Injectable delivery devices - Requirements and challenges for the functionality testing

Vetter is a global leading contract development and manufacturing organization (CDMO) in the aseptic filling of syringes, cartridges and vials and in packaging of drug delivery systems, e.g. safety devices, pens and autoinjectors. Before the prefilled syringes or injectable devices are used on patient, they must go through rigorous quality control testing. ISO 11040 is a testing standard that addresses the design and functional properties of prefilled syringes and is critical for ensuring that syringes work properly in a clinical setting or in combination with a delivery device. The requirements for needle-based injection systems are defined in the ISO 11608 standard to guarantee all the functionalities of the combination product for the parenteral administration and to reduce the likelihood of improper function. Carrying out these tests requires a clear understanding of the testing requirements listed in the ISO standards and the individual customer specific needs. The functionality tests must be implemented and qualified in accordance to GMP standards. The tests are usually destructive tests and there is a fine balancing act required in determining the minimum number of test samples and acceptable levels of quality and risk.