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Gaining Organisational Acceptance of a Data Analytics Programme in Eli Lilly

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Abstract

This paper describes how Eli Lilly overcame barriers to enable new use of data. This was achieved by adopting a deep understanding of end-user needs and the support of site leaders and end-users to standardise process monitoring. A standard approach of 'Contexting', 'Data-Extraction', 'Model build', 'On-line Config', 'Deploy', was utilised, using a commercial off-the-shelf software. The paper describes proof of concept demonstrations undertaken and discusses the ingredients to make the journey a success.

What is the business context before this new use of data took place?

At Eli Lilly's API manufacturing facility in Kinsale, Ireland, data-driven decision-making is at the heart of its philosophy to support its manufacturing operations. However, barriers still exist that limit getting the most out of the data, including time-consuming manual work to extract and clean data, data analytics tools not fit for the job, and skillsets gaps to perform data analysis. The company actively seeks data analytics solutions that will provide more efficient ways to extract deeper process insights from our manufacturing processes. In recent years, the business focused on providing training on advanced data analytics to employees to build capabilities internally. Although there was some success in this, due to competing priorities the value obtained was limited to on a few areas on the manufacturing site, the data analysis was retrospective in nature, and involved a lot of manual non-value-added work.

It became apparent that an alternative approach was needed to achieve a broader reach across the site that would provide deeper process insights in an automated manner to remove non-value-added work. To achieve this, there was a shift in focus towards a real-time/predictive approach to process monitoring, rather than the conventional retrospective analysis of manufacturing data to assess process performance. In addition, standardising process monitoring approaches was seen as a key enabler to ensure the whole site conducts process monitoring in the most efficient and effective manner, and therefore a data analytics solution was needed to ensure everyone on site (operations, technical support, engineers, scientists) could extract process insights.

How did it come into existence, what drove it?

The initiative to develop an advanced real-time process monitoring solution at Eli Lilly's API manufacturing facility in Kinsale, Ireland was based around a deep understanding of end-users needs. The tangible needs for operators and technical support performing daily process monitoring, along with the pains (manual and heavy workload analysing process data) and barriers (difficulty accessing the right data) they encounter was central to developing and piloting the data analytics solution. In addition, a drive from the business locally on site to standardise process monitoring was another reason to pursue this effort.

There is a global digital plant strategy in operation at Eli Lilly. The approach was taken in line with the strategy whereby organisational "buy-in" could be achieved through multiple highly impactful use cases combined with a clear "value-added" argument for the business. Therefore, this real-time advanced process monitoring solution was initiated at the Kinsale API site, rather than a globally driven digital solution. This global digital plant committee would then prove pivotal to ensure expansion of successful digital solutions across the manufacturing organisation, which was the case for this initiative. Developing and piloting the solution locally ensured the programme was kept grounded, close to end-users, continuously confirming it was meeting the needs of manufacturing sites. This will be elaborated upon further in the sections below.

Along with having the commitment from the business and organisational governance in place, availability and bandwidth of a working team was pivotal to ensuring that this project could start. Led by the site statistician, a small team that was passionate, that had the technical capabilities and bandwidth, spent the early days on this project focused on exploring solutions, understanding the detailed aspects of building a process monitoring tool and initiating a proof of concept.

What is this effort or journey?

Eli Lilly initiated an advanced process monitoring programme through the utilisation of commercial software solutions along with in-house built data infrastructure. This journey started from a concept at the Eli Lilly API manufacturing site, Kinsale, Ireland. It was sponsored as a proof of concept through the global digital plant governance committee. During the proof of concept stage, the effort was at the local site level where a small team of statisticians, IT, scientists, engineering and operations engaged to build and pilot a multivariate process monitoring (MVPM) solution. The high engagement from end-users in the plant and positive feedback led to this concept being approved as a global solution with replication in multiple manufacturing sites.

New software tools were introduced to the site, which were capable of extracting value from historical process datasets and integrating real-time data streams. A data historian and off-the-shelf software were used to enable multivariate model building and online integration of the models. By leveraging commercial software, the team spent their time on value added activities such as process understanding to build appropriate multivariate statistical models, rather than building in-house data analytics solutions and data infrastructure. This enabled quick build and implementation of the process monitoring solution for a unit operation. The turnaround of a model for each unit operations was approximately 4 weeks during this pilot. Very quickly, it was realised the implementation of such monitoring models could be standardised, breaking the effort into a number of distinct exercises described below and in Figure 1:

1. Contexting: Identify triggers to define beginning and end of each sub-step – enables automation of data extraction and modelling in real-time

2. Data Extraction: Based on needs and scope identified by process SME

3. Model Build: Using statistical modelling software to build appropriate model for process monitoring

4. Online Config: Configure the model to connect to the real-time data source to allow online real-time multivariate process monitoring

5. Deploy: Train end users and go-live.

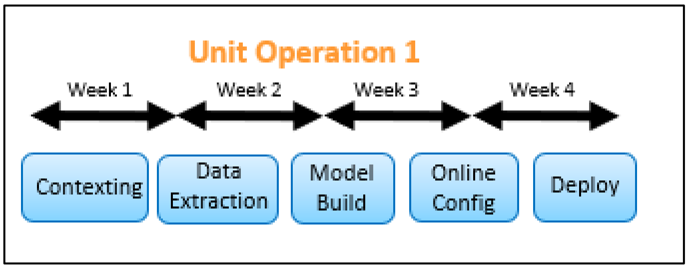

Figure 1: Standardised approach for the model building and deployment activity

The combination of utilising commercial off-the-shelf software (avoiding the need to build in-house solutions) and standardising the model building and deployment allowed the business to realise value within a few weeks of starting the work in a process area. The standardised approach gave expanded responsibilities to model builders to not only build multivariate statistical models, but also learn the unit operation automation steps to identify phase contextualisation triggers, extraction of data, and training of end-users. This also minimised the time required from process experts (due to their limited availability). This resulting fast and agile deployment approach was a significant factor with the acceptance and commitment of this programme from the business.

Who is the responsible person(s) at the centre of the effort?

Globally, the Digital Plant governance has responsibility for sanctioning proof of concept related to digital technologies and subsequent expansion. However, it is the manufacturing sites themselves that have responsibility for identifying concepts and resourcing proof of concepts. Such was the case for this advanced multivariate process monitoring initiative. At the core of this initiative is the application of statistical multivariate models in real-time to aid process monitoring for technical support and operations. As a result, the site statistician, Anthony Maguire, was responsible for initiating and leading this project through from concept to deployment. Along with having bandwidth to pursue this initiative, Anthony's physical presence on-site and relationship with end-users was critical to ensuring the programme's success. In addition, for success of this initiative, knowledge was also required on the automation control system, data historian, and the data infrastructure on site.

Since this project was primarily based on implementing and configuring off-the-shelf commercial software, most of the effort was the statistician working with process experts to build the process monitoring models. In addition, input from data historian administrators and the IT infrastructure team was also required to setup and configure the system. Once setup, the maintenance of the system was minimal, and most of the effort was the statistician working with process experts building models.

Since the completion of the proof of concept work to implement advanced multivariate process monitoring, the effort focused towards the full deployment within the Kinsale site and replication in other manufacturing sites. The programme’s vision is to build process monitoring models for all unit operations. To accelerate deployment, a small team of model builders was established with the responsibility of collaborating with process experts to build and deploy multivariate models for process monitoring.

Intentionally, the business decided it was not a requirement that those building models should be specialists in statistics and data science. This business model was supported by the fact that modelling software was standard off the shelf that did not require specialised knowledge. In addition, as mentioned previously, statistical modelling is only one aspect in the deployment. Individuals that understand the site data infrastructure, ability to work closely with operations and tech support, ability to work independently to study how the process operates and is automated was deemed a more appropriate fit for this programme. As a result, we looked internally within the business for individuals who have a passion for this work.

What impact was delivered / is still being delivered?

This new paradigm in real time MVPM ultimately provides deeper process understanding and a range of enhancements and efficiencies, such as early fault-detection, detection of aberrant process behaviour as well as risk- and resource management. These have immediate quantifiable savings in terms of reduced FTE hours on process investigations, batches saved etc. There are also less quantifiable efficiency gains. Examples include a shift from reactive to proactive operator monitoring and increased opportunity for more standardised workflows in process monitoring both enabled by moving large, complex process datasets, captured in real time, to simpler multivariate monitoring graphs.

The new paradigm of process monitoring is agnostic of process type. Small and large molecule batch manufacturing, as well as continuous manufacturing for small molecules, all take place at the Kinsale site and real-time MVPM has been implemented in all of these processes. Hence, a wide range of unit operations (each using an identical platform and user-interface) have been brought into the new process monitoring paradigm including bioreactors, purification systems, crystallisation, centrifugation and different continuous manufacturing process operations.

Where the real-time MVPM has been implemented, the end-users such as the operators as well as the process scientists and engineers are seeing significant benefits through easy and efficient access to data, enhanced process insights, as well as detecting potential process deviations in real time. This high engagement was evident when operators even asked for specific models to be built that would help them in their work.

To summarise, the success of this initiative is primarily as a result of the overall impact to the business, providing deep process insights in a simplified way, with a broad reach (operators, engineers, scientists, manager).

How did this effort or journey progress from inception to POC to current state?

The programme was initiated with low-risk, high-impact proof of concept (POC) demonstrations. Real time MVPM was implemented for a bioreactor in a step wise manner, from data-contexting, extraction, off-line multivariate model building, on-line model transfer and configuration to final deployment. Notably this effort was achieved within a high-intensity period of four weeks.

In order to deliver these high-intensity, high impact POCs, several ingredients were required. Good documentation of control strategies, control parameters and plant systems were significant in enabling the effort. The POC effort was anchored primarily by an employee with significant process knowledge, experience of site infrastructure as well as a core statistics and data science skillset. This facilitated a very lean operation in delivering an impactful POC where the face-to-face time with the process SMEs could be minimised – as mentioned previously.

Critical to developing the site-wide real time MVPM capability was the need to listen to the end user, often an operator, and to take an iterative approach i.e. develop and demonstrate, accept feedback from the end-user and then version up to improve the offering and capability.

Having successfully proven the feasibility and efficiency of the rapid model building roadmap, and the suitability of the selected software tools, the results from first POC study were presented to the manufacturing site directors. A live demonstration of the MVPM model in action was subsequently performed for the shift supervisors. Positive feedback was received from both, resulting in a request for an expansion of the POC resulting in a pilot for other operations on site.

The second model was for a Steam-in-Place (SIP) operation used for sterilisation of a bioreactor and demonstrated its value just eight minutes into its live demonstration, when it detected abnormal behaviour of an agitator seal control valve, avoiding the potential for a seal breakage and leakage into the bioreactor, preventing a major process deviation. Acting on this early warning, the process operator was able to resolve the issue with no impact to the batch. Armed with functional models and an increasing body of real-time data, further demonstrations were prepared to illustrate the positive outcomes of this real-time multivariate process monitoring approach.

Over a 12-month piloting period, real-time multivariate process monitoring models were built for seven unit operations. Live demonstrations of the real time MVPM capabilities were particularly persuasive tools in gaining support from senior management. An immediate visual and real demonstration of the capability made an impact.

The programme received cross-functional support and sanction to expand its scope to develop a site-wide multivariate process monitoring programme. In the following year, a small team was established to build and deploy models. Using the same data source and analysis tools across each project, the team was able to easily build in standardisation and harmonised data flows. Fifteen months after the first POC project at Kinsale was initiated, the Eli Lilly approved a global programme for a plant-wide multivariate process monitoring programme, with commitment from key global function heads across Operations, Technical Services, Engineering & IT.

Along with expanding the programme in the Kinsale manufacturing site, this process monitoring programme has expanded to multiple other sites within Eli Lilly.

What were the ingredients to making the journey a success?

Support from business: Focusing the results of this real time MVPM effort on the core business needs of making medicine, with a focus on safety and quality was critical for success. Where the manufacturing business believes in the solution offered and decides to champion it all the way from POC through deployment, transformative use of data is possible.

Broad Reach: This programme brought value to many key functions within the manufacturing sites (operations, technical services, engineering). This broad reach increases the overall impact and value to the business and therefore has a higher chance of success and global support.

Real time Visuals: Real time visuals and demonstrations of the MVPM model in operation presented to senior management helped to communicate the value and gain endorsement.

Listening to the end user: It is important to understand the needs of the end user. Walk-the-walk of end user – listen to them.

Delivering New Capability: Early warning signals of atypical events in process manufacturing were captured.

Automated data extraction and contextualisation of data: This delivered data at almost no effort for end-user in terms manual data pulling or data cleaning. The platform was easy to use and does not require knowledge in data analytics.

'Off-the-shelf' software: The effort also benefited from true 'off-the-shelf' software, so no new custom software or IT infrastructure build was needed (appropriate electronic data source, e.g. historian was available). The software was also agile so that it could be easily applied to many diverse types of unit operations and replication was easy with everyone using the same platform/interface.

POC and pilot were delivered quickly: During the initial POC and pilot phase the focus was solely on delivering end solutions in an agile and fast manner. This speed to build and deploy many models during the pilot phase to get broad end-user exposure was a significant factor in the success and support of this program. Documentation and procedural requirements and engagement with other business functions (Quality, Training, etc) were addressed after commitment from the business.

Analytics were automated: Training of personnel alone was not enough to initiate new ways of using data.