A Faster Track to Market

The pharmaceutical industry should look to welcome the prospect of a digital transformation, starting with the revamp of automation systems to optimise data access and market delivery

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To pharmaceutical data scientists and process engineers, automation is a largely hidden world, but one that has a significant impact on the ease of data analysis and routine process monitoring. By the time these end-users are looking to access data, they may face paper and electronic records, multiple databases, or automation systems which are already delivered and challenging to update. This article looks at how the design of automation systems can improve access to data, the speed of product delivery to market, routine product manufacturing, and maintenance, as well as shorten the supply chain.

Automation and Data

The genesis of automation was the desire to automate the running of machines rather than have operators do it manually, thus increasing reliability, safety, and, in most cases, leading to greater efficiencies. However, the benefits of automation can only be fully realised when implementation is performed correctly and when data is being used to inform and improve all processes.

The next significant milestone in the automation story was the shift from paper to electronic records using manufacturing execution systems (MES) and laboratory information management systems. Nowadays, almost all data is in (or is moving to) an electronic format, and the industry is gradually capitalising on that and using it to improve reliability and quality wherever possible.

Its inherent benefits have made automation more than a showpiece for high-value lines, but a major component in modern manufacturing. Depending on the age of their facilities, manufacturers may have a mix of automated, semi-automated, and manual processes in place, with new facilities tending to automate everything they can. However, the key to success is integration. Every system and piece of equipment needs to be able to record and distribute data and communicate seamlessly with other systems and equipment to access relevant data reliably.

Once this connectivity is in place, operational teams have the basis for making better choices or have the need to make choices removed, as self-learning systems do this automatically by interpreting data.

Full cross-system integration is the aspiration of every plant manager. Brand new facilities tend to deliver this as standard or at least have a technology roadmap to make this happen, whereas legacy facilities can struggle to bridge the gap – rather than a negative, however, great opportunities are still available to improve processes.

Automation Design

Poor integration and connectivity are significant roadblocks to success, closely followed by flawed communication approaches.

Connectivity between equipment and software to the likes of MES and enterprise resource planning systems is readily achievable, but is ultimately pointless if the connections do not improve or error-proof the process compared to a standalone configuration.

Making sure the correct and useful data is making it from sources all the way through each layer through to analytical tools is imperative. Most companies spend a great deal of time configuring control and transactional systems to perform a particular function or run a process. However, less time and focus is given to ensuring more subtle data, such as equipment heath parameters and transaction metadata, are readily accessible with the required context. When setting up the automation systems, automation engineers work off design documents that may not have significant input from the process engineers, who are the end-users of the data. This can result in data which is perceived as 'nice to have' being omitted due to cost and time constraints. What is unfortunate is that including the information at the early stages of

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system configuration is much easier than updating the systems once they are qualified.

Similarly, the process engineering team may only realise they need the information a few years after the initial decisions around automation design and data transfer were made. Again, this is down to timing – it would not be uncommon for it to take three to four years or more from when design documents are first created to when a plant is running commercial volumes. This is the point when the data considered a 'nice to have' starts to have true power in the context of preventative maintenance, process improvements, and business process improvements.

Put simply, there is a disconnect between the early-stage decision makers influencing the automation systems and those who will ultimately end up using the data. One potential resolution to this disconnect is to identify and include the requirements of these supporting processes upfront and ensure that the data is not only readily accessible, but also contextualised.

Contextualising Data

Process data is vital, and it is a given that manufacturers throughout the life sciences sector want access to it. One area where a great deal of opportunity remains is in contextualising data. This can be relatively easy if working within the same system, but, very often, process engineers and data scientists need to align data from multiple systems, and this proves more of a challenge when the systems do not have common identifiers, such as a batch number. What should be a simple task can quickly become time-consuming and arduous.

By adding information such as product or recipe names, process phases, or batch identification to time-series data in process historians, the value and usability of the data for process engineers is greatly increased. A simple edit in the recipe layer, such as adding a text description to a step number, can save hours trying to add this context manually through, for example, lookup tables every time that dataset needs to be accessed. Another critical piece of information which is often overlooked and causes more issues than warranted is timestamps. It is a given that timestamps need to accurately reflect when an activity occurred, but having timestamps of different formats means that it can be very difficult to align or cross-reference data from mixed sources. Appropriate metadata and consistent reference points can create valuable context on process data, allowing process engineers to use it straight away without any manual sorting or interpretation, thus eliminating the need to infer where one is in a process because the system has actually described so.

The ability to search data over a specific timeline and visualise all related events in that timeframe quickly and efficiently will allow users (and eventually machines) to predict more precisely what is occurring or what will occur across industrial processes. Automation engineers are perfectly positioned to resolve these issues at source when setting up new processes, but often do not as the requirements have not been identified upfront or because it is not obvious how challenging some decisions will impact activities at a later date. This approach will only change once design teams and those involved early in the process engage with the end-users and consider data analytics as a critical requirement in the design phase.

Industry 4.0

Industry 4.0, or the fourth industrial revolution in manufacturing,

is the name given to mark the transition from the initial adoption of computers and automation of manufacturing in the third revolution to full digitisation- using smart systems and evolving technologies, such as cyber physical systems and Internet of Things systems. For pharma manufacturing, this is both exciting and daunting because many companies are still in the early stages of embracing full automation as the technology has been proven reliable. In many instances, the technology leap to fully embrace Industry 4.0 concepts will require a significant shift in focus and expertise required to run facilities securely using these new methods. However, the benefit of embracing this new technology and the data it will generate is that advanced techniques in data science, which were previously available to only the most data rich, will now be available to all. For manufacturing lines, this could mean real-time adjustments which require no human intervention in either the adjustment or response to the potential error that has been avoided. The potential financial benefits of reduced errors and increased up-time and throughput are huge for facilities under increasing pressure to manufacture continuously and flawlessly.

Embracing the Revolution

Underpinning the potential to improve pharma manufacturing is data. Contextualising and ensuring access to relevant, high-quality data will be the lynchpin of the pharma industry's success in coming years.

To facilitate this, the integration across all platforms and systems and incorporation of data analysis considerations at the automation design specification stage should become a standard industry approach. While the life sciences industry has been slower to adopt cutting-edge technologies than other sectors, fully connected and automated facilities that can create, interpret, and act upon reliable data will take advantage of all that digital manufacturing has to offer.

Embracing the Industry 4.0 revolution is going to be critical to future operational efficiency for all manufacturers. It may be some time before the pharma industry is able to complete the digital transformation and have fully automated and connected facilities that can take advantage of what digital manufacturing has to offer, but it is something that all companies need to be planning for.

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