Navigating the Complexity of Clinical Trials
Navigating the Complexity

Almac’s Jim Murphy discusses with Stephen Las Marias the company’s plans here in the region and the clinical trials outlook in Asia.

The Almac Group, an established contract development and manufacturing organisation that provides an extensive range of integrated services to the pharmaceutical and biotech sectors.

In its Singapore facility, Almac is establishing a new secondary packaging facility that will open by year-end. Through this facility, the company will better enable just-in-time supply management and support drug pooling strategies, which further optimise the supply chain, minimise wastage and reduce costs.

Jim Murphy, President and Managing Director of Almac Clinical Technologies, spoke to PharmaAsia’s Stephen Las Marias at BioPharma Asia Convention 2014 to discuss the company’s plans here in the region, the clinical trial outlook in Asia, as well as the challenges being experienced by drug manufacturers here. Excerpts:

What can you say about the state of the drug manufacturing industry right now, and what factors are driving the manufacturing shift from the West to Asia?

I think there are a lot of different aspects that are driving manufacturing from West to East. For some organisations, it might be a cost consideration; for many, it’s more about proximity to the end-user. If we think about the clinical phase of drug development—that’s really about patient recruitment, and making sure that you have appropriate representation in the geographic markets that you eventually hope you’d get your drug approved in.

Since Asia is the big growth market, any pharma company not yet here will soon arrive if they are focused on being around in the longer-term. There are a lot of things happening in the manufacturing space. Singapore, for example, has become a biosimilar hub, and there are many reasons for that, including intellectual property (IP) protection, high education bases, and historical success with very high-end manufacturing activities here. But just Asia in general? It’s all about demographics, demographics, demographics. From untapped market potential to treatment-naive patients to in-region manufacturing and distribution, the possibilities are simply too promising to ignore.

What are some of the major trends last year, and how is this year shaping up?

The biggest trend last year, from a global perspective, is an extension of a trend that’s been brewing for years – pharma companies have not had extremely productive pipelines and R&D efforts. And it has resulted in a huge amount pressure on them. Some pharma companies have had to make some very difficult decisions in terms of which programs to advance to later stage trials.

These pressures have forced vendors to be more responsive and innovative as they look for new models, new ways to achieve those goals and how to demonstrate that value. In my view, this is a good thing, especially considering that all of these challenges are exacerbated in Asia, where many companies may lack international trial experience.
Certainly, from an Almac perspective, we’ve become best able to support those needs, whether it is how quickly we can build and implement IRT technologies, or by engineering out process inefficiencies, and by using new technologies in ways that accelerate study startup. On the drug supply side, we’re applying more intelligence that allows companies to produce less investigational product (IP) and make sure that it’s at the right place at the right time. Overall, we’re able to help clients, particularly those in emerging markets, better understand and navigate the trial process.

What are the opportunities for Almac here?
Almac has been supporting trials in the region for a number of years. We have been supporting a lot of global pharma companies here; and those companies have rebalanced their portfolios and rebalanced the labour force within their organisations to be here more. So our prospects are very strong. We come with strong bases of clientele that we are already supporting, which we will be able to support more effectively from a local position.

In terms of long-term growth, I think it is very easy to see that there are growth markets here. Whether it is the continued expansion of the Japanese market beyond the domestic trial market looking to obtain market opportunities in Asia and globally, or whether it’s the rise of R&D and the innovation in China, there’s a huge amount of activity that we’ll certainly be focused on participating in.

Are there any differences between clinical trial services in Asia and the West?
Asia is highly complex; consider the fragmentation by country and by regulatory perspectives. In the United States, for example, you have the luxury of having one common regulatory authority for quite a significant population and that makes it so much easier to drive continuous improvement and streamline the work between regulators and the industry in the country. In Europe, even though there’s more fragmentation, they just have a slightly more mature alignment effort in their regulatory.

I would say the biggest challenges in Asia, from my perspective, are country-specific regulatory challenges, whether protocol approval or importation and duties, comparator sourcing, and level of experience of investigator sites – all of those add to the mosaic that challenges the efforts of clinical trials here. But the needs and opportunities are so much greater than the sum of the parts of those challenges that you’ll have to look through it.

That is actually an exciting opportunity for us because we come to Asia bringing in an international clinical trial experience; and that’s the platform from which we support our clients who are staffed by staff that may not have as much international experience whether in the region or globally.

So providing education is an important part of what we do because ultimately, what we are trying to accomplish is achieve a more-efficient and more-effective clinical trial.

Can you tell us about your secondary packaging activities in Singapore?
Secondary packaging is really an important part of the puzzle. Although we have for years used a suite of regional depot provider-partners to gain access to a lot of different countries throughout Asia, we believe that it’s critical to be able to control key processes, key GMP-related processes within the supply chain. So having a place where you can send a great deal of study medication in the region, park it, and then carry out just-in-time labelling and product pooling related activities, that has a tremendous value especially with expensive supplies.

What differentiates Almac from other companies that might also be able to offer secondary packaging is that we’re combining the actual IRT technology, which really controls the inventory for a clinical trial, and linking study medication to the patient. With Almac, you have the technology and the secondary packaging, and all of the professional services related to that, in one facility.

This is essentially a totally integrated mechanism to optimise the drug inventory in the region: what’s going to which country, how it’s going to be labelled, how long it takes, when it needs to be ordered, how much lead time and so on. So, you minimise the number of necessary shipments, thereby saving the client a great deal of money, as well as reduce any amount of overage that’s necessary.
As you can imagine, drug expiry ends up causing a great deal of wasted drug. Often, people label drug in a certain way, and then it doesn’t play out the way they expected in that specific country. Having the right supplies in the right place at the right time requires agility, and our model of the technology and the actual secondary packaging maximises the amount of agility in a way where it’s not available anywhere else. It’s a unique proposition in the market.

What can you say about the patent cliff?
It’s obviously a major concern for everyone in our industry, and one of the major catalysts of that pressure on study start-up timelines, costs, and budgets. There’s a realisation in pharma that there has to be greater efficiency. There’s more pressure than ever to think about the way things have always been done – and to do them differently the next time.

What about supply chain strategies regarding the movement of temperature-sensitive products?
When we started seeing an increase in the number of trials that involve sites in the region, it was very difficult to easily move supplies everywhere you needed to move them. What you ended up doing is using premium carriers for everything. It was incredibly effective. We’ve developed a greater experience working with a wider array of different logistics providers, and we’ve been able to see that whole industry as it applies to clinical trial materials mature, and build their routes and their networks in a way that allows a much higher level of consistency and predictability.

This has enabled sponsors to take advantage of opportunities for more efficient distribution in the region.

But that’s not to say things are simple and easy. You don’t have any one provider that can get you on the ground from everywhere you go. Look at China: you have to use at least three different logistics providers to get to all the different regions. In Japan, it’s a similar situation.

There is a collection of different regions within certain countries where there is a predominant player that you need to use to support to get to certain sites. So I would say it’s still a mosaic, but it’s a mosaic that’s more mature, and as long as you have the experience to understand who to use and what the pros and cons of it are, you can pass value on to your sponsor organisations, through consistency, through cost savings, and through all that transparency.

How do you see the harmonisation of regulations, in line with the ASEAN Economic Community initiative, impacting the pharma industry?
I am hopeful that that effort can yield progress and harmonisation across regulatory considerations: whether it is in the drug approval process, protocol improvement standards, or different factors of drug importation. It’s a very complicated landscape, and no matter what happens next year, it will be the beginning of a long road towards that sort of alignment. If success can be achieved, the impact is that you’re going to have a much more efficient flow of goods and a much easier operating environment for drug development.

How do you stay ahead of the competition?
The first thing that we need to do to be successful is focus on the customers, and focus on the changing needs of the market. That involves listening, being flexible and quickly adapting to changing circumstances. We’ve always done that. We’ve always retain very high repeat business ratios, and we have strong partnerships with major international pharma companies for a long time. I am confident in our ability to retain business once we’ve established relationships.

Almac focuses on creating unique value by combining services that are not connected with other organisations. We are totally unique in our supply chain solution. No one has got a first tier end-to-end solution that links all the way from planning down to primary packaging, secondary packaging, labelling, and distribution; an IRT solution that connects the patient with the supply chain, and manages the patient activity, and then even has the assignment of the study medication of the patient, then you have the return, and reconciliation and destruction of the study medication – all handled in one continuous system, with one audit trail, one ability to see all of that visibility throughout the lifecycle of the study medication.

We believe that that is a unique value proposition, and combines a different organisational expertise that we just don’t see in the environment competing against us right now; and we hope to make sure we are able to use that unique view of how to create value in the supply chain, to try to continue to focus on pushing the envelope on efficiency and quality.

There will always be competition, but the goal is how you are reinvesting to try to make sure that your staff and your services and solutions are staying ahead of the competition. And that’s how we think we are going to do it. PA