Connected ecosystems for drug delivery
The healthcare market has been undergoing significant change in the last few years as the cost burden weighs heavily on some of the world’s largest economies.

**Market drivers**

A perfect storm is brewing as an increasingly competitive industry looks for ways to improve health outcomes and technology reaches a level of maturity that makes it both accessible and affordable for previously unavailable applications. Within the pharmaceutical sector, there have been concerns about the spiralling costs of new drugs, especially with the difficulty in getting reimbursement levels commensurate with the high costs of discovering and bringing new chemical/biological entities to market. Pharma companies therefore need to develop approaches that reduce the overall cost of drug development and also find ways of enhancing or prolonging the value of existing products. This can often be achieved via differentiated delivery devices.

As the focus shifts from incident-based treatment and care delivery to continuous disease management, the interest in patient engagement is growing. Tools made possible by wireless medical devices could be a potential route to reducing the high levels of non-adherence seen for many therapeutics. Moreover, preventive care is taking centre stage, making way for solutions that keep people healthier and out of hospitals.

At the same time, communications technology such as short-range wireless (eg Bluetooth) is being widely adopted, with chipsets reaching an acceptable price point as a result of their incorporation in high-volume consumer electronic goods such as smartphones and tablets. Speaking of which, these powerful and user-friendly computing platforms are gaining popularity in healthcare settings, with almost 80% of doctors in the US using some type of mobile device in the professional setting. This provides a fantastic opportunity to the medical device and pharmaceutical industries as they can leverage these readily available platforms to reach their customer base and deploy interesting solutions.

**The opportunity**

While the medication adherence problem continues to loom large, it can now be tackled quite well via smart deployment of wireless technology. Adding electronics to drug delivery devices can open a suite of possibilities. Small sensors can track device activation and usage. This information can be relayed to the outside world via wireless technology embedded within the device itself. The data can provide great insight into usage patterns.
and enable a large number of services, ranging from reminder systems to rewards. It can bring caregivers and clinicians into the loop with patients and allow for active management of disease via regular monitoring. Titration of dosing can be achieved if actual drug intake is correlated to benefits or side effects. In addition, wider correlations can be drawn via deployment of other sensors in the patient’s environment to track things such as activity, sleep, breathing, vital signs etc. Moreover, smarter devices with additional functionality such as usage guidance can be developed once an initial electronic platform is available. Such devices can provide a competitive edge and help with lifecycle management in a market where expiring drug patents and reimbursement challenges for new drugs are becoming a cause for concern.

Clinical trials could be viewed as an easier first step when embracing electronic systems in drug delivery devices, allowing them to be tested in a controlled environment in smaller volumes. Data from these ‘connected devices’ can be immensely valuable for the trials themselves, to confirm appropriate protocol is being followed and to correlate efficacy (or lack thereof) with actual usage of the medication.

The path to success

Before embarking on a connected ecosystem development, a market strategy and business model must be determined. The particular disease condition(s) to be served, competition in the space as well as the individual company’s appetite for risk will determine whether the connected system is launched as a new revenue-generating offer or whether the add-ons serve as an indirect revenue source. Reimbursement for a connected health solution will only be obtained if improved outcomes can be demonstrated. Some modalities are starting to see reimbursement for disease management solutions, while others are still in early stages. However, this new technology can be a source of indirect benefit to pharma companies by improving brand recognition and increasing market share.

Incorporating electronics in simple needle and syringe based systems is not commercially viable, but specialised devices such as auto-injectors and infusion systems lend themselves well to such functionality, particularly given that these devices are generally used for self-administration away from direct supervision of a healthcare provider. Moreover, some applications and drugs might be able to better cope with the cost increase than others.

Important differences in the development of devices with electronics and software in them as compared with those without must be acknowledged before embarking on such a project. The electronics architecture, as well as partitioning of functionality between electronics and software, drives key device performance such as its power consumption. Furthermore, the choice of architecture can also substantially affect the effort required for design verification. Choosing the appropriate wireless technology is critical and must be done with the overall use scenarios in mind. For example, devices which need to communicate over a relatively short range could use cheaper, lower power technology such as NFC, whereas others that must communicate over a longer distance need different technology like Bluetooth. The choice of battery is dictated by the wireless technology as well as the use scenarios, and thought must be given to replaceable versus rechargeable batteries. Regulatory requirements dictate the development process for the software and the criticality of the device function will dictate the level of concern associated with the software and therefore the
level of testing that must be undertaken. Finally, careful consideration must be given to partitioning functionality between the device and the receiver, which in many cases is likely to be an off-the-shelf device such as the smartphone. Proper allocation of key functionality, as well as maintaining independence between drug delivery capability of the device and its auxiliary functions such as dose tracking, will enable a smoother path through regulatory approvals. It is likely that a smartphone app will be launched as part of a connected device solution. In this case, attention must be paid to the features incorporated in the app and their intended use – to determine if it will be treated as a mobile medical app by the regulatory bodies. If so, it will need to be developed using a compliant development process and undergo the same level of test and documentation as any medical device software.

Last but not least, some thought is also required to the data that will be collected and the purpose it is likely to serve. That will guide decisions regarding infrastructure for data hosting (in-house vs. outsourced to external parties) as well as ownership and sharing.

Conclusion

In summary, tomorrow’s healthcare market will be different, one that demands tangible outcome improvement and higher engagement from consumers (patients). Electronics platforms in drug delivery devices could serve as an avenue to a larger portfolio of services that enable pharmaceutical and device companies to increase their brand loyalty, and generate recurring revenue from adjacent offerings. Moreover, if the pharmaceutical industry is forced to accept payment for outcomes, then connected health technology may well provide the means to demonstrate and prove improved outcomes. While this may seem like a significant jump into unknown territory, a smart strategy and sound technical approach can help minimise risk and deliver a platform for future growth.
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