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## High precision syringe labeling

Thermo Fisher Scientific develops innovative approach to enable high precision labeling of pre-filled syringes

### Innovative syringe labeling capabilities for comparator blinding

A large pharmaceutical company was planning to conduct an infectious disease trial for the treatment of Hepatitis C. The global trial would cover over 40 countries and require the labeling and distribution of more than 250,000 pre-filled syringes over the course of the study. The investigational drug product had to be maintained at a temperature of 2 to 8° Celsius, with a maximum time out of environment (TOE) of 6.5 hours. Only one comparator drug was suitable for use in the study. The comparator product came in a single use pre-filled syringe, with a ½ inch needle and a needle-stick protection device (NSD). The comparator syringe could accommodate 180-mcg, 135 mcg, 90 mcg and 45 mcg dosing regimens.

**The sponsor faced two significant hurdles in executing its trial:**

- The comparator had to be blinded using a label that met the exact dosage specifications of the branded product.
- The sponsor company had to match its own investigational product packaging and labeling to the comparator. This required not only same size syringes but also labels that contained similarly precise dosing regimens for patients.

The sponsor however, could find no supplier in the market that could meet the level of labeling precision required to blind the comparator or to similarly label its investigational product.

The sponsor had experience with Thermo Fisher in the past and approached Thermo Fisher project management team to discuss possible solutions to the hurdles it was facing. The Thermo Fisher team felt that they could develop an innovative approach that would meet the specified level of labeling precision the trial required. To do so, Thermo Fisher assembled a global team representing its engineering expertise from the United States, United Kingdom and Switzerland, to convene and develop a solution. This team was able to engineer high-precision labeling equipment and labels that could be used to meet the exacting dosage requirements of this, and future trials, where labels require precision dosing graduation.

The High-Precision labeling capability was designed to include vision system verification of label position. To ensure precision labeling, the equipment had to be programmed for the exact dimensions of the pre-filled syringe as well as the label. In coordination with packaging engineers and the sponsor team, a label was designed that would achieve the best possible blinding against the comparator product and could be placed on the pre-filled syringe within a detectable tolerance level of +/-0.7mm.

Together with the sponsor, the team developed acceptable precision standards and conducted extensive testing where extractable volumes were compared to the measured distance on the label, to ensure the level of precision was met. The complete system was ultimately qualified according to the co-developed precision standards.

Since 2011, 19 production runs have been executed and more than 50,000 syringes have been successfully shipped to over 40 countries. Thermo Fisher global team of engineers was able to develop a first-in-industry capability that is now available to all sponsors requiring varying level of precision dosing graduation on labels.