

Biography

Dunnuthala Krishna Veni is a student of JSS College of Pharmacy, JSS University, Mysore, Karnataka, India. She has completed her B.Pharm from P. RamiReddy College of Pharmacy, kadapa, Andhra Pradesh during year 2012. Presently she is pursuing M. Pharm in Pharmaceutical Quality Assurance in JSS College of Pharmacy, Mysore. She has attended various National and International Conferences. Her current areas of interest are Quality Assurance, Regulatory Affairs, Quality Management Systems, GMP Auditing and analytical method development.

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