



New Horizons for Clinical Trials

Robert Dunlop at Almac Clinical Services offers his perspective on new challenges in the sector Robert Dunlop is President of Almac Clinical Services. Robert has a BSc and PhD in Chemistry from Queen's University, Belfast, and is a member of the Institute of Directors. He has over 20 years' experience in the pharmaceutical industry, of which the last 15 has been in clinical supplies. Since 2001, Robert has been responsible for the strategic leadership of Almac Clinical Services, UK and US divisions.

Q. What bottlenecks do you see in the supply chain process for CTM and how are Almac Clinical Services attempting to remove/improve them?

Traditionally bottlenecks have been concentrated around the primary and secondary packaging activities but these can and have been substantially reduced by utilizing automated technology.

Currently a major area of focus is on efficiency in the clinical supply label process – from text proofing through to approval and label production. Almac Clinical Services has been developing several key projects that will tackle this particular aspect of the supply chain. Automated label verification (launched Sep 06) using optical character recognition is an industry first in that we have developed a vision checking system that completely verifies variable and fixed label information thus not only improving compliance but dramatically reducing the time needed to make labels available for clinical supply production.

These approaches will significantly reduce the timelines required for all aspects of label production for trial materials. Ultimately this will result in supplies becoming more readily available to the patients.

We also find that Pharma and Biotechnology companies with little or no in house resource frequently rely on a high number of vendors to partner in the push for each new drug candidate. Within the Almac context , continued integration between all our service related business allows clients to outsource multiple activities to one vendor, for instance formulation development, bulk manufacturing, trial supplies and IVRS. This helps in the overall development of new treatments by reducing the number of vendors per protocol and allowing in house management of issues that previously would need intervention by the clients.

Q. How do you face up to the challenge of the globalization of the clinical trial market?

A. It is an interesting time within the marketplace. We have seen the push into emerging markets for quite a few years now with the eastern European countries gaining interest initially. Trials continue to be conducted in even more distant territories - Asian and Latin American countries are now being considered for many protocols that would benefit from their target patient populations and ease of recruitment. This leads to many logistical and regulatory challenges for both Clinical Supply organizations and client companies alike.

As a result of this ever changing landscape we have implemented a global strategy to facilitate the distribution of clinical trial materials. In 2004 we further expanded our global depot network and now have over 19 depots to ship in country within the new territories – such as India, China , Latin America and South East Asia.



Also, clients expect to deal with multiple sites belonging to one organization on a frequent basis. This requires a global GMP system both for key procedures and documentation production, along with consistent project management practices. Our business is now truly global in every sense and the client companies within the trial supply market require their vendors to offer flexibility and coverage across the globe – a challenge to be met for any business.

Q. Where do you think information technology can assist in providing supply chain solutions?

A. Many organizations are actively using or devising approaches to harness the tools available for information management particularly the use of the internet. Traditionally, many approaches to data management have been on a “point to point” basis resulting in multiple solutions, unconnected and with no generic integration. With the availability of XML and application of an integrated data layer, the wholesale approach is to develop IT based solutions that can utilize data from multiple data sources in real time from an unseen data layer to optimize the clinical supply chain. This strategy has the benefit of allowing many applications such as IVRS, EDC and inventory systems to share data in real time and reduce the risk of gaps in the overall supply process and facilitate real improvements in time and cost.

The platforms and technologies that allow us to develop new tools for the clinical trial supply chain are vital to our company as we continue to reposition ourselves as a full clinical supplies management organization. We already have harnessed web-based applications for online patient randomization and trial supply management (via our WebEZ™ system) and are furthering our integrated offering with Almac’s interactive voice and web response systems (IVRS/IXRS™). We feel that this is a key opportunity in the market by offering expertise in supply packaging , logistics and IVRS systems.

Q. Cold chain is a visible industry-wide issue; how are you positioned to tackle the growing requirements for cold chain shipping?

A. The growth in the Biotech market has fuelled the need for increased 2-8C storage and distribution capacities. We have responded to this by substantially increasing our 2-8 Capacity across all of our main sites (Craigavon, UK, Audubon PA and Durham NC) in this area in terms of facility storage size and the ability to ship large volumes of refrigerated patient kits worldwide.

We recognize also the consulting aspect of this area in that many clients are having huge difficulties with materials going out of specification and are experiencing issues with the size of the global supply chain in a refrigerated context. In response to the this and to focus our own resource to better meet the needs of our clients, we have uniquely developed Cold Chain Specialist positions within Almac Clinical Services. These personnel work with couriers, depots and shipper manufacturers to improve the performance of the supply chain and build a framework of procedures and best practices to drive down the out of specification results. This is another aspect of building a better and more robust clinical trial supply chain.



Q. How do you see Almac Clinical Services moving forward in the next five years?

A) Our evolution as a business will continue – Almac Clinical Services will be clearly positioned as a full service Clinical Supplies Management company. The company has progressed from being a leading Clinical Supply packaging and distribution partner to a company that can offer consulting and management services to aid specifically the Biotech and virtual segments of the market.

We feel these client organisation types benefit greatly from the value- added services that we can provide. Already we see significant growth in our Qualified Person and analytical services and also growth in requirements for our expertise within project and distribution management.

As an organisation, one of our key strategies is to develop our clinical supply management service. Our Durham site, already staffed by qualified Pharmacists has evolved from serving a particular client segment that is keen to leverage our input into clinical trial packaging and label design, dosing information and management of packaging / resupply campaigns. This frees up internal resource at client companies which enhances the development of a single point of contact model

This strategy allows us to act as the clinical supply team on the client's behalf. We feel that there is great strength in this offering and are developing global systems and processes to support this key service.

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