



Executive Insights From Robert O'Connor: Identifying Time & Cost Efficiency for Product Development

By Rob Wright

I recently had the opportunity to interview Robert O'Connor, Ph.D., Vice President of Product Development and Technical Services at Norwich Pharmaceuticals, a full service contract pharmaceutical development and manufacturing organization. O'Connor conducted a Q & A with *Life Science Leader* magazine on ways to identify time and cost efficiencies in pharmaceutical product development.

Life Science Leader (LSL) - What are some of these efficiency challenges generally being experienced in product development organizations?

Robert O'Connor, Norwich Pharmaceuticals: Well some of my answers may sound a little self-serving due to the fact that we are in the contract development business. But having a clear vision of the target profile or the final dosage form is extremely important to us to be able to conduct efficient product development. A lot of people start their product development effort without clearly understanding what the target profile is for their finished dosage form. In addition, many of our customers arrive with some starting data, either for the active pharmaceutical ingredient (API) or for an early formulation. The strength of those data are extremely important in how quickly we can get up and running in a product development mode. Another thing that is sort of a conflict with the notion of time and cost is that as we go through product development we find many people have a desire to conduct one at a time type of experimentation as opposed to more of a designed approach. Their notion is that this will get them to the final formula a lot faster and indeed that is often not the case. Initially, it may seem more efficient, but in the long term it often ends up costing more time and perhaps even more dollars in doing repeat work.

LSL: What specific recommendations or applications can help reduce various costs in the areas of product development?

O'Connor: In feeding back to what I just indicated, spending a little time looking at the starting data and the starting information will form a solid foundation for a strong and efficient product development process. One of the items that we find to be very helpful is to use smaller scale equipment that actually matches up with transfer equipment as well as commercial equipment. So while we are not getting exactly the same parameters, we get great learning at the early stage which allows us to move more quickly into technical transfer.

LSL: How should product development be organized to meet the broad demand of innovative technology and still

achieve efficient product development?

O'Connor: Building on the previous discussion with regard to the types of equipment, especially when you get into innovative technology, often times you doesn't have the large scale equipment to match at the small scale. So to be efficient and to be cost effective, one would buy the small scale equipment first to do the development work. This minimizes capital spending. Secondly it allows product development to proceed even to the point of producing clinical trial material or submission batches. Then the purchase of large scale equipment can be held and done during the review of the submission to be ready for commercial production. We just had a customer come to us with an innovative approach to a product. We took that product through a small scale version of the equipment that we would purchase for commercial and in fact we were able to take that product all the way through to a five arm pilot bio-study with remarkable results.

LSL: Would you share an example of how departments, such as human resource planning, schedule forecasting and others come into play in the development process to reduce costs?

O'Connor: We actually start that very early on in the development process. We run a four to six week rolling schedule for our development projects. And that rolling schedule is used to plan our activities, including resources. It helps us to be much more efficient in our approach to product development. This gets everyone used to working under time constraints and



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working within the developed schedule. It gets all of those components that were described earlier working together very nicely. In addition, I think the other thing that contract manufacturing organizations can do is to have a site master plan to look out three to five years. In this way, you can determine what products or projects you are producing or developing and be ready for those in your site master plan for commercial production at the time when one anticipates getting approval. This is also important as we talked earlier about small scale equipment for innovative technology. When you don't already own the commercial piece of equipment, it is very important to have a site master plan that takes into account all of the products that are in development and what will be needed at what time frame in the future.

LSL: What do you foresee as the next business planning strategy for improving both time and cost in product development going forward?

O'Connor: I came across a presentation that was given at a recent joint regulatory conference in Washington DC. It describes the FDA's approach to filings using the quality by design (QbD) approach. QbD is essentially a science based approach to product development. Using QbD allows for an understanding between the formulation and the process parameters to the critical quality attributes of the finished goods and that leads to efficiencies and lower costs because you are not finding yourself in a position where you need to repeat things. While to some people this sounds like something that the regulatory body has brought up to change the way in which we interact with them, this is in just good business. It provides for an understanding, not just that the final product that we've produced works, but gives an understanding of how the different parameters interact and provide data that will allow us to make decisions even while the product is in commercial production.

For additional information, you can go to our website www.norwichpharma.com.



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Bob O'Connor is responsible for the functional leadership of Product Development and Technical Services. Prior to joining Norwich, Dr. O'Connor held the position of World Wide Vice President, Product Support and Technical Services, for Cordis, a Johnson and Johnson Company. He also held senior technical positions with Janssen Pharmaceutica in Belgium and Pharmaceutical Sourcing Group Americas. Dr. O'Connor has more than 30 years of international pharmaceutical experience in research and technical operations. A registered pharmacist and Certified Six Sigma Black Belt, Dr. O'Connor received his PhD in pharmaceuticals from the Philadelphia College of Pharmacy and Science.

