

Competitive Clinical Supplies

Presented by Marty Boom, Eugène van Dijk and Mike Hannay

Schwarz Pharma is a medium sized pharmaceutical company based in Germany that has, historically, focused on the development, manufacture and marketing of differentiated, branded generic products. Schwarz recognised the opportunity and business imperative to develop innovative New Chemical Entities (NCE). A business model focusing on collaboration with drug discovery groups and adding value internally through pharmaceutical development, manufacture and marketing was developed.

This major shift in strategy has required fundamental cultural and organisational change. Schwarz moved quickly and developed four programmes in Phase II, and one in Phase III; a major achievement for an organisation so new to the demanding world of NCE development. However, it was clear that there were opportunities to improve efficiency and effectiveness. The systems that had been in place for product development were not as efficient or effective as they needed to be with the increasingly successful development pipeline. One of the areas where Schwarz Pharma recognised this need and has been able to improve over the last two years, to become truly competitive, is Clinical Trial Supplies (CTS).

In late 2002 Schwarz Pharma was planning another Phase III Clinical Trial. CTS was desperately short of capacity. Outsourcing seemed to be the answer, as has been the trend within many other pharmaceutical R&D organisations, but the cost of outsourcing was four times what had been originally budgeted. 'They were horrified,' tells Marty Boom from WCI. 'Not only because of the money, but the outsourcing process had not always been done on time, to budget, or to the standard of quality they needed.' This made the team re-evaluate their in-house capabilities; perhaps there was an opportunity to improve internal efficiency, reduce the need for outsourcing, save money and increase quality?

WCI was asked to help. 'There were other issues which were hindering how the CTS Team worked,' Marty continues. 'They had too many internal processes and procedures that did not add value and there was a lack of effective communication between the Clinical Development and Clinical Trial Supplies teams who needed to work in harmony. CTS believed that critical information on trials was being received too late from Clinical Trial Managers, whereas Clinical Trial Managers complained that CTS had ridiculously long lead times.'

Both teams were working to achieve the same goal of getting a successful drug to market, but there was no shared vision.' Communication was cloudy: lots of e-mails flying around but limited real communication about what needed to be done. It was unclear who should provide what information. Some of the information when it arrived was incomplete and added delay and complexity. This meant communications and relationships between the teams suffered.



Simplify what you do

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WCI worked with the teams to create a shared vision and rethink the current processes to enable them to get the right information at the right time and accurately plan the supply chain. WCI led the teams through a structured analysis of what was needed, when it was needed and what was the impact of not having the information.

‘With them we built a Gated Process,’ Eugène van Dijk at WCI explains. ‘A Gated Process means each decision has key milestones in place and defined decision points that everyone adheres to; meaning consistency and smoother, faster working. It encompasses clear decision criteria, requirements, transfer points, and accountability. It would have a big impact on the way they design the Supply Chain for a Clinical Trial’

‘Clinical Supplies and Clinical Development are now working together in designing the Supply Chain,’ tells Marty. ‘This means they can set up a supply chain in a timely way that is, most importantly of all, compliant but also cost effective. WCI’s gated process software was introduced after the process implementation and facilitates decision making and communication. It helps to embed the processes that the teams have designed and to stay competitive.

‘Linking the gated process with improved, simplified packaging and distribution processes has been a key element in the success of this programme’ comments Mike Hannay, Head of the Formulation and CTS groups. ‘WCI have helped us to design, develop and implement a “joined up” supply chain that enables us to deal with current demand and provides a bed rock for the future expansion of our development pipeline.’

The benefits of the new processes are enormous. On one trial, savings of 32% were made in Clinical Supply costs alone. Approximately, 80% of packaging activities are now dealt with in-house which has had huge cost and time benefits. Other lasting benefits are more accurate planning, increased flexibility and streamlined processes.

The teams now work more effectively and there is reduced bureaucracy. ‘All Pharma companies accept that they are in an industry that is heavily regulated and requires red tape, signatures and waiting times,’ says Marty. ‘But Schwarz Pharma have found a way of combining the best of both worlds, excellence in innovation with more streamlined working practices, leaving them free to focus on providing the best in science.’



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