

How Academia Participates with Animal Health Industries: Development

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Academic institutions, especially this nation's land grant universities, colleges of veterinary medicine, and agricultural experiment stations, are particularly suited to doing development research for the animal health industry. Indeed, academic scientists often participate in development of animal health products, but some academic institutions as well as individual scientists may have been reluctant to do this type of research or even actively discouraged it, viewing money accepted for commercial development as somehow "tainted". However, given the marked decline in research funding from government sources of the last few years, academic institutions have become much more receptive to commercial contract research.

Having academic institutions do development research has advantages and disadvantages compared to such research conducted in-house or with outside commercial contract laboratories. This paper will address some of these issues.

Advantages

The advantages of contracting product development with an academic institution are many. They include obvious items such as the opportunity for significant cost savings and access to a broad range of physical resources and scientific expertise. However, there are many important but less concrete advantages such as association of the product with the scientific reputation of the institution and the collaborating faculty member and access to a different set of views on how best to use the product.

Expertise and Facilities

Commercial contract laboratories that do a broad range of animal health research are few in number and are not present in all geographic regions. In contrast, the United States has a massive scientific infrastructure which, in animal agriculture, is centered around its land grant universities and agricultural experiment stations. This, in combination with this nation's many colleges of veterinary medicine, presents an animal health company with a vast smorgasbord of academic facilities and expertise from which it may draw in any geographic region of the United States. In these institutions can be found collaborators with highly specialized skills and facilities, the diversity of which is far beyond the resources of any one company. Types of studies that can be conducted include safety and environmental impact studies, pharmacokinetic and residue depletion studies, dose confirmation and dose titration trials, and clinical trials of efficacy and acceptability, as well as studies now required to support label claims of enhanced productivity through use of the product.

Cost Savings

Since salaries and facilities are subsidized by the institution, particularly at state funded institutions, the contracting company may see a substantial cost savings over in-house work or contracts with a commercial research facility. Even if a percent salary release is built into the contract, salaries of faculty and staff at

academic institutions are often substantially lower than that paid to in-house researchers and top notch private laboratories. Furthermore, institutions that have been less successful in competing for federal grants may be "hungrier" and therefore willing to contract otherwise idle faculty and facilities at less than full reimbursement for indirect costs and salaries.

Reputation of the Institution and its Faculty

The academic institution and its faculty are likely recognized for their high scientific quality. Beyond the actual data generated by the research, this factor may help both with the approval process and with later marketing efforts. In addition there is a perception of independence and lack of bias on the part of the faculty member, because the academic researcher's salary is not dependant upon the contracting company. Thus, that individual usually can be counted upon not to cover up a product's weaknesses. This perception of independence along with the faculty member's many lines of contact with the intended consumers of the animal health product can provide the contracting company with a strong second source for dissemination of information to those consumers.

A Different Perspective

Academics often can provide another view on what will and will not work in the field and what products and/or label claims are needed in terms of formulations, target animals and disease agents. This can be a useful source of fresh ideas that are different from the in-house corporate mentality.

Disadvantages

Unfortunately, working with academic institutions carries some disadvantages. The major disadvantages are bureaucracy, intellectual property rights and patent issues, publication rights, and confidentiality. Less significant but none the less important issues are

prioritization of the research, faculty stability, cost, and record keeping.

Bureaucracy and Timeliness

Large academic institutions are fraught with bureaucracy. As a result, project approvals must pass through many hands and need plenty of lead time. Additionally, gaining a local IACUC approval to conduct research involving animals may be a slow and cumbersome process. In this respect the more nimble private contract laboratories, particularly the smaller and more specialized ones, may be a better choice for research in which a quick result is needed.

Intellectual Property and Patents

Academic institutions have begun aggressively seeking patents for ideas developed in house. Any contracts with these institutions for development research should clearly state to what extent the contracting institution does or does not share intellectual property and patent rights with the animal health company.

Publication Rights and Confidentiality

Most academic institutions are a "publish or perish" environment. Collaborating faculty will expect to publish the results of their research. Furthermore, most will tolerate little of what they perceive as interference with their right to publish or attempts by animal health companies to regulate the content of their publications. Academic research is generally conducted in an open manner with results available to all. In such an environment, confidentiality is often viewed as an anathema. Also, some states, notably Florida, stipulate that all work conducted by state funded institutions is open to the public except for proprietary information specifically excluded by the terms of a research contract. Therefore contracts should clearly state to what degree the work must be kept confidential, what are a faculty member's publication rights, and what are the animal health company's rights of prior review of any publications that may result from the research. Draconian limits on the

discussion or publication of research results without valid reason may result in the faculty member or a higher university official rejecting the contract or demanding additional payment for giving up publication rights. Likewise, for work that is truly of a confidential nature, discussions between the study monitor and the faculty member as to what may and may not be disclosed are strongly advised.

Record Keeping

Nearly all research performed for animal health companies requires that records be kept according to GLP or GCP standards. Many academic researchers are not trained or experienced in GLP or GCP record keeping. The study monitor should clearly explain the record keeping requirements, and any requirement for the use of GLP or GCP standards for record keeping should be stated in the contract.

Commitment and Priority

Often development research is of a mundane and repetitive nature. Given the low opinion much of the academic community has for this type of research, it may not be given a high priority. Collaborators must be chosen with care to ensure that the research will not be delayed if something more interesting comes along. The final report may be difficult to extract from a researcher who has moved to other, more exciting work, particularly if the contracted research was viewed as a stop gap measure to keep the lab operating between federal grants that pay for "real" research.

Stability

Faculty may come and go at an academic institution. Indeed, advancement is most rapid if a faculty member relocates every 5 years or so. Studies can be left hanging if the involved faculty departs the institution, because hiring of a replacement is often a slow process. Remember, the contract is with the institution, not the faculty member. Thus some quiet investigation should be made as to any key person's likelihood of departing before contracting an expensive, long term research project.

Cost

Universities vary greatly in how they bill commercial contracts. In addition to the direct costs of the project most will bill indirect costs. Indirect costs at state run universities range from 10 to 50 percent of total direct costs and they may go much higher for private universities. Furthermore, the researcher may view an animal health company as having deep pockets from which substantial surplus funds may be extracted.

Conclusions

Collaboration between animal health companies and academic institutions offers many advantages for development research. The primary advantages are the tremendous array of facilities and expertise available in virtually any geographic location. Most types of studies can be conducted at these institutions, including safety and environmental impact studies, dose titrations and dose confirmations, and clinical trials of efficacy and acceptability, as well as studies to support label claims of enhanced productivity for that product. Lower costs and the association of the research with the good reputation of the researcher and his or her institution are additional advantages.

On the down side, a number of problems can arise. Disadvantages result primarily from inexperience on the part of academic institutions and, more importantly, the collaborating scientist at conducting this type of research. Patent and publication issues can be resolved through carefully worded contracts, but most problems are a result of the low priority often given to this type of research and a misunderstanding by the faculty member on just how this research should be carried out. The animal health company should use careful judgement in selecting both individuals and institutions with which to collaborate and should look for situations where the nature of development research is understood and appreciated. Finally, close monitoring of individuals who have not yet established a record of successfully conducting development research is a must.