Developing a Complex, First-of-its-kind Antiparasitic Drug for Dogs

In the evolving field of veterinary medicine, the need for innovative treatments for parasitic infections in pets is more pressing than ever. Parasites such as ticks, roundworms, hookworms, and pinworms are persistent threats to animal health, demanding solutions that are both effective and easy to administer such as oral palatable chewable tablets.

The development of these treatments is a complex, multifaceted challenge that requires not just scientific expertise but also sophisticated manufacturing capabilities. This is where Contract Research and Development Manufacturing Organisations (CRDMOs) play a crucial role, offering a unique blend of research, development, and manufacturing services that can significantly accelerate the delivery of new therapies to the market.

The role of CRDMOs in the pharmaceutical industry, particularly in animal health, is becoming increasingly important as the demand for specialised treatments grows. These organisations offer a strategic advantage by providing end-to-end services, from initial research and development through to large-scale manufacturing. This model allows veterinary pharmaceutical companies to leverage the specialised expertise of CRDMOs, accessing cutting-edge technology and innovative solutions without the need for significant in-house investment.

In the context of anti-parasitic drug development, the challenges are particularly acute. Developing a drug that can effectively target multiple parasites often involves combining several active pharmaceutical ingredients (APIs) into a single formulation. This process requires not only a deep understanding of the pharmacological interactions between these ingredients but also sophisticated techniques to ensure stability, efficacy, and palatability – especially in veterinary medicine, where patient compliance can be difficult to achieve. Moreover, the regulatory landscape for veterinary drugs is becoming increasingly stringent, with higher standards for safety, efficacy, and environmental impact. CRDMOs are well-equipped to navigate this complexity, offering tailored solutions that meet both regulatory requirements and market demands. By partnering with a CRDMO, veterinary pharmaceutical companies can accelerate their development timelines, reduce costs, and mitigate risks, all while maintaining the highest standards of quality.

One company that exemplifies the potential of CRDMOs in this space is Syngene, a leading CRDMO that recently developed an innovative and complex multi-antiparasitic drug formulation for a prominent animal healthcare company.

Syngene partnered with a leading animal health company to deliver a 'first-in-class' complex formulation that could treat a range of parasitic infections in dogs, including ticks, roundworms, hookworms and pinworms. The complexity of this task lay in the need to combine multiple APIs into a single tablet, each with its own chemical properties and stability concerns. In addition, the formulation had to be palatable to ensure that dogs would willingly consume the medication, a critical factor in the treatment's overall effectiveness.

The technical challenges were significant. One of the APIs was highly prone to degradation under acidic conditions, posing a risk to the drug's long-term stability. Syngene's approach involved conducting extensive drug-to-drug and drug-to-excipient compatibility studies, which were crucial in ensuring that the APIs could coexist without compromising the drug's efficacy. These studies included preparing prototypes and subjecting them to stressed stability tests to quickly identify and mitigate potential issues.

Beyond the scientific challenges, the need for a palatable formulation required Syngene to explore various flavour profiles that would appeal to dogs without destabilising the drug. The bitter taste of one component was masked by appropriate polymer selection. This aspect of the project highlights an important trend in veterinary medicine: the shift towards patient (or pet) centricity. By considering the behavioural aspects of animal patients, CRDMOs like Syngene are helping to redefine what successful drug development looks like in the veterinary field.

Syngene also demonstrated its strength in process development and scale-up, ensuring that the final formulation-maintained content uniformity across all tablets, even with one API present in a very low dose. This level of precision is critical in veterinary medicine, where dosage accuracy can directly impact the effectiveness of the treatment. The successful scale-up of the manufacturing process, from development to clinical supply production, was completed in just six months – a testament to Syngene's efficiency and expertise.

As veterinary medicine evolves, the complexity of developing multi-functional, stable and palatable drug formulations is a challenge that not all organisations are equipped to handle. While many CRDMOs can provide standard services, what distinguishes the truly innovative players in this space is their ability to address unique scientific and technical hurdles. In this case, Syngene's deep expertise in managing complex drug formulations – particularly its ability to stabilise multiple APIs and ensure both content uniformity and palatability – demonstrates how sophisticated CRDMOs can play a pivotal role in advancing veterinary care. Rather than simply filling capacity gaps, Syngene brings a

solutions-oriented approach that integrates cutting-edge R&D with scalable manufacturing, ensuring that even the most challenging formulations meet the highest standards of safety and efficacy. This level of innovation and precision is essential in today's veterinary pharmaceutical landscape, where the stakes for timely and effective treatments are higher than ever.

The collaboration between Syngene and its client on this multi-antiparasitic drug formulation highlights how CRDMOs can drive meaningful advancements in veterinary medicine. This project underscores the importance of bringing together scientific expertise, innovation, and agility to overcome complex challenges in drug development. As veterinary health needs evolve, so too must the approach to developing treatments that are not only effective but also accessible and well-tolerated. Syngene's success in creating a complex, multi-drug solution serves as a reminder that strategic partnerships are essential to pushing the boundaries of what's possible in animal healthcare, enabling the industry to deliver next-generation treatments that improve the lives of pets and the people who care for them.

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Alex is the Senior Vice President, Manufacturing Services at Syngene International and has three decades of experience in developing, commercialising and life-cycle management of products in various life science industries. Holding positions in both the US and Europe at Syngene International, his experience includes senior roles with global P&L responsibility. As a member of the Executive Committee, Alex plays a techno-commercial role, providing technical expertise to the API plant at Mangalore while building a sustainable client base for the business in collaboration with the commercial and business development teams. In addition, Alex is also responsible for biologics operation at Syngene International.