Developing A Generic Drug Product In A Novel Drug Delivery System – From Selection To Launch

The Challenge
Having overcome the hurdles associated with drug development, Accord Healthcare, a generic drug manufacturer, was looking for a device to be used in combination with their generic methotrexate prefilled syringe for the treatment of active rheumatoid arthritis in adults, among other indications. Accord felt that mimicking the innovator device would not differentiate them sufficiently in a competitive marketplace, and there was an advantage to be gained by picking a device that enabled a superior and unique patient experience, which is their company ethos. The challenge was to find a device that gave the drug an edge over its competition while also enabling a fast move to market, without a requirement to have an internal device team to manage the project. In a culture where generic drugs often copy the innovator device, this shift put even more emphasis on making the right device decision.

Considerations
Accord needed to assess and select a device that would become a critical part of their drug delivery program. More than that, they needed to select the right partner to ensure success. The assessment of a device and its vendor became a multi-faceted decision-making process; not only assessing the functional aspects of devices available, but also seeking a vendor who would become a trusted partner. Having a partner, rather than a vendor, who was equally invested in bringing the combination product to market was of pivotal importance to the program.

The Solution
In May, Accord became the first company to commercialize an injectable drug product in West’s novel SelfDose® patient-controlled injector. West provided a technical package to support the EU regulatory submission and sent a team to India to support final assembly of the injector. West supplied valuable human factors data, which saved Accord both time and money. Accord felt strongly that the SelfDose patient-controlled injector would significantly improve the patient experience, and that working with West enabled a successful move to market.

About Accord Healthcare
Headquartered in the United Kingdom (UK), Accord Healthcare Europe is the fastest growing generic pharmaceutical companies in Europe. Accord has an extensive supply chain through its four UK based sites, helping to ensure a consistent supply of life-enhancing medicines for patients, whilst supporting customers to react quickly to dynamic market conditions.