People Perspectives in the Deployment of Data Analytics for New Knowledge Generation in Pharmaceutical Manufacturing

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Abstract

Digital medicine manufacturing of the future will almost certainly involve greater use of advanced analytics tools for more data-driven decision-making. In this article, the role of people in the deployment of data analytics tools within the pharmaceutical manufacturing setting is explored. Some perspectives are presented for how people can make sense of working cross-functionally on the analytics journey to deliver new knowledge and insights that enable data-driven decisions to be made. Data analytics is defined and is proposed as a critical common ground between the "on-the-ground" data practitioners and the decision-makers who act on new knowledge. Reference is made to published cases on the role of people in deploying advanced analytics tools for gaining new knowledge and insight across pharmaceutical manufacturing.

Introduction

The rapidly expanding volume and variety of data, coupled with the drive to integrate data analytics and other digital technologies as standard ways of operating, is transforming all sectors and all organisations. A quick google search of data likens it to "oil", "gold", "sunshine" and the "raw material" of business. While there is an air of hype to such representations, the potential value to be gained from working with large data sets and advanced analytics tools can't be ignored. In the case of pharmaceutical manufacturing, analytics tools are enabling advanced multivariate process monitoring for improved process robustness, operating efficiency, cost reduction and improving knowledge during technology transfers.[1,2] Advanced Process Control (APC) strategies, including inline spectroscopy-based Process Analytical Technologies (PAT), are being implemented to reduce or eliminate manual sampling and QC testing, to maximize yields and minimize batch-to-batch variability for improved supply chain stability and even to support real time release testing of products. [3-5]

Statistical data analysis plays a central role in managing risk, developing product control strategies, and to continually deliver quality compliant medicines for patients. The pharmaceutical industry is going through significant change to adopt more advanced statistical analytics and digital technologies that improve supply chain robustness. The FDA reported in 2019 that 62% of medicine supply shortages arose due to quality issues.[6,7] This prompted the development of a on-going pilot program by the FDA that attempts to reward companies based on their quality management maturity.[8] A mature approach to quality and risk management involves a mature approach to knowledge management which, in turn,

necessitates a mature approach to the deployment and integration of analytics tools to generate new insights and understanding for making data-driven decisions. While much emphasis on has been placed on the use of new systems and technology in the age of industry 4.0, people have, and always will be, at the heart of integrating and driving organisational change.

The aim of this article is to share some current perspectives on the role that people play in integrating advanced analytics solutions to support knowledge enablement and data-driven decision-making. Highlighted below are some perspectives for how people can make sense of the cross-functional analytics journey to deliver new knowledge and insights that enable data-driven decisions. These perspectives reflect just some of the findings of a good practice to data analytics for pharmaceutical manufacturing, which was the product of an industry-regulatory-academic partnership facilitated through the Pharmaceutical Manufacturing Technology Centre (PMTC - www.pmtc.ie) based at the University of Limerick in Ireland.

Speaking the same Language

Definitions are important. Definitions provide an anchor point for people across the interdisciplinary landscape of pharmaceutical manufacturing. Pharmaceutical regulatory documentation and guidance is careful to include relevant glossaries with its key documents for this very reason. Definitions around data use and data analytics are no different. So then, isn't data analytics just analysing data?

The PMTC has created a good practice guide to data analytics in collaboration with its industrial, regulatory and academic partners.[9] In an attempt to clarify the language and terminology around data use and data analytics, the PMTC good practice guide contains a detailed pharma-centric, well-referenced glossary of terms for data analytics. One of the critical terms defined is, of course, data analytics itself. According to the ISO definition, data analytics is defined as a composite concept consisting of data acquisition, data collection, data validation, data processing, including data quantification, data visualisation, and data interpretation. Data analytics is used to understand objects represented by data, to make predictions for a given situation, and to recommend on steps to achieve objectives. The insights obtained from analytics are used for various purposes such as decision-making, research, sustainable development, design, planning, etc. (ISO/IEC 20546:2019) The ISO also define data science as the "extraction of actionable knowledge from data through a process of discovery, or hypothesis and hypothesis testing" (ISO/IEC 20546:2019). The term data analytics, or data science, may well be used interchangeably. Both seek to be data-driven in their understanding and decision-making. And both require people executing across a range of often overlapping functions and roles.

People for Progress

It is generally accepted that data science or data analytics leverages skills across three areas: (1) computer science and IT, (2) mathematics and statistics and (3) subject matter or domain

expertise. Siebert has argued for a fourth relevant area, namely, intra/entrepreneurship qualities, [10] typical of the business and finance domains. Figure 1 below illustrates a structure for data-driven decision making which highlights the central and significant role that people play when organisations arrive at data-driven decisions. The fundamental domains of expertise are shown at the base of the pyramid. The synergies between the domains give rise to the roles and functions that people must execute across when working with data and deploying analytics-based solutions. Drawing on its industry case studies, the PMTC good practice guide highlights that more than one role may be performed by a single person, or many persons may be dedicated to performing a single role. [9] Subject matter experts (SMEs) in particular, are often critical players in delivering the analytics-based solutions. For example, they can help to appropriately define a model, perform activities such as gathering and contextualising data sets, screening variables and providing the feedback to generate deeper scientific process understanding. More is given to this topic of coupling subject matter expertise with data analytics in the PMTC good practice guide. [9]

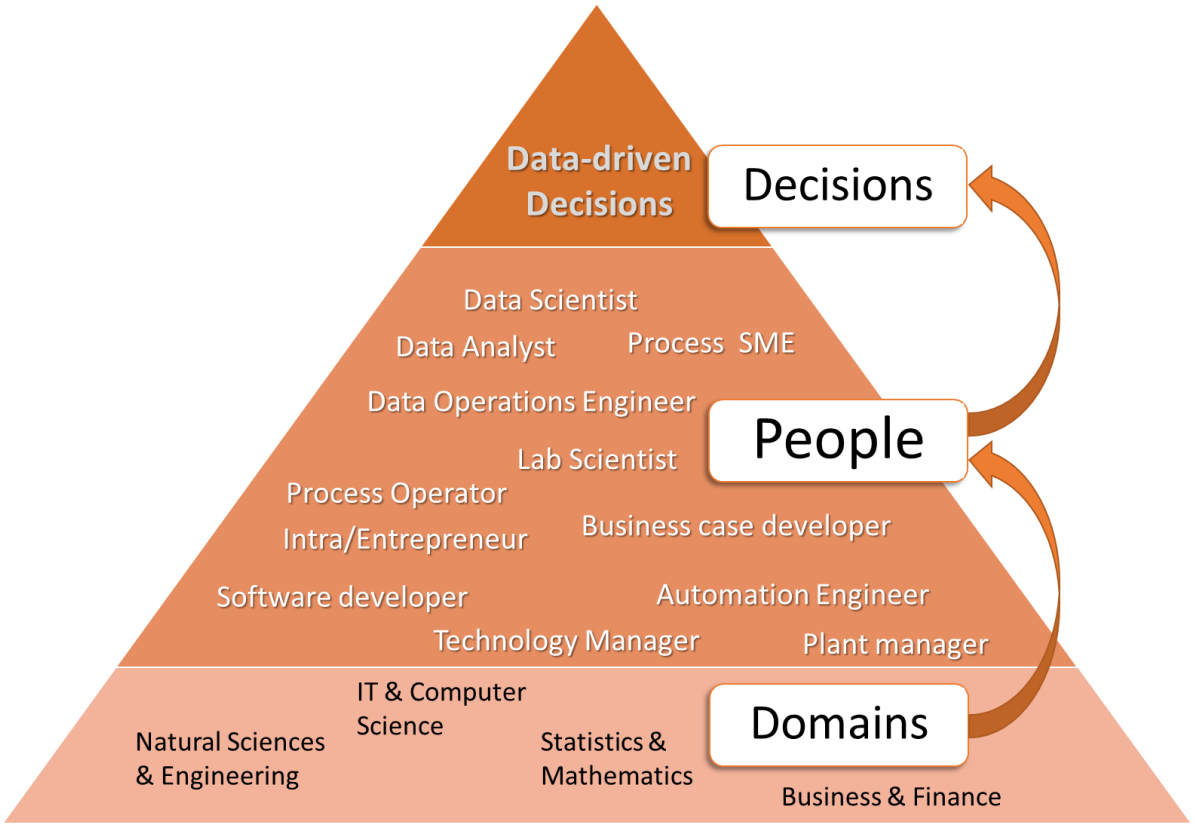

Figure 1: The structure of data-driven decision-making and the role that people play in getting there

Reports on the role of people in deploying analytics-based solutions have highlighted that pure data scientists are not always needed to deliver value and that statistical model builders only support one aspect to deploying value-adding, analytics-based solutions. The global advanced analytics team at Janssen have reported that while there is a place for purely trained data scientists, some of their top data scientists are self-taught chemical engineers, process SMEs and biologists. These self-taught data scientists, through their experience and

learning, have applied data science to solve key business questions, such as yield increases and more agile tech transfers using data science.[2] At Eli Lilly, a global program for multivariate process monitoring highlighted that statistical modelling was only one aspect deploying the advanced analytics solution.[1] Individuals internal to the company that understood the site data infrastructure, had ability to work closely with operations and tech support, had ability to work independently to study how the process operates and is automated, were deemed a more appropriate fit and were sought internally within the business. Both of these examples above identify the critically of people in delivering valuable new knowledge and insight through the deployment of advanced analytics solutions.

People's ability to quickly access data means quicker access to knowledge for greater insight and understanding. Again, people and analytics-based activities are central to making this a reality. Searching for data is frustrating and time-consuming. In a case study from Alkermes, where a data architecture was built to support product development, the ability to find relevant data at will had a noticeable, positive impact on job satisfaction and team productivity. [11]

The change management process is about managing people through organisational change. It is at the core of deploying new analytics-based solutions for new knowledge and insight. Pitfalls to avoid and markers for success have been well highlighted.[1,2,11] Change management is a key area for enabling better knowledge capture and knowledge management and this has been somewhat explored. [12] The change management process in the context of deploying analytics-based tools within the pharma manufacturing environment requires greater exploration and investigation. This will be a key topic of future publications.

People to Help make the Leap from Data to Knowledge

Data and data analytics are vehicles for knowledge which, when integrated with existing knowledge and expertise, can lead to greater process understanding. Ideally, the end destination of new knowledge and better process understanding is its integration within the pharmaceutical knowledge management and quality risk management systems. (ICH Q10) Obviously, people are, once again, core to all these activities and the key enablers for integrating across different system boundaries.

Figure 2 illustrates an adapted representation of an information theory diagram [13,14] that was first presented in the PMTC good practice guide to data analytics.[9] It shows data as it progresses to greater levels of understanding across different context and boundaries. At low levels of understanding, raw data are bound up in different (infra)structures and access frameworks. Accessing the data, working it up and transforming it through data engineers, automation engineers and data scientists generates predictions, insights and knowledge not previously available. The ability to integrate this data and knowledge further to greater process understanding will rely on people again, for example, often plant managers, operators or subject matter experts. Finally, teams of people involved in knowledge

management and product quality risk management are needed to integrate this new knowledge further to manifest its full benefit to business and patient.

There are two notable divisions of the role of people in Figure 2; data practitioners and decision-makers. The data practitioners are those who are "on-the-ground" working to make the data accessible, transform it, visualise it and make predictions and classifications from it. The decision-makers, who must use it and integrate it to deliver value for both business and patient. Note there is natural overlap between the roles, and people may well play the role of practitioner and decision maker. In any case, data analytics is proposed as a critical common ground between the "on-the-ground" data practitioners and decision-makers. Recognising and understanding those roles and boundaries may help to make the leap from data to knowledge sooner while also better enabling data-driven decision-making.

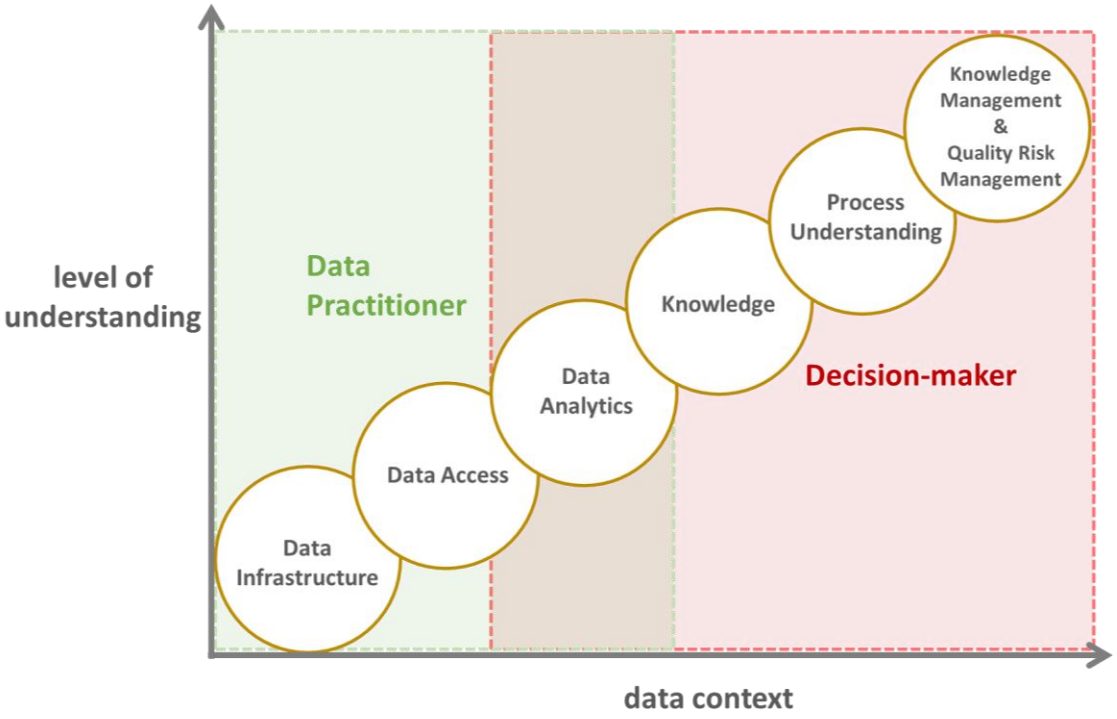

Figure 2: Information Theory in the context of pharmaceutical manufacturing illustrating how data are transformed to new knowledge via analytics and opportunities for its further integration into knowledge and risk management systems. The overlapping roles of people, categorised as data practitioner and decision-maker, is also highlighted.

Conversations between data practitioners and decision-makers are also critical. A recent report by the HMA/EMA subgroup on data analytics is an excellent pharma relevant reference and resource to aid conversations between the decision-makers and data practitioners. [15]

A Pertinent Example in Technology Transfer

A final technical example pertinent to this particular special journal issue on knowledge enabled technology transfer illustrates how advanced analytics were used to ensure how knowledge-enabled tech transfer could take place between different manufacturing sites.

Data analytics has been shown to enable more agile, smart tech transfers. Figure 3 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 drilling 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. [2]

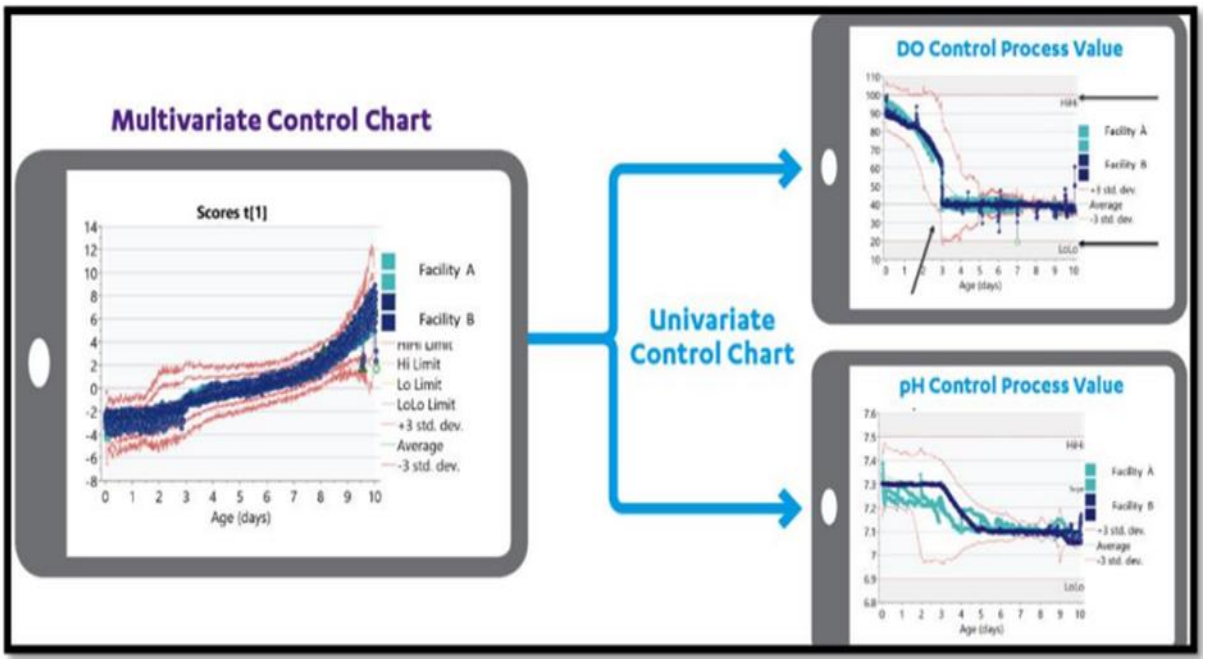

Figure 3: Model used at Facility A to support Tech Transfer of product to Facility B. Multivariate Control chart demonstrates that both facilities perform similarly in batch production (reproduced with permission – see reference 2)

In conversation with its industry partners, PMTC has identified, in similar examples, that the benefit to operators and people on the ground when deploying analytics for new process knowledge has been significant and transformational - with some making reference to the deployed analytics tools as their “Digital Arm”. These positive stories (along with less positive ones) are part of the change management journey for analytics deployment in pharma manufacturing. This requires more exploration and will be detailed in a later publication.

Summary

Currently, most of the focus of industry 4.0 has been on developing new systems and new digital technologies. When it comes to successful deployment, people are the key drivers and

integrators of change. This article has highlighted some of the roles and boundaries that we must integrate across in the deployment of advanced analytics tools in order to encourage a more knowledge enable future for medicine manufacture. Data analytics can be seen as a critical common ground between the "on-the-ground" data practitioners and decision-makers when deploying analytics-based solutions. The people working in pharmaceutical manufacturing using data and advanced analytics tools for new knowledge and insight have the potential to deliver tremendous value for both business and patient. Advanced analytics is a key pillar of the digital age for supporting data-driven decision-making, and people are its critical enablers.

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