Manufacturing Intelligence

Using analytics to achieve operational excellence

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In an effort to efficiently use the data obtained through various Pharma IT solutions, Enterprise Manufacturing Intelligence (EMI) goes beyond the realm of raw data derived from Manufacturing Execution Systems (MES), relying on the use of analytics to create and sustain operational excellence. Recently, I spoke with **John Oskin,** founder and executive vice president of Informance, about the latest EMI solutions, in particular, the company's IMPACT Professional Services, which were deployed at GlaxoSmithKline's Clifton, NJ and Aiken, SC manufacturing facilities last July. —*KB*

Contract Pharma: *Please provide a description of Informance and the EMI services offered to pharmaceutical manufacturers.*

John Oskin: Since 1995, Informance International, Inc. has focused on working with manufacturers to improve performance using manufacturing intelligence solutions. Over the years, our solution evolved into a real-time analytics system covering the entire factory floor. Our EMI solution allows global manufacturers to track, analyze, and address plant and enterprise issues. Additionally, Informance benchmarks the pharmaceutical industry and publishes best-in-class and average performance on over 30 metrics.

Our key goals include: accelerating initiatives using analytics to pursue six sigma or lean initiatives; provide expert advice on Overall Equipment Effectiveness (OEE) and performance metrics; and provide intelligence in the form of actionable information.

CP: *How do EMI solutions differ from MES?*

JO: We're the analytics side of the MES space, where a lot of the value is being derived. I think what MES tried to do was provide a lot of raw information and what manufacturing intelligence is doing now, is providing more context around that.

CP: *What are some the latest IT offerings for pharma manufacturing?*

JO: One of the latest Informance offerings include our Batch Analysis module. This application analyzes total cycle time as a batch progresses through a plant. With this tool, we have found that the time lost during batch acceptance can be up to 70% of overall batch cycle time; most pharma manufacturers don't have this kind of visibility.

Normally there are two main operations, the manufacturing side, where a lot of the formulation takes place, and then there's the packaging piece. There's a major disconnect between those two kinds of operations. We found that when you track the overall cycle time of an operation, 70% of that cycle time is actually spent in the lab, when things are being validated.

For example, we had a client that looked at their process and thought it took about 20 hours to produce a batch of product. On paper, if you did a theoretical analysis, you came up with a number like 12 hours. Then they measured the actual time it took and it was closer to 40 hours. There is a huge disconnect there: 12 hours perfect world, 20 hours perception, and 40

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hours actual. That was a huge eye opener for them. When they were able to dive in further, that's when they learned that 70% of those 40 hours were spent in the lab.

There are huge benefits if you can shorten up that cycle time and take enormous amounts of inventory out. If you cut that cycle time in half, you can cut inventory in half, so you're talking about hundreds of millions of dollars in a large pharmaceutical company.

CP: *Please talk about your service relationship with GSK.*

JO: GSK has fully deployed Informance solutions and advisory services at two of its manufacturing facilities in Clifton, NJ and Aiken, SC, as part of a global framework agreement for global business intelligence to drive and sustain manufacturing operations performance. Under the agreement, GSK names Informance as a preferred solution to assess improvement opportunities, align plant tactics with corporate strategies, and exercise the most efficient use of the information to sustain the effects of operational excellence activities. They've had tremendous improvement from the use of Informance technology and as a result, GSK has named us as a preferred vendor for this type of solution.

CP: *What's the main motivation for implementing EMI solutions?*

JO: Pharmaceutical manufacturers are under tremendous pressure to increase product volume in their own plants and improve margins. They must often achieve this higher volume with optimized resources — a challenging task without the help of real-time discovery analytics for operational excellence. They usually find that simple OEE tools are not adequate to drive improvement, and leading manufacturers, especially pharmaceutical companies, look to solutions that deliver facts, pervasive visibility, and maximum knowledge transfer, along with real data, actual root cause analytics, and a deep understanding of problems. The four main reasons companies implement EMI solutions are: productivity, reduced Capex expenditures, inventory reduction, and support of lean six sigma initiatives.

CP: *What's involved with the implementation of EMI solutions? Are there specific challenges?*

JO: There are challenges in the pharmaceutical sector around validation and the whole regulatory environment. However, our approach is a non-invasive solution that doesn't require validation, which allows us to deploy very quickly and get almost immediate value out of the information obtained. In a regulatory environment, many solution providers go through a validation exercise, which is very expensive for the customer and is incredibly time consuming. It could take six to nine months to go through a validation process for this kind of solution. In our case, EMI doesn't require validation, so for us, it literally takes weeks. The benefit for clients is rapid deployment and very quick access to information to help drive operations excellence.

CP: *How does that work, is validation obtained through another source?*

JO: Most vendors take an invasive approach in the way that they interact with programmable logic controls (PLCs), for example, that necessitates validation. That's what drives the processes and because we don't need to do that, we're not subject to a validation scenario.

PLCs are the computers that run the machines. If you're communicating with these machine controllers, there's obviously a lot of sensitivity around any parameters that can change, which affects the process and therefore everything has to be validated to make sure that doesn't happen. We take a more passive approach where we simply read this information and we have technology thåat can overlay the top of the PLC layer. As a result, we can't alter or affect the process and therefore a validation is not needed.

CP: *What kind of training is required?*

JO: We have a unique training model. Where most software vendors have a two-phase process involving pre-implementation and implementation activities in order to commission a system, we developed three additional steps for IMPACT. After our solution goes live, we come back 30 days later and certify the data to make sure it's accurate. We actuate a baseline of operations to see how the plant is performing and then we do the actual training 30 days after they go live. We like to do the training with the client's data because they're much more engaged with it. Then, for the next two months, we have a consulting concept where every two weeks we do a 90-minute conference call with the plant to review the data. We navigate the software, looking at information together and provide insight on what the client is seeing. They get tremendous benefit from that and normally it helps accelerate their improvement efforts. Finally, after a couple of months, we have a few workshops where we infuse our benchmarking data.

In November, we released our latest IMACT benchmarking study of 725 global manufacturing operations. We take the pharmaceutical sector and map clients with metrics such as best-in-class, OEE levels, asset utilization, and capacity numbers, to see how they stack up in our benchmark database using their real-time information. We take three months of real-time data to compare and it makes for a much richer benchmark analysis, as compared to a survey concept for example. There's no other software vendor in the market that does this.

CP: *Can you provide an example of ROI for this software?*

JO: One example is companies that are driving OEE improvement. Typically, for a $4 billion pharmaceutical company, every 1% left in OEE translates to $6 million in benefit. So, if you get a 10-point lift, that's $60 million in savings. We have one client that got a 16-point lift in their OEE that translated into $30 million in savings. Another client reduced their base cost by 12% across approximately 12 plants. It's broad example, where on average they were getting a 12% base cost improvement. ■