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Cost-Effectiveness in Radiopharmaceutical R&D

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Streamlining Management Practice in Small- to Mid-Sized Companies

It is common knowledge that the development of a new pharmaceutical is prohibitively expensive. Blue-chip pharma companies have quoted figures in the range of hundreds of millions of US dollars, costs that are rising year by year. In today's market, even larger, more established companies hesitate to engage themselves in new pharmaceutical development projects unless the product is considered to be low risk. As a result of this, the number of approved 'New Chemical Entities' has decreased in recent years. This cost explosion is driven by the increased requirements from regulatory authorities, and ultimately, of course, serves the patients' need for safe and efficacious pharmaceuticals, and society's need for cost-effective drugs. When even big companies have difficulties in financing new projects, it is easy to understand that small- and medium-sized companies are facing an even more onerous task to get a radiopharmaceutical project off the ground. As CEO of such an enterprise, we have had to engage new strategies in order to offset and reduce the considerable costs for this R&D process.

A Cost–Ef f icient Team

Most small- and medium-sized companies meet the cost containment challenge by hiring a staff that is small enough to be cost-effective, but large enough to at least cover the need for people with the required expertise for the specific project they are running. This usually means that the company has a small management team consisting of a General Manager, Financial Officer, Scientific Director and a Technical Development Officer. The management team is supported by a limited staff of experts including a Manufacturing Officer, Regulatory Officer, Preclinical Expert, and experts in Clinical Development and Patent Management. Though some by necessity serve multiple responsibilities, the payroll can easily have to cover a team of over fifteen to twenty individuals who, with extensive education, experience and professional background, demand fairly high salaries. However experienced staff may be, a certain number of their tasks will involve work where they have limited experience, since it is impossible to hire staff with every required competence, and different types of bottlenecks usually occur. To meet the challenges of cost containment, our company has chosen a more advanced strategy.

Optimal Organisational Structure

Our organisational structure enables us to engage the best possible competence for each specific task. All procedures in the development process are done at the highest possible quality level according to existing regulations. The management of the development project must strive to be effective, competent and with quick throughput. The permanent staff of our enterprise numbers only three persons, a Managing Director, a Scientific Director and a part-time Financial Director. These people all have extensive experience in running pharmaceutical development projects with special focus on contrast media. Two members of staff are qualified medical doctors, one who is both M.D. and Pharmacist. This means that our permanent staff is highly competent in the area of radiological pharmaceuticals. We have initiated a project management structure for our team as we have found it more cost-effective than the traditional line officer approach, and all the special functions for which our team are not responsible, are outsourced to subcontractors with expertise in those areas. The complete pharmaceutical development, including analytical development, manufacturing, packaging development, documentation and filing is done in co-operation with a GMP-certified pharmaceutical contract manufacturer.

On one hand, of course, outsourcing highly specialised services can also be quite costly, in fact substantially more costly than a regular employee with the same competence. On the other hand, a subcontractor will only bill for actual time spent engaged in the required service. In pharmaceutical research and development projects, the need for different competencies varies a lot over time, and in my experience, this extensive use of subcontracting has turned out to be extremely cost effective in the long-term.

Development of Contrast Media: Speci f ic Requirements

Contrast media are legally classified as pharmaceuticals. In our case, we are developing a manganese-based, orally administered contrast medium for enhancement of the liver and bile ducts in MRI. However, the development of radiological contrast agents is less complicated

compared to other pharmaceutical development. This is mainly due to the fact that contrast media are administered to patients in some cases over a few individual sessions. Therefore, no extended periods of monitored follow-up are needed, reducing the need for complicated toxicological investigations. In this way, costs associated with bringing a contrast media product to market are lower than for other pharmaceuticals.

One important aspect of pharmaceutical research and development, is the gathering and systematic filing of total competence and specialised knowledge. Outsourcing and subcontracting present unique problems. As competence and knowledge are spread among different persons and groups, and various subcontracting companies, we must avoid dilution of expertise, and maintain very well-managed, interactive business relationships to keep up continuity with each subcontractor, and ensure that competence remains in as few hands as possible. In our case, we have made one person who is a very experienced toxicologist, responsible for following the whole project through.

This person serves as head of preclinical development and toxicology on a subcontracting basis. In this way, we can save costs through efficient staff management and organisation without losing knowledge or expertise.

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