



Outsourcing Through Seamless Integration – A New Standard In Pharmaceutical Development

Over recent years, companies have embraced outsourcing for numerous reasons, most of which are well understood. With the ever increasing complexity of pharmaceutical development programs it is unlikely that any company will have access to all of the areas of expertise that are required to develop all types of compounds. As a result they tend to look for some of that expertise outside of their own organisations.

Several studies have shown that additional speed can be generated throughout the development process by use of outsourcing. Undertaking a variety of tasks outside of an organisation allows for conduct of a greater number of activities in parallel - effectively broadening and shortening the critical path. As the cost of developing a pharmaceutical continues to spiral, risk management, particularly in the area of capital expenditure, has become increasingly important. There are many technologies that can be brought to bear on aspects of development programs that would require significant investment should a company choose to develop the expertise internally to handle these techniques. The alternative, namely going to a provider who has already undertaken that investment, is far more attractive financially.

As companies seek to bring more products to the market place more quickly the risk of bottlenecks in the development pipeline becomes acute and one way to solve this is through provision of additional resource.

In looking at the possibilities that seamless integration in outsourcing might bring to client relationships it is as well to consider what the client wants and needs from a strategic partner.

a) Strong Service Culture

This is something that is often claimed but very rarely delivered in vendor-client partnerships. It is critical that any vendor fully understands the client's needs. Without such an understanding it is impossible for the vendor to provide the level of service that the client requires, let alone deliver the product that the client expects. Once the vendor has an understanding of what the client wants it should seek to align its internal capabilities with those of the client. Communication at all levels is key. This does not simply relate to communication between the vendor and the client. Communication within the vendor's organisation has to be just as strong if they are to be able to translate their understanding of the clients needs into a cohesive plan for delivery.

b) Speed of Response

This does not simply relate to response to any initial enquiry, but to all stages during the process of supply. It is important that appropriate systems and procedures are in place to allow for efficiency in activities. Capacity must be managed in such a way that it generates flexibility in response for both people and equipment. Most importantly, performance must be monitored at all stages to ensure that the right levels of response are being achieved throughout the collaboration.

c) Quality

To maintain the highest standards of quality, the organisation as a whole must not only keep up with, but also exceed recognised current standards. This does not only apply to regulatory standards but also to those of clients, each of which will have their own interpretation of any given regulatory requirement. It is vital that the client's expectations on quality are well understood. Again, this can only be achieved through strong communication by both parties. Quality does not simply relate to the systems and procedures in place in the organisation but impinges on the activities of all people across the organisation. As a result it is key that people resources continue to be developed alongside systems and procedures.

d) Technology

Broad relationships will thrive on a broad technology base. Providers should look to be diverse in the technologies that they supply and focus on those which can have a strongly positive impact for the client. However, one of the most contentious issues in any vendor-client relationship can be of intellectual property. IP that is developed during the course of a relationship must be handled appropriately for the benefit of both parties. It is important that clients are allowed to claim ownership of the IP that is developed during a relationship given that they are paying for the service. However, it is equally important that the vendor is allowed to develop their knowledge and know-how and exploit that knowledge and know-how in other relationships. After all, it is the possession of this expertise, gained across a large number of client relationships that encourages any particular client to approach a vendor to work on their behalf in the first place. The application of technology is also an important area to consider. As a vendor, just because you have a particular piece of technology in your tool box does not mean that it is the most appropriate piece of technology to solve a given client problem. Too many vendors suffer by looking to lock-in a client by using their proprietary technology inappropriately.

e) Comprehensive and Comprehensible Access to Data

One area where time is lost in outsourcing compared to normal in-house activities is that of data provision and review. If clients can be given real-time data access, substantial amounts of time can be saved. However, it is not sufficient for data acquisition and management to be comprehensive, it must also be comprehensible. Instead of vendor staff having to collate data, prepare reports and send those reports (which may or may not be in the correct format for the client to handle) for review, it is possible to provide clients with data on-line in a mode which is fully searchable using their own formats and systems. This can be complemented by strong data management and data acquisition capabilities. Of course, with the rapid approach of electronic submissions, the potential for clients to take data in a format that is compatible with those submissions can save substantial amounts of time in the registration process.

f) No Need to Reinvent the Wheel

In any relationship where technology transfers must take place (of which a large proportion relate to vendor-client relationships in the development arena) it is critical that such transfers are handled in the most robust and efficient manner possible. However, before even getting to the point of transfer it is important to ensure that any technology that is developed is suited to the client's needs. Fail to achieve this and there is not much point in even starting the transfer. During any relationship vendors must ensure that learning is not lost to the client whether this is simply through provision of information or through client witnessing of activities. Any subsequent transfer will be made easier if the client already has knowledge of the learning gained.

g) “Down the Hall” Feel

Historically, one of the difficulties with outsourcing relationships has been the very nature of those relationships. Typically, these have been arms length and little has been done to include the vendor in any wider program. As a consequence, when issues have arisen, vendors have not had sufficient stake in the outcome of a program (beyond issue of an invoice) to take the client’s part in resolution of their issues. This can all be exacerbated by any situation where the vendor is geographically remote from the client either in distance or in time. However, time and distance must not be a barrier to communication and relationships cannot be undertaken at arms length. For partnerships to succeed, the vendor must be accepted as a part of the client’s organisation. Similarly, the vendor must be prepared to act as part of the client’s organisation. The client should feel as though the vendor is down the hall rather than several hours travel or several time zones away. Again, communication is key to any outsourcing relationship and the closer that communication can be, the more successful the relationship is likely to be.

h) Integrated Capability

When referring to Seamless Integration we are not simply referring to integration internally within the vendor organisation. We also refer to integration between the vendor’s organisation and that of the client. The vendor’s processes and systems must be integrated internally in such a way that allows transparency and comparability to the client when dealing with different business units within the vendor’s structure. This does not mean that all business units have to look and behave in exactly the same way, but there has to be sufficient commonality between those business units that the client can recognise them as having the same underlying business principles and processes. However, it is not enough for the vendor simply to integrate their processes internally. To achieve success in outsourcing relationships the vendor’s offering needs to be tailored and aligned with client systems and needs. Again, this comes back to the need for a detailed understanding of the client’s requirements.

Historically, outsourcing partners have tended to focus on particular technology platforms whether they are related to chemistry, pre-clinical service or some other area of pharmaceutical development. However, lateral integration of capabilities can generate an offering that reduces the time, cost and risk associated with drug development.

Pharmaceutical companies still have lateral integration within R&D and successful development comes from the resulting strong interactions between the different groupings. The key is the ability to link capabilities efficiently and cost-effectively across different technology platforms underpinned by an enabling infrastructure based around data management and transfer, strong IT capabilities and with short, efficient links to the client base. By achieving this, time can be taken out of the overall development timeline. However, it is not as straightforward as simply providing several technologies to a client. Clients should be able to pick and choose the technologies or services that they wish to source within the breadth of the offering.

Integrated CROs should not try to be all things to all clients. The reason that pharmaceutical companies outsource is a recognition that they cannot do everything themselves, so why should any CRO think that they can? Better to focus on a range of world-class technology platforms that can have an impact on pharmaceutical development activities. With a focus on speed in both a micro- and a macro-sense, it should be possible for the client to gain time through working with individual operating units and through working across a range of operating units in parallel. This can only be achieved if the organisation is underpinned by a true integration of its business units.

Critically, the offering must be aligned to client requirements. This is by no means trivial since these requirements change as the pharmaceutical development landscape evolves. Similarly, different clients will have different requirements and it is important that the vendor organisation is flexible enough to meet those requirements in all of their various guises.

About This Article

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Neil was born, raised and educated in Scotland and now runs the Essential Science office near Glasgow.