

The Most Powerful Name in Corporate News

Global Supply Chain Service Provider to the Pharmaceutical and Healthcare Industry



Wes Wheeler
Chief Executive Officer

About Marken:

Marken is the only patient-centric supply chain organization 100% dedicated to the pharmaceutical and life sciences industries. Marken maintains the leading position for Direct to Patient services and biological sample shipments, and offers a state of the art GMP-compliant depot network and logistic hubs in 43 locations worldwide. Marken's 630 staff members manage 50,000 drug and biological shipments every month at all temperature ranges in more than 150 countries. Additional services such as biological kit production, ancillary material sourcing, storage and distribution, shipment lane verification and qualifications, as well as GDP, regulatory and compliance consultancy add to Marken's unique position in the pharma and logistics industry.

CEOCFO: Mr. Wheeler, would you tell us about Marken?

Mr. Wheeler: We are a global full service supply chain service provider to the pharmaceutical and healthcare industries.

CEOCFO: What are some of the challenges unique to the industry that you are able to address, perhaps in a manner that others do not do quite as well?

Mr. Wheeler: We have two types of businesses in our company and provide many services within those businesses. Breaking our business into two sides of the clinical supply universe; we have, on the one hand, drugs and supplies, patient kits and everything a doctor needs to conduct a clinical trial in his office or his clinic. Those

supplies, whether they be syringes and drugs or bottles of drugs or various types of equipment that a doctor needs in his office to conduct a clinical trial, are what we specialize in delivering to the doctor's office or clinic. We call those offices or clinics 'investigator sites', the places where clinical trials are conducted. Depending on the type of drug and where the investigators are located determines whether we get involved in the logistics or not. We specialize in getting materials to the investigator sites within a certain minimal time frame to meet the needs of the clinical protocol and the regulatory requirements of, both of the country involved and also within specification. That is one side of our business; getting the outbound materials to the investigator sites. The other side of the clinical supply chain is drawing blood from the patients and transporting it to the central laboratory. Blood is the currency of clinical trials, at least today, until technology allows another means. Once a drug is administered to a patient, the blood must be returned to the lab for data collection. The pharmaceutical industry measures the safety and efficacy of a drug, once it had been administered to a patient, by drawing blood and drawing samples specimens, whether they be blood, urine, tissue, or even tumor cells. Those samples have to go back to the central laboratory within a very, very short period of time. If they do not arrive within twenty four to forty eight hours, in some cases, they expire and they are no longer usable. Therefore, companies like ours exist because getting the drugs to the patients and then getting the blood back to the central laboratories is a time and temperature sensitive operation. Only companies like ours can do this around the world in very, very remote places, weekends, holidays, during hurricanes; if the blood does not come back in time the patient could be removed from the study. Therefore, it is a very important niche that we operate in. We are the leaders in the blood recovery and delivery part of the business. We are one of several companies that specialize in delivering time and temperature sensitive drugs to the investigator sites in all countries of the world.

CEOCFO: What are some of the challenges in delivering time and temperature to the remote areas? Does it rest on how you package it originally, on the carrier you use, on e your knowledge of customs? What are the elements that you have figured out to make it work?

Mr. Wheeler: Let me back up a second and talk about the challenges in our industry today which are different than the old days. Most conventional drugs that you know from your past came in the form of a white tablet. Many people take statins

or antibiotics or pain relievers which are typically taken in a solid dosage form, such as a pill or a capsule, because most of those drugs were made from synthetically derived small molecules; basic chemistry. These days, because of the advance of cancer, different types of cancers and different types of neurological diseases, many of the drugs these days are derived from biologic material, such as protein, peptides, antibodies, T-cells or derived from plant material or even recombinant DNA. These biologic materials are being used now to create new therapies that sometimes disrupt cancer cells or influence the patient's own genes and DNA. Biologically derived drugs are very temperature sensitive. They are extremely expensive to make and very difficult to handle. They are almost always delivered in a sterile format, a sterile liquid or a sterile powder inside of a glass vial. Because so many of these drugs are being developed today, even the generic forms of these drugs that are being developed today, our clients are becoming more cautious about how they are handled in all parts of the supply chain. It does not make sense to necessarily put glass vials, derived from a very expensive biologic source that need to be temperature controlled, that cannot be lost, into a typical FedEx or DHL packet. Therefore, most of our clients are now relying on companies like ours to deliver these very sensitive, very expensive, very unique drugs. That is the first consideration. The second consideration is that every country is different in terms of how they allow these drugs to be imported and exported. Every country is different and it takes a specialty company like ours to understand how to quickly move these drugs, which are in most cases not currently marketed, not fully labeled, to get these drugs across international borders. We are experts in getting them out of the country from their factories and getting them into the country where the doctors and the patients exist. We have to know exactly how to do that within a very short period of time.

"We are tracking the location, temperature, light conditions, even humidity and pressure for some of these important new medicines to prove to our clients that we have chain of custody, chain of identity and chain of control... We want to provide an absolutely perfect logistics service to our pharmaceutical clients and not be distracted by anything else." - Wes Wheeler

CEOCFO: Would you tell us about your new Moscow Depot?

Mr. Wheeler: It is interesting. I have been in this drug business for a very long time. I have actually launched drugs of my own when I was at GlaxoSmithKline and also at Valeant Pharmaceuticals. What I have learned in developing drugs is that a very large and growing source of patients for diseases which are unique or even for diseases which are not so unique are coming out of Eastern Europe. The reason for that, not to go into details, I think they are very sophisticated countries and the patients are well educated and the patients do look for advanced healthcare in countries where the socialized medicine may not be adequate for these patients that are looking for innovation; they will easily and gladly sign up for a clinical trial. Therefore, countries like the Ukraine, Belarus, Russia and Israel; these countries are very, very important sources of patients in our clinical trials industry. That is historical. It has been this way for many years. Now that some of the regulations have improved in some of these countries like Russia, we are seeing renewed demand and many new trials. I recently read in the third quarter of 2015 that two hundred new clinical trials were registered in Russia. That means that there will be a continued source of patients in that country. Therefore, we chose to build a depot near the airport to allow us to bring drug product in; either in bulk form or in finished dosage form, to store in the depot so we can be ready to distribute it to the patients. It is a very, very important location for us.

CEOCFO: Do you have access to virtually all drugs? Are there drugs that you might have that others would not?

Mr. Wheeler: That is a good question. Drugs in the US and in most countries follow the FDA designation for how drugs are designated. There are various types of drugs that are considered narcotics: some dangerous and some less so. There are, of course, illegal narcotics, which are designated 'Schedule I' narcotics. Of course we do not handle any of those. However, drugs that typically effect the neuro pathways in the human body, such as 'Adderall XR' will be 'Scheduled' according to their addictive traits. The 'Schedules' vary from 2-5 for legal drugs. Schedule 2 drugs in the US are very carefully handled. They operate under quotas which determine how much of an active ingredient such as amphetamine can be allowed into the country. The Drug Enforcement Agency, the DEA in the US, tightly controls the movement and storage of Scheduled narcotics. We do not store these drugs in our US depot yet, but we do have the ability to store some of these drugs in other countries. Aside from that we can handle virtually anything which is required for a clinical trial. Today on the blood side of our business, we have the ability to handle patient blood draws that are HIV positive, for example in Africa. DHL and FedEx will not handle these shipments. We handle the Ebola virus. We have the ability to ship small specimens of virus used for development of new vaccines. We can handle virtually any vaccine, any biologic sample and any drug, with the exception of storing certain Scheduled narcotics in our US depot.

CEOCFO: How are you able to maintain that real strict quality control?

Mr. Wheeler: That is a good question. It is a matter of hiring great people, to be honest. We have two full time registered customs brokers in the company who are based in the US. They understand very, very well how to pack these products,

how to designate them in the airway bills so that when they do fly they are properly documented. When we cross borders the exportation of these drugs and these materials are properly labeled. It does mean that you have to know exactly the regulations in each country. I have a team here based in Raleigh who are experts in labeling, packaging and documentation for those kinds of things. It is very specialized. We get many questions from our clients on a daily basis. We advise and consult very frequently.

CEOCFO: *What has changed, if anything, over time in your approach. How is Marken operating better today than it might have been a few years back?*

Mr. Wheeler: I have to say the one big change is that the regulators have stepped up their vigilance. The US and the European Union have created new guidance and regulations which of course that spills over into Argentina, Brazil and Japan. The US really led the way in the definition of what good distribution practices (GDPs) mean to a pharmaceutical drug product. It seems that someone woke up one day and realized that if you trace the supply chain from cradle to grave or from start to finish, from the time it is manufactured to the time that it is actually consumed, there is still one area which is still not tightly controlled. When I say 'supply chain' I consider the time that that drug is transported, from the time it leaves the dock at the manufacturing factory until it arrives at the pharmacy. That period of time, which can be days or weeks, has historically been relatively uncontrolled. There are few regulations that have recently focused on this part of the supply chain. Therefore, just by being forced by regulations we are changing. We are now having to geofence some of our lanes to prove to our clients that the drugs do travel along the route that we claim and that they expect. We are tracking the location, temperature, light conditions, even humidity and pressure for some of these important new medicines to prove to our clients that we have chain of custody, chain of identity and chain of control. All of these regulations are coming now quite rapidly in the last five years, I would say. Regulations are forcing us to be different. However, we are also trying to innovate, so we are actually adding many, many services for our clients so we can be a full service supply chain company. That includes innovative packaging, innovative tracking devices, track and trace, cloud based booking systems and so on.

CEOCFO: *Are there services you offer that your customers are not taking advantage of in the way you think they should?*

Mr. Wheeler: I do not think that our industry has necessarily decided yet that logistics is something that they should completely outsource. Yet we are prepared to take it on. One service that we offer is what we call 4PL, the 'fourth party' logistics opportunity. Instead of a pharmaceutical company maintaining a department of supply chain and logistics people, why not consider outsourcing the entire function? Marken can acquire those employees on our own payroll and can operate independently and pretty much run the supply chain for the pharmaceutical company. It will take time, but I do believe there will be a wave of these opportunities for us in the future, as companies decide what is their bread and butter, what is their core competency verses what they are able to outsource. If we are able to do more of that we get the benefit of volume, we get the benefit of consolidations, we get the benefit of cost efficiency and we pass that on to our clients. I would say that is probably the most important thing that we are selling that we are not necessarily seeing companies take advantage of.

CEOCFO: *Why is Marken an important company? Why does it stand out in the industry?*

Mr. Wheeler: I have been in the pharmaceutical industry now for over twenty five years and before that the oil industry. I came to Marken to transform the company from a rather straightforward courier service to a full service supply chain company. That is why I came here. I know how companies should be professionally managed. We have decided to focus only on life sciences and we are the only specialty company which is one hundred percent dedicated to our industry. We do not get involved with anything outside of our specific industry. We don't deliver aircraft parts, ice cream, food or flowers. We deal with drugs and blood and patient samples and specimens. We want to provide an absolutely perfect logistics service to our pharmaceutical clients and not be distracted by anything else. That's our special sauce. We specialize in what our clients do and we want to be partners with each of them. We are not just a service. We are not just something you book online. We are a partner with our clients and we take it seriously. We think that everything we ship is a life saving medicine; a medicine which will affect someone's life. We are there 24/7 in serving 140 countries from 43 locations. We are everywhere. We will pick up anywhere, everywhere, anytime, including this holiday season when DHL shuts down.



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GLOBAL LIFE SCIENCE SUPPLY CHAIN SOLUTIONS

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