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New Drug Delivery System: Regulations and Patent Registrations

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Discovering a New Chemical Entity (NCE) and developing a New Drug Delivery System (NDDS) is perhaps the most pressing challenge for a pharmaceutical scientist today. Drug companies are targeting diseases that have unmet need and are developing delivery systems to capitalize on their patents and to increase their portfolios.

The drug approval process is based on the evidence of safety and efficacy of the drug product. The regulatory requirements for NDDS depends on several factors, whether it is a NCE in NDDS or an approved drug in a NDDS. Very often, NDDS is developed to capitalize on patent expiry and to extend the life cycle of an approved drug, for e.g., introduction of Extended Release product after Immediate Release dosage form and introduction of Transdermal Drug Delivery System (TDS) of an approved marketed dosage forms. Reformulation is perhaps the most common strategy for pioneer pharmaceutical industry to extend the life cycle and increase the revenue. Adding value to the original product thru new formulations has the highest return on investment. Another avenue of extending the patent life includes 'new indications for the old drug'.

Regulatory requirements of NDDS of an approved drug are simpler because safety and efficacy of the drug is already established. However, it may require specific safety related studies for specific NDDS, for e.g., local irritation and patch adhesive test studies are needed for TDS. Efficacy studies are commonly based on comparative pharmacokinetic study profile or exposure-response comparison. Studies for drug approval often needs to be customized and are largely based on the critical nature of the drug, medical and biopharmaceutical rationale and experience with the drug and/or drug delivery system.

In today's world of emerging technologies for drug delivery system, the regulatory requirements are very complex. A scientific challenge lies ahead to improve drug delivery and dosing rates. Quality control and drug release specifications are dependent upon the drug delivery system. Regulations and patent registration requirements will be illustrated with examples in the presentations.