

# Effective outsourcing: the virtual drug development model

Outsourcing parts or all of the drug development process has logistical and organisational advantages. Advanced management methodologies and processes, such as virtual drug development, increase the effectiveness of R&D outsourcing with proven cost, time and risk benefits.

Outsourcing at all stages of the product life cycle is becoming common practice in the pharmaceutical and biotech industries. Applying external skills and expertise directly when and where they are required avoids a dependence on fixed resources. This flexibility reduces the need to reallocate or recruit additional personnel, with a corresponding reduction in overhead costs. However, additional benefits such as reductions in time to market and overall development costs are not necessarily associated with contracting out. Using outsourcing organisations may avoid delays in initiating projects, but there is no guarantee that deliverables will be on time and within budget.

## Choosing a partner

The following factors are critical for the commercial success of any outsourced drug development programme:

- **The right team.** A team should be experienced, committed and flexible, with dedicated senior leadership to ensure project continuity and communication.
- **The right skills.** The team should have excellent project management skills, with appropriate R&D expertise and therapeutic area knowledge.
- **Documented work processes.** Effective project and knowledge management systems can be cost-, time- and risk-efficient.
- **Best-fit suppliers.** It is worthwhile to use validated, experienced suppliers that are specifically selected for their complementary skills, and access should be provided to the appropriate resources and expertise as required.
- **Good contracts.** Effective contract management will clarify responsibilities and timelines between client, outsourcing company and suppliers.
- **The right locations.** Both local focus and global reach are required to work effectively across markets.

No single organisation has the specific in-house people, skills, knowledge and systems to manage and execute projects optimally. A unique business methodology is required to satisfy the demands of drug development in today's competitive industry, where key objectives are reduction in time to market and extended patent life.

Virtual drug development is an advanced management model that operates by combining unique skills and business processes in drug development

strategy with teams of experienced suppliers and independent experts. Each 'virtual' team is specifically tailored to fulfil project or product requirements, and is led by a dedicated senior project director to ensure continuity and focus.

## Successful relationships

Significant development cost and time savings are made by combining experienced leadership with specifically selected suppliers on local and global platforms as required. The success of the model relies on implementing effective project and supplier management through validated core business processes. These can include documented operational processes, project and knowledge management systems, and contract and financial databases.

One advantage of the virtual drug development model is rapid access to the expertise, technologies and facilities that best fit the particular project at every stage in development. Under the consistent leadership of the project director, the project team is infinitely adaptable to requirements, incorporating suppliers and particular problem-solving skills on demand.

This flexible method of strategic drug development also accommodates forthcoming changes in the industry. European drug development processes will be affected by the EU Clinical Trials Directive that comes into effect in May 2004. All sectors of the clinical trial industry will have to adapt the way trials are managed and performed. The virtual project team approach will provide a smooth and successful transition to the new regulations by integrating advisers and experts with the necessary skills and insight to navigate the changes.

## A happy marriage

Forming a partnership with the right outsourcing company can produce many advantages in terms of project and resource management. Additional benefits arise from being part of an advanced management approach that uses an intelligent, tailored approach to drug development, with senior in-house expertise and on-demand access to a global network of specialists. ■

### AUTHOR/COMPANY PROFILE

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