Nirma Univ J Pharm Sci; 2019, 6(2) 1-2

ISSN 2348 –4012

ARTICLE

PARADIGM SHIFT IN PHARMACEUTICAL BUSINESS WITH RESPECT TO IMPORTANCE OF PHARMACEUTICAL DEVELOPMENT

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The pharmaceutical industry is the technology sector with the highest added-value to the industry. According to the 2018, EU/US Industrial R&D Investment Score board, the pharmaceutical and biotechnology sector amounts to 18.9 % of total business R & D expenditure worldwide. The average spending level on new products launched in 2019-2023 is expected to reach to $45.8 billion, slightly greater that the $43.4 billion observed for products launched in 2014-2018. Now a days pharmaceutical industries are developing molecules especially in the specialty segment like, orphan, biologics and oncology areas, thus confirming the trend towards an increasing role of precision medicine where a new treatment is supposed to reach fewer patients. Huge amount of efforts are also going for development of generic products by various companies. The need of common technical documents for market authorisation is also increasing even in developing markets. All these is leading to increased requirements of usage of knowledge in pharmaceutical operations.

Developing a pharmaceutical product had always been a challenge for the pharmacists, when it comes to approval from the various countries in International markets. It was always a challenge in the previous years as the documentation requirements for marketing authorisation (product registration) were largely varying (diversified) as per the individual country's requirement, not only in regulated market but also semi regulated and emerging markets.

Due to the lack of uniformity amongst the countries in framing the registration documents requirements, the task of Regulatory Pharmacist, always remains challenging. With lot of efforts by International organisations like WHO, ICH and ISO which lead to the need of

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common technical documents (CTD). Globally, most of the countries started implementing uniform platform as CTD, which forced the pharmaceutical manufacturers to implement good documentation practises, to survive in the competitive market.

For the development of finished formulation, QbD (Quality by Design) approach lays more emphasis on continuous improvement rather than end-product testing. The principles of Quality by Design have been adopted by majority of pharma industry. QbD makes certain that the product is of predictable and predefined quality. The adoption of QbD includes defining a target product quality profile; designing the manufacturing process from basic principles with a very good understanding of the mechanism involved (good Design of Experiment); identifying critical quality areas, process parameters and potential sources of variability; and finally controlling manufacturing process to achieve the most consistent quality.

QbD will become a regulatory requirement for filing dossier to international regulatory. Hence many pharma companies have now started engaging with QbD, with numerous projects now underway. Adopting QbD will increase costs and development but this would be offset by more successful launches, less loss in production, fewer deviations, and fewer recalls – so there should be an overall net gain. It applies the concept of 'First Time Right' from the manufacturing industry to the pharma.

The CTD dossier necessarily is asking for complete information about the product with respect to Product Development Report, Analytical Development Report, Complete Pharmacokinetics, efficacy and safety of the product. All these information means a lots of development work to be done by manufacturer.

Product Development can give manufacturers much more confidence in the robustness of their product, potentially increases the efficiency and quality of their development and manufacturing process as well as reduces profit leakages.

*(Source of data: EFPIA member associations (official figures))