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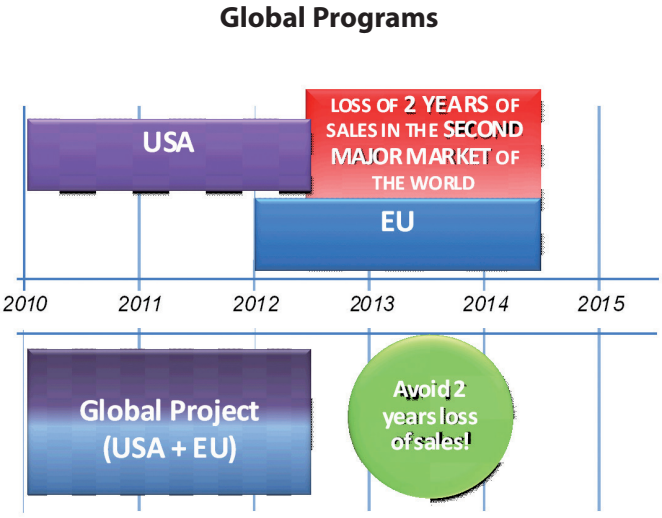
Outsourcing to cut development costs and generate faster sales

Julian Braidwood, managing director of Triveritas

Changes to global animal health industry regulation and the product development capabilities available offer new opportunities for small, medium and large companies in the sector to increase profitability. Using an expert contract partner can maximize these benefits in a cost effective manner, argues Julian Braidwood, managing director of the Triveritas CRO.

Approximately two-thirds (65%) of world animal health revenues are generated in the US and EU markets, with both these major territories following the VICH guidelines. Furthermore, one third of the global sales are from dog and cat products, with 80% of the total coming from just 10 national markets. In short, large commercial opportunities can be concentrated in just a few markets, notes Mr Braidwood.

Historically, companies have tended to develop and, more importantly launch, their products sequentially into major markets, he continues. However, this typically results in a revenue loss of at least two full years of sales.



The main reason for working in one territory first appears to be the avoidance of excessive stress on finite in-house R&D expertise.

Mr Braidwood says that apart from the potential direct loss of sales due to a delayed launch in a territory, development costs can actually be increased through a two phase approach – for example, US followed by EU development. He illustrates this by considering the price of GCPv clinical trials, often the most expensive single part of a product development. For regulatory purposes, each GCPv trial needs to show a clinically relevant and statistically significant result. If it takes say 200 dogs to be recruited for such a result in one trial, then to show the same effect in each of two trials (e.g. an initial one in the US and a later one in Europe) a total of 400 dogs will be needed, with all the associated costs entailed, such as payments to Investigators, laboratory fees, monitoring costs, quality assurance, treatment costs, protocol and report writing.

Therefore, performing a single GCPv trial with patient recruitment being in both the USA and EU simultaneously, will provide substantial savings, he says.

Triveritas is already performing clinical trials that involve internet-based FDA CFR compliant electronic data capture, at sites in both the USA and the EU, advises Mr Braidwood. This not only allows real time updates of global recruitment, but, with careful design and execution, greatly reduces the time spent on data queries and data management. This factor alone can deliver a time saving of up to three months in the case of large studies – assuming the clinical trial is on the critical path, this could enable an earlier launch date with 12 weeks of additional new product sales.

The global programs with the highest return on investment are likely to include those where there is a similar clinical situation in each major regulatory territory, Mr Braidwood continues. He sees clear opportunities in dog and cat development projects, especially in the ectoparasitic, osteo-arthritis, cardiac, renal, cancer, analgesia, anaesthesia, and reproductive areas. At the same time, there can be conditions which are sufficiently similar to allow savings from some product development projects in cattle, pigs, poultry, horses and other species.

The major US and EU markets not only share key VICH regulatory guidelines, but also are actively promoting collaboration of their approaches to new product developments, he states. The Center for Veterinary Medicine in the US and the EU Committee for Medicinal Products for Veterinary Use actively offer Joint Scientific Advice for the development of veterinary medicines and vaccines.

In short, there is a clear opportunity for companies to minimize the potential loss of two years of sales, while reducing product development costs, emphasizes Mr Braidwood. The main barrier to achieving these frequently appears not to be financial, but more often is due to limited and finite in-house R&D and regulatory expertise. "To put it simply, the key in-house R&D and regulatory staff simply cannot do everything at once!" he observes.

Some animal health companies do recognize that their staff cannot manage a global program alone, or even at all where the existing R&D or regulatory workloads outstrip the resources available.

This is where a suitable expert contract partner can help. Choice of contractor is critical, since the partnership is responsible for helping to generate the future life-blood of the company, warns Mr Braidwood. Important selection criteria would ideally include being located in both the major US and EU markets, with expert regulatory and clinical resources in both territories. Having the expertise on both continents under one management ensures excellent compliance, he adds.

Hiring in this additional help as and when it is needed will help businesses maximise both their return on investment and their future profitability.

This new approach is not only limited to multi-nationals, but is also already being embraced by small animal health companies. Small companies realise that a commercial distribution agreement will overcome any infrastructure shortcomings in either USA or EU.

Contract product development expertise and capability has changed, concludes Mr Braidwood. There is a global regulatory structure that is becoming increasingly user-friendly, while new opportunities exist in the form of global developments and partnerships that can both reduce total R&D costs and increase global sales through an earlier product launch. ●