Interview: Dermot Oâ??Callaghan â?? Cofounder & Director of Business Development, Enterprise System Partners, Ireland

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Dermot Oâ??Callaghan, cofounder and Director of Business Development, tells us the exciting story behind the genesis of Enterprise System Partners, an Irish success story providing manufacturing execution systems (MES) and serialization solutions to the pharmaceutical, biotechnology and medical devices industries. He outlines how the industry within Ireland has grown along with MES, their expansion into the US and continental Europe and their ambition to become the global partner of choice for consulting and project engineering software solutions.

What is the story behind Enterprise System Partners (ESP)?

ESP was formed when its founding members were the lead team implementing the first Manufacturing Execution System (MES) electronic batch record (EBR) system for a project with Pfizer as a group of independent contractors; Liam Oâ??Brien, our managing director, led it as overall project manager. Liam had introduced technical innovation to the pharmaceutical industry in Ireland when he established ProsCon (now a Rockwell-owned company) in the early 1990s as the first provider of automaton integration services in Ireland. Two years into the Pfizer project, it was perhaps no surprise that he initiated the formation of ESP to focus on the next wave of systems in MES.

As a result of stringent regulations, the pharma industry can be very conservative and slow to incorporate new technology. This first project with Pfizer was, therefore, critical, and a number of factors led to us securing it. Firstly, all of us had over a decadeâ??s worth of experience providing services to the pharma industry, which provided a certain credibility. There was an IT officer within Pfizer personally willing to take a risk on what was an innovative project (MES) at that time, and more broadly, there was perhaps some institutional support within Pfizerâ??s management for technology that could drive better performance.

Even then, the Pfizer project did not guarantee success for ESP. I spent the next two years searching for our next client during which we spoke to all the pharma companies with a manufacturing presence in Ireland but they were simply not doing projects in this space because of how new it was. The four of us came this close to going our separate ways.

Then a month before the Pfizer project ended, we won a front-end study from Genzyme. It was only a consultation but a few months later, another project with them in Waterford moved fully into the MES space. Implementation of that project was comprehensive and very complex, but it ultimately went well and we built up a team of around a dozen people. That generated more momentum for ESP and we have been growing ever since!

What does ESP bring to the pharmaceutical industry?

We are technology people with a focus on processes. Our business is in understanding the processes used by the pharma industry as well as the available software system solutions out there, and then bringing the two together for the best fit. Software providers often lack the in-depth industry knowledge required to really understand client processes and needs, while the industry may not understand the full functionalities, scope and limitations of the software. We support our clients in choosing the best solution options and then we can help them configure and integrate them into their existing systems landscape.

To illustrate, if a small business were to consider using Excel to do its accounting, Microsoft writes the software and our client would be the finance person in this small company. ESPâ??s role would be to provide people with technical proficiency in all of Excelâ??s functions and capabilities, on top of a thorough knowledge of accountancy, so that the finance person would know which Excel tools to use and how to best use them.

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Has the biotech revolution in Ireland, particularly as manufacturing shifts from API to biologics, affected the way ESP responds to client needs?

Not fundamentally, no. There were a number of new biologics manufacturing processes we needed to understand in more detail as they became more prevalent. On the whole, pharmaceutical manufacturing is a linear process, which means that things occur within a set sequence. Biotech processes are more iterative, meaning that they typically require more human intervention to assess when stated requirements for each cycle have been attained before the product moves on to the next manufacturing stage, which is similar to API from a process systems prospective. Beyond that adjustment, the standards of rigor and quality to which we must deliver the project remain unchanged.

What are some of the exciting developments you see within the MES and systems management industry?

The industry has already begun to move towards paperless solutions but there is still a long way to go on the path in front of us. Wherever you see paper on the shop floor, there is a system behind it. Once that system is automated and interacting more naturally with users and other systems, it will open up a whole array of possibilities for data collection and analytics. It is a natural progression for ESP to be involved in this space because our systems already store and manage the data.

There is a constant drive to make these tools more user-friendly and easier to configure. Using these tools in the cloud is also another hot topic. When data storage and migration of that data come into play, an associated theme is data integrity: how to ensure that a copy of data is true to the original

with all the nuances preserved. Most of our clients are understandably conservative with regard to having full ownership of and access to their data all the time. Pharma companies also want constant access to the original manufacturing data. There are a lot of considerations surrounding digital data that need to be addressed before we move to the cloud. With time, however, I expect the allure of having all your data on the cloud so that it is easily and constantly accessible, will overcome the security and data integrity challenges we currently face.

Where would you say Ireland stands when it comes to the use of such technology?

As far as MES is concerned, it is certainly being used in plants in the US and elsewhere in Europe but I believe that Ireland has utilized that suite of tools more comprehensively than anywhere else.

Fundamentally, I ascribe this to the Irish hunger for innovation, often through necessity. Given most of the big pharma companies are headquartered outside of Ireland, local manufacturing plants here are motivated to work harder to justify that investment. They compete with manufacturing plants globally so they are always pushing to keep ahead of the internal competition. Being a small country is also very conducive to collaboration and dialogue, and I would say there is a strong culture of information sharing and openness and networking in Ireland. Cross-pollination of ideas is key to innovation! Beyond that, the institutional setting with the great education system and the business-friendly environment round out Irelandâ??s competitive advantages.

In addition to MES, ESP also has a focus on serialization, the tracking of individual units of medication with a unique serial number of barcode. What is the significance of this?

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Firstly, most major markets are implementing some form of serialization legislation so that by the mid-2020s, each unit of sale will have a unique identifier. This is primarily an anti-counterfeit measure so that end-users can ensure the veracity of the drug. That in itself could lead to new developments as the supply chain becomes more secure. Today, I would never buy a drug online, but as this technology develops, we could see more prevalent use of legitimate e-pharmacies emerge as consumer confidence grows.

But there are a number of more immediate benefits that could develop. We will soon be able to track all units sold through the entire supply chain. Manufacturers will be able to trace the movement of their stock, prioritize its distribution according to need and even ensure simple measures like best utilization of all stock before it moves past the expiry date. For patients, serialization will lead to improved patient safety. Drugs could be scanned before administration to ensure the correct product and dose for the patient.

There are opportunities to improve product adherence by end consumers by scanning the product to obtain an instruction booklet they may have discarded. This could be even trigger the download of a user-friendly phone app for example, which could use clever ways to encourage the consumer to use the product correctly. This approach could also enable pharma companies and manufacturers to gather feedback on how their product is truly being used, which could be useful for product improvement. Doctors and healthcare providers could also see if a patient has been following the recommended treatment plan linked to their electronic health records. The possibilities are endless.

The obvious question then becomes, why has this not already been done? Sticking a barcode on boxes of medicine should not be that difficult! However, it is in fact a very complex issue. The serial numbers have to be unique, which makes any serialization program a global one by default. It is not an innovation like MES or automation, where a local affiliate of a pharma company can test it in a pilot program. Serialization is something an entire pharma company would need to implement. Even

if they use a company-specific code, there will be billions of numbers to manage within the organization itself, and systems need to be put in place to distribute, track and consume these numbers globally. There are numerous technical challenges, but perhaps the biggest is aligning a large cross-functional team across a manufacturerâ??s supply chain, from shop floor to pharmacy.

What is ESPâ??s plan for further growth?

We have been growing at around 30 percent per annum, entirely organically, in the past few years and I fully expect that to continue as the full capabilities of the MES suite of technology still have not been fully exploited by the industry.

We currently have around 140 people and we are operating predominantly in North America and Europe, which is where most client project execution is, but we also provide consulting services on a global scale.

As far as Ireland is concerned, we have completely dominated the market; we are seeing steady-state growth. I would say 90 percent of the external provision of MES services within Ireland comes from ESP. The next market for us in the US and the rest of Europe. Like many Irish service providers, we have moved abroad with our Irish clients. We broke into the US market based on the credibility we built with big pharma companies on their projects in Ireland. In the same vein, our first project in mainland Europe was with Genzyme; as we had set up their very first MES system in Ireland, it meant that we influenced how they set up their MES standards within the entire organization.

One of the biggest challenge facing ESP at the moment is human resources. Marrying people to project wins has always been the limiting factor on growth for us. We spend more time selling ourselves to potential employees than we do to clients! We are working hard at improving our own in-house training capacity to develop the staff we need in an attempt to offset this in the future..

Looking forward, what are your hopes for ESP?

We are definitely playing to win. We are perhaps the largest group in our defined niche globally but we still have some way to go to offer our global pharma clients a complete service solution covering all geographies comprehensively. We can do this already when it comes to consulting (strategy & design) services but we do need to do a lot more work to develop local or regional teams able to work on client sites in regions outside of North America and Europe. I would like to position ESP to be a true global provider of MES and serialization services, and then branch into a number of additional complementary strands like data analytics and data integrity.

Our biggest challenge will be to stay as hungry as we were on day one and to stay on top as we continue to grow at a steady pace, whether it is tomorrow or ten years from now!

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