Dechra acquired Putney in order to add new products and critical mass to its US business and a highly performing product development management system and process. One of the key projects in the Putney development process was a generic to an antibiotic consisting of amoxicillin and clavulanate potassium, which is one of the most commonly used antibiotics in small animal medicine. Clavamox tablets for dogs and cats were originally approved in the USA in 1984 and, despite patent protection and regulatory marketing exclusivity having lapsed several years previously, the high scientific and regulatory approval hurdles for a generic of this product in the USA had prevented any alternatives from being approved. This meant that the original product continued to be sold at high prices, however, it still commanded a significant market due to its high efficacy.

Bringing a generic product to market requires formulation and manufacturing to the highest quality copy of the original product and demonstrating that the new product will work in the patient in exactly the same way as the original by showing bioequivalence. The development of this particular generic product required the need to overcome several significant technical challenges. Amoxicillin is a penicillin antibiotic which can only be manufactured in dedicated facilities to avoid cross-contamination with non-penicillin products due to widespread penicillin allergy in people. In addition, clavulanate potassium is extremely sensitive to moisture so even the slightest exposure of the product to moisture will result in the loss of clavulanate potassium activity. There are very few manufacturing facilities that can both handle penicillins and the low humidity manufacturing environment required for this product.

Once a suitable manufacturing partner was identified extreme care had to be taken with the supply of every component that went into the product to ensure that moisture was prevented from coming in contact with the individual ingredients or final product. In addition, a novel manufacturing step was developed to keep the product stable throughout the shelf life.

Another hurdle that the team faced was achieving bioequivalence to the innovator drug. The tight criteria set by FDA are hard to meet even with one molecule in one species but achieving bioequivalence for a combination product in two species was much more difficult and added a lot of complexity and risk to the development program. To make things even harder, the absorption of clavulanate potassium turned out to be extremely variable making it very difficult to achieve bioequivalence.

Following collection of blood samples to measure the absorption of the amoxicillin and clavulanate potassium in bioequivalence studies, the clavulanate potassium continued to be a problem as it was not stable in the samples. Special sample handling and stabilisation methods had to be developed to reliably and consistently measure the amount of the clavulanate potassium in the samples and ensure that degradation did not compromise the study results.

Despite all of this complexity, the Product Development team was successful in overcoming these hurdles to manufacture a high quality product that was successful in bioequivalence studies in both dogs and cats and Dechra was the first company to achieve a generic amoxicillin/clavulanate potassium product approval in the US.

In only nine months since launch, the product has become a phenomenal success capturing significantly more market share than expected. This is a momentous achievement for Dechra.