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### Ageing pharmaceutical assets: Regulatory strategies

Drug delivery systems with novel characteristics and patentable features have been developed for molecules nearing patent expiry. The primary objectives are to have enhanced therapy management and provide competitive edge in marketplace. Patented platform technologies have given rise to multiple product ranges for different molecules. Product repositioning strategy is an integral part of R&D and business development with efforts directed in sustaining the drug's market value. Advanced drug delivery systems not only bolster the commercial value but it also serves as a tool to improve the pharmaco economics by increasing the safety, efficacy, compliance, reducing the side effects and superior patient convenience. One of the paramount concerns is to navigate through the regulatory necessities. Specific supplementary studies may be required to prove the safety and efficacy of the newly developed pharmaceutical system depending on the quality target product profile. The regulatory pathway with regards to the product being developed should be an integral part of the product development plan and should be appraised at the commencement of product development activity.

#### Biography

He earned his Ph.D. from University of Mumbai (India) and Post-doctorate from Kyoto Pharmaceutical University (Japan). He has published and presented several original research papers, articles and abstracts in peer reviewed journals and conferences. He has conceptualized innovative drug delivery platform technologies and is an inventor in number of patents. He is an invited speaker at international scientific meetings and conferences. He serves as reviewer for more than 30 scientific international journals and is on Editorial/Advisory board of various journals.

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