Volume 16
Issue 1 *Steps Towards Digital Transformation in the Pharmaceutical Manufacturing Landscape Linking Data, Analytics, Knowledge and Risk*

Article 3

12-15-2021

"Deployment of Data Analytics to Support Manufacturing at Janssen"

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Deployment of Data Analytics to Support Manufacturing at Janssen

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Abstract:

This paper describes two key areas of value that data analytics supported for Janssen: yield optimisation and Tech. Transfer. By focusing on two key business areas the definition of success and scope was clearly understood by all stakeholders from key business leaders to shopfloor operators. Thus, the value of data analytics was apparent. The paper discusses key pitfalls to avoid and identifies two key investments for success.

What is the business context and what is the new use of data that took place?

Janssen Supply Chain is made up of sites and functions globally including Janssen Sciences Ireland, a world economic forum recognised lighthouse site where data analytics played a pivotal role in this recognition. In the time prior to such accolades, Janssen, like many other organisations went through a change management journey with data analytics at its centre. In recent years, there has been much hype around data use and data analytics, but the important questions remain unchanged - what is the value? who can benefit? and why do we need it? Data analytics provides organisations with significant opportunity for taking a proactive rather than reactive approach to organisational operation and management. While data structure, access to data and the delivery of a data pipeline were foundational activities that had to be completed to enable value-driven use of data at Janssen, the key ingredient to taking data analytics from proof of concept to broadly supporting the lifeblood of the business has been a long-term vision. However, while vision is critical, the journey has also involved an approach that assures our business users, the motivating business question and the associated value drivers, were, and are, at the core of Janssen's data analytics programmes.

As demands for Janssen's key products continue to increase across the business, the need to optimise manufacturing processes using new technologies such as data analytics has moved from a *nice to have* to a *must have*. However, prior to this realisation, the first step was proving the capability through "test and learns" executed in the manufacturing facilities to demonstrate the value of data analytics in a plant on live commercial processes. The key focus areas of value that data analytics could support were yield optimisation and integration of data analytics in tech transfer. Having identified two such key business imperatives to support and with an agreed definition of what successful delivery would look like, ensured that the scope was understood at the beginning of this journey and also ensured that all, from key business leaders to shopfloor operators, felt that data analytics was helping them directly and that they were on a meaningful journey with the technology. With the increased amount of data captured during the manufacturing process of a monoclonal antibody, advanced analytics-based monitoring systems are becoming more important factors in decision-making for management and day-to-day production activities, in particular, to ensure our products are always the highest yielding possible. Through the use of modelling techniques, such as multivariate analytics modelling with a focus on increasing output of product, yields have increased for key strategic products within our supply chain. Figure 1 below shows an Advised Future Model advising to adjust bleed rate of bioreactor within its specification range to increase total amount of product output.

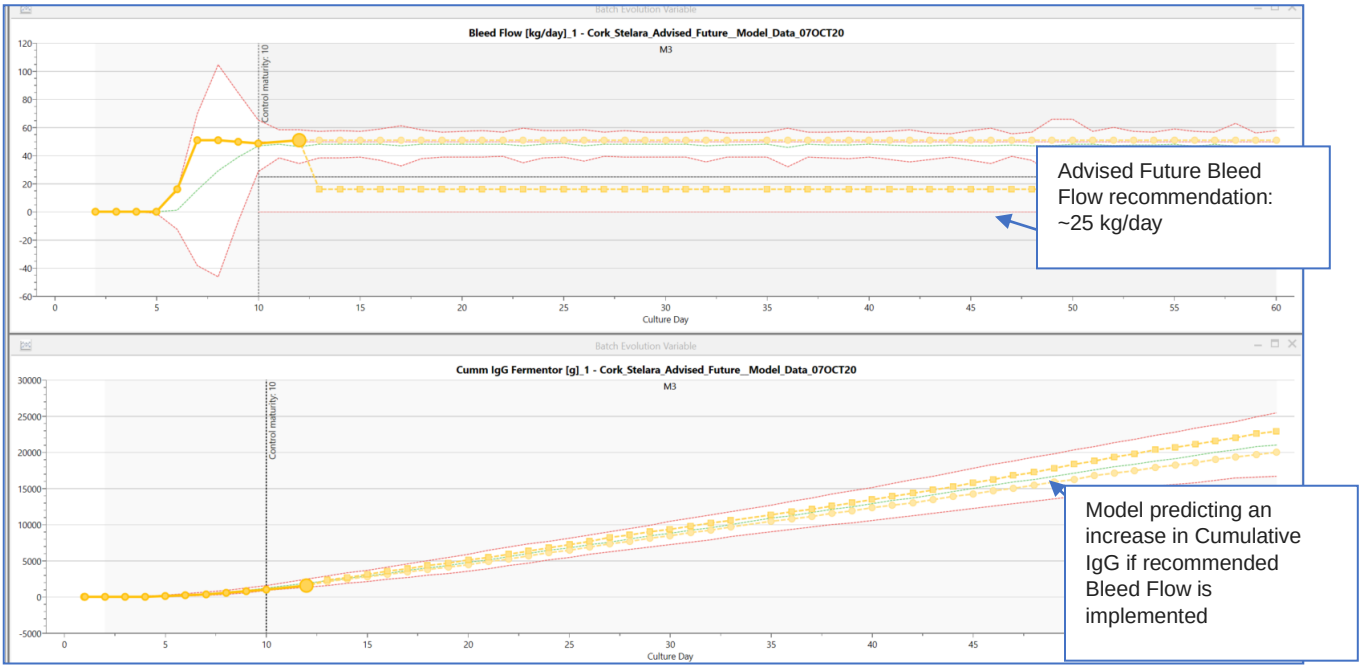

Fig 1: Advised Future Model advising to adjust bleed rate of bioreactor within its specification range to increase total amount of product output.

The Advised Future model was achieved through compiling historic data sets of the manufacturing process to represent common cause variation that exists. And through such variations, correlations to total output could be made from the process step. Additionally, use of data analytics has led to a more agile, smart tech transfer. Similar to yield optimisation, this has occurred through creating models representing the current manufacturing process at the representational scale of the process, and deployed with the product at its new facility to monitor real time differences e.g. varying pH profiles, flowrates, media addition patterns and similarity to the originating site of tech transfer. Figure 2 shows how a multivariate model was used to support the tech transfer of product from facility A to facility B. The multivariate Control chart demonstrates both facilities perform similar in batch production, however, on drill down, slight variation can be seen in pH providing SMEs real time information to determine if this is impactful, expected, and/or of concern prior to batch/PPQ completion.

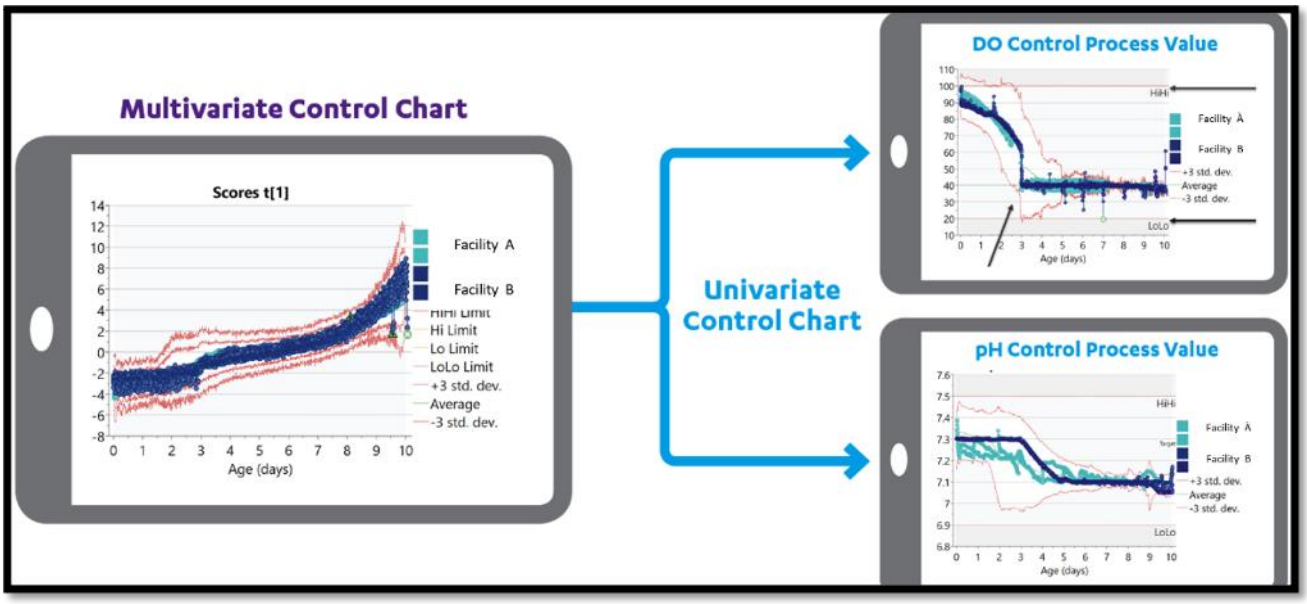

Fig 2: Tech Transfer Model

Fig 2 Model used at Facility A to support Tech Transfer of product to Facility B. Multivariate Control chart demonstrates that both facilities perform similarly in batch production

What drove this new use of data? What was the Journey and what was the impact?

Pharmaceutical and Biopharmaceutical processes are complex. The high levels of regulation in the industry requires that process variation be well understood for a given manufacturing process. The Janssen Supply Chain identified that, with so many investigations always ongoing, why does the same product with the same process and same equipment perform different at two different sites? how is there a 5% yield difference between two batches from the same campaign? These are key business questions that have lived with Janssen for many years now that can potentially be answered by just looking at the data in a different way via data analytics. Data analytics, through Mechanistic and Multivariate modelling along with other techniques, have shone a light on these areas that were otherwise potentially overlooked. For example, variation within the specification range of Critical Process Parameters (CPP) that may impact a response parameter such as Viable Cell Density which in turn can impact the yield of a product. Key to this effort has been technology management, which has ensured our leadership understood, and related directly to, the value generated by data analytics.

Under Janssen Supply Chains, an Advanced Process Control (APC) strategy, for a proof of concept, a real time, multivariate analytics tool was deployed across three key sites to understand in real time the variations occurring in the process. Currently Janssen's APC programme is focused on monitoring and forecasting its biologics and vaccine processes in real time with extension to a number of strategic contracts manufactures (CMO). In 2021 these tools will be expanded broadly to the small molecule platform within Janssen, and begin the journey to start using these tools to enable full feedback loop control of the biologicals manufacturing process. The key initial driver of the APC programme was to focus on opportunities for 'yield optimisation'. The APC strategy spoke for itself, as it raised yields for key products by between 5-30%. In order to ensure that data analytics could be fully adopted and endorsed by the business, a journey of change management with leadership and local users had to occur in tandem. This change management journey wasn't focused on the 'why' we *should* do it, but rather consisted of walking users across varying levels in the organisation and sites, showing what data analytics could do, the value it could bring in other areas of the business such as tech transfer, and that investment ultimately would be needed in data pipelines, cloud technology etc. which would transform the way in which Janssen supply chain operates.

Who are the person(s) at the centre of the effort?

At Janssen everyone is responsible for quality and the journey to having data analytics at the very core of our organisation was no different: everyone had a part to play. At Janssen the Advanced Technology Center of Excellence (ATCOE) initially led this proof of concept and the "test and learns" by being the incubators of innovation, identifying the key models and data analytics techniques that could bring the most value to the organisation. Today the ATCOE remains steadfast in identifying the most relevant and critical techniques to bring value from our data as well as supporting the technology management to ensure successful integration into our sites and platforms to enable adaptation across our entire supply chain. With this, the global team has centralised ownership for ensuring the business maintains and grows the value from data analytics consistently with long term vision and/or roadmaps in place.

Local sites have a key role in adapting these technologies and ensuring they are correctly deployed to their local sites in respect of site culture, maturity and skillsets available. A site additionally has a key role in ensuring they have a centralised talent pool available to create and maintain new data-based solutions. Often this is seen through local process SMEs e.g. chemical engineers with a natural background in data that can develop data analytics skills. This enables a hybrid approach to data analytics deployment i.e. one that is both process SME and data science led (see next question below for more details).

Access to data is key in ensuring that the value data analytics brings through e.g., yield optimisation and tech transfers, is robust. A core global team comprised of data engineers building a common data layer exists. This team ensures that all required system data is piped into a cloud-based solution for easy access for end users i.e. data scientists, chemical engineers, etc. to access. In tandem to this, an integrated data management team ensures such pipelines and data access is easy to execute, and incident management is in place to investigate and identify failures in the pipeline. Ultimately there is no one responsible person but a group of functions joining together, from the shopfloor operators at the site level to the global representatives in Centers of Excellence working towards one common goal - extracting value from our data to bring the best product to our patients.

What are the key pitfalls to avoid when implementing data analytics solutions?

Access to Data: Robust data is the key element required for any data analytics project. At Janssen the initial "test and learns" showed the gaps that existed in uncontextualised and non-centralised data sources. Source systems were reviewed, and unique identifiers created for all key data for easier end-user access. Key systems e.g. Manufacturing Executions Systems, eLIMS, SAP etc. were put into one common layer, based in a cloud solution. Finally, an end-user application was built so that the end-user e.g. Chemical engineer, data scientist, process SME, had the option to use an easy app. that would pull data through in their own unique data configuration or otherwise pull directly using e.g. Databricks or SQL.

Talent Recruitment: Like many companies, talent recruitment in this space has not been easy and Janssen has not been immune to such challenges either. Starting this journey, Janssen began quickly recruiting qualified data scientists to fill the gaps in what was determined as a critical need. However, while data scientists were and are required as SMEs in the area, it was found that those that brought the most value initially were already existing data-savvy members of the Janssen team. Chemical Engineers, Biotechnologists and Chemists, all individuals whose academic background required numerical assessment and often forms of programming, had a key role to play. These persons have knowledge of the current manufacturing process tied together with ability to process and analyse data, creating what might be termed a 'hybrid' data scientist. Recruiting across already existing talent can impact the retention of those you are today on your team, and these persons can be equally, if not more capable, given their knowledge of the current operations of the company and opportunities that exist for improvement.

Corporate Maturity: Maturity is roughly defined as the ability to know how to behave in your environment based on circumstance. Corporate maturity can be defined as the ability for an individual to adapt their natural work style to innovate, integrate and collaborate within the culture of their organisation and/or function to provide consistent value. Often 'pure' and 'hybrid' data scientists are like artists: they are of genius quality but can be explosively passionate with their work, particularly when constructive criticism is offered. This passion, however, can be seen by many, including leadership, as the inability to receive feedback and having lack of understanding of how the operations of a corporate organisation works.

Having such maturity to adapt the way you work and communicate in particular in new technical areas such as data science is critical. Corporate Maturity is a key element that companies such as Janssen need in order to ensure our new and current talent are supported, particularly our technical talent, to learn how to communicate and when and how to push back if needed. The story and interpretation associated with data is as critical as the analysis itself. Some put the pitfall down to the individuals 'not being leadership material' however, it is down to corporate maturity, a lack of exposure and learning for the talent to understand why this style may not work to every audience. Do not be mistaken: corporate maturity is not about standardisation but about helping the technical talent find their own personal style and then mature that to adapt it to the corporate world. A pillar of this maturity, which organisations such as Janssen must grow, is our talent's approach to how they solve a problem, and to know that it is ok to use tools already in the tool box for a new purpose or use an off the shelf software - we do not need to recreate the wheel. Like in life, as one matures and gets older, one learns to think before proceeding. However, like life, corporate maturity is not linear to age and corporate maturity is not linear to years of service: it depends on the individual, situations they have been exposed to, and natural personal style. Corporate maturity is a fundamental factor to ensure data analytics continues to grow within the life sciences to ensure that data analytics is not a *nice to have* but a *must have*!

Technology Management: If a data scientist is like an artist, then a technology manager is the curator. A large pitfall Janssen faced was creating these game changing data analytics tools but not having someone to project manage, to communicate with the business partners, develop strategic deployment plans, resource models, carry out spend/value tracking, and have someone to sell the data analytics solution itself. Take a car company: they do not just build the car. They have to identify their customers, they have to market it, build showrooms to sell it and sometimes even offer finance so people will buy it. The pitfall is sometimes we build the car and forget the remaining steps. Technology Management ensures that the data scientists and SMEs can focus on what they are good at, i.e. building the product while the Technology manager (TM) looks after the rest. In a sense the TM is a project manager who understands the intricates of the product being built i.e. data analytics based solutions. At Janssen we have seen project failure simply because the deployment strategy was wrong. The deployment did not fit in with a tactical roadmap and/or a site wasn't made aware that a solution was even being worked on by a global team. Technology management enables success and prevents failure. It ensures that consistent, robust value is always derived from data analytics-based projects, and that it leaves the artist do what they do best.

What were the ingredients to making the journey a success?

It would be remiss to say that the journey to data analytics is not tough and often costly. However, the value obtained from the end solution heavily outweighs the investment of time and money through increasing yield outputs, reducing non-conformances, and ultimately delivering a robust supply chain. This journey requires two key investments: Talent and Data.

- Having the correct **talent** is key in data analytics and having them at the time of creating the data pipeline, creating the business questions to address, and creating the tools that will be used to execute is critical. This involvement ensures that the creator is familiar with the process, the journey and the why. Many organisations often see hiring too early as counter-intuitive. However, in talent investment, and in particular in data science, having them on board leads to a higher level of engagement moving forward. Equally, hiring the correct talent in this space is critical. At Janssen many of our top data scientists are self-taught Chemical Engineers, Process SMEs and Biologists, who, through hands on experience and learning, have applied data science to solve key business questions such as yield increases and more agile tech transfers using data science. This is not to say there is not a place for 'pure' data scientists to be part of the Janssen community but to say that in our manufacturing and technical operations environments, we have seen first-hand that the most valuable models that have been implemented to support yield optimisation and/or tech transfer have been completed by these 'hybrid' data scientist or modellers (previously referred to above). The largest contributing factor to the 'hybrid' data scientist, is the corporate maturity of existing SMEs who know the culture, the process, the people and the journey that has to be completed with new innovations. Often the biggest changes have to come from those within before exploring external options. The 'hybrid' data or process scientist who knows the complex science, data maturity and complex process has generated significant value throughout the supply chain in the form of product optimisation and tech transfer. This hybrid approach has not negated the need for formally trained data scientists, but it highlighted to Janssen that talent in this space isn't a standard recruitment process but a technology journey that can also be supported from within.

- Janssen like many organisations had their systems isolated on data islands without bridges to connect, or a unified location. To process live data is now the fundamental requisite for the successful realisation of Industrial Internet of Things (IoT) in the pursuit of improved industrial performance through data analytics. With this in mind, Janssen moved from isolated source system data environments to a consolidated real time cloud based common data layer environment bringing process equipment, ERP and manufacturing execution systems together, with easy end-user configured output for all to ensure users have access to the correct, robust data for their use - whether it is for data analytics or general use. Prior to this, data were hard to get at with limited ability to use in support of data analytics and machine learning capabilities. While this may be a costly effort along with significant time contribution, it is a foundational element of all value that will arise from data analytics solutions.