Innovating Labeling Process for Animal Health TAS Study

A top ten animal health company whose products target and treat some of the most harmful animal diseases. This client develops health products across the board from companion animal to food animal treatments and drug therapies. Singota Solutions has been working with this client for over four years in service areas that include supply chain, production, development, and analytical testing.

Problem

The client submitted one of its products with promising data to the CVM for approval to begin Target Animal Safety (TAS) studies within the European Union. The product is administered using a syringe, where one syringe equals 1x the dose concentration. To achieve higher dose strengths for the study such as 2x and 3x, the client planned to use multiple syringes (i.e. 2x strength would be 2 syringes for the target animal). However, the CVM requested that another dose strength be administered, 2.5x, as an additional data point in the safety study. The TAS study was already scheduled and the target animals had been purchased and prepared for the study to start, in which the timing was critical. The client had limited options in order to come up with the additional data. They could either reformulate and manufacture the product so that they could have a syringe with 0.5x strength (costing them several thousands of dollars and setting them back for their study timeline) or come up with a creative solution to develop a 2.5x strength dose, keeping the end-user in mind and not compromising the integrity of the study. Additionally, they needed the syringes of each dose strength to be labeled, kitted, and delivered to the international site on time.

Solution

The client and Singota worked together to come up with a creative and cost-effective solution. Through open communication and idea-sharing, it was determined that the 0.5 point could be found on the syringe and marked so that the syringe could be expelled to the 0.5 point at the study site by the administrator. This made the most sense for maintaining sterility, economical reasons, and keeping the end-user in mind. Singota designed and manufactured a fixture to use during the labeling execution that would guide the placement of a 0.5 mark for the syringe. The client and Singota worked together to write a protocol and calculate upper and lower limits of tolerance for the 0.5 mark. These limits were then shown on the fixture so that the mark could be made accurately and quickly by those performing the labeling activities. The execution had to be efficient to meet a tight timeline and ensure international delivery to the site.

Impact

The syringes were labeled and delivered to the study site on time and with a protocol that each party was satisfied with. The project was executed in one month from the point of initial conversation, meeting the tight timeline. Ultimately, through a good partner relationship between Singota and the client and creative thinking on both ends, they were able to save thousands of dollars, meet a tough timeline, and not compromise their TAS study or the eventual approval of their product for commercial use.