

From the Patron's Desk

Drug delivery devices - the next frontier of innovation



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Drug Delivery systems have evolved over a period of time. However the recent breakthroughs in the portable and affordable computing in the past decade has opened a new and exciting frontier in drug delivery leveraging on the capabilities of IT and medical devices industries. The earlier "conventional" models of drug delivery are getting revamped. The conventional novel drug delivery systems based on excipients, solubilization or nano-sizing techniques are having limited applications when therapeutic goals and patient compliance are concerned.

In a brave new scheme of things – the current drug delivery devices have bridged the gap between the "drug and the device" and have multifunction capabilities not only to deliver but also to monitor. A long list of drug delivery devices, many of them having smart monitoring and delivery capabilities have emerged, and a non exhaustive list is as follows: programmable drug delivery pump, peritoneal dialysis systems, ocular inserts, disinfectants for medical devices, hormonal and spermicidal preparations, drug eluting stents, catheters loaded with anticoagulant drugs, bone cements with antibiotic, dry powder inhaler, metered dose inhaler, syringes, pre-filled syringes, i.v. administration bags, nebulizers etc.

The advantage of these devices is the ability of the device to target the drug *in situ* and the sophisticated control they have over the delivery of drugs. The bigger advantage these is the patient compliance. Breakthrough innovations in programmable drug delivery pumps, self injecting systems, coupled with real time continuous monitoring (thanks to the advances in biosensing applications) have given us the capabilities to give just the right amount of drug in the right time. This has in fact increased the TDM capabilities for treating immuno-compromised or patient populations with diminished renal or hepatic functions. Another breakthrough these devices have provided is the ability to administer. Many pharma majors are developing devices that would enable the delivery of more viscous drug products; large molecules and higher dose concentrations are often more difficult and painful to inject through manual delivery methods. In addition to benefiting the patient, drug delivery systems can also be beneficial to manufacturers. The development of a drug delivery device can help extend the patent protection on a drug in the manner of the innovation of their administration.

The consensus on how to regulate this new class of products is on the emergence. Since the description of these products might be a instrument, apparatus, appliance, device with or without the combination of software to run the system. Because of the differences in the manner pharmaceutical and medical device products are regulated a new consensus is emerging from pre-eminent regulators like USFDA to regulate these "combination products". Because QA, QC and regulations work very differently across the

pharmaceutical and medical device industries, companies that are considering developing a drug delivery device incorporate necessary research and development early in the planning process to help mitigate problems that could arise later in the production process.

These synergies across pharmaceutical, medical device and IT industries have opened up a new frontier of innovation in effective drug delivery and compliance.