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ESTABLISHING DATA-DRIVEN DESIGN AND MANUFACTURING FOR MEDICAL DEVICES

In this article, Frederick Gertz, Manager of Data and Process Innovation at SHL, explores the benefits for medical device design and manufacturing organisations of adapting to the use of big data and analytics.

Drastic changes in the development and manufacturing landscape mean the typical tools established for decades in the manufacturing space – lean processes, total quality management, just in time and enterprise resource planning (ERP) systems – no longer provide the edge or the guarantee of competitive profits that they once did.[1,2] Industry stalwarts will point to a variety of reasons: lower costs, globalisation and increased regulations being the common scapegoats as the medical device industry tries to pinpoint the exact genesis that leads us to where we are now. But everyone agrees the last few decades have seen a drastic change within the community as it shifts to becoming increasingly competitive, cost sensitive and high paced.

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The introduction of multiple consumer tech players such as Google, Amazon, Samsung and Apple has only served to increase the pressure, pushing established and new players alike to innovate both in product and process. Modern enterprises are now turning to big data and analytics to guide them in producing enterprises that are more agile, efficient and robust. These data-driven enterprises are increasingly becoming the norm in the industry, although adapting your organisation to such a paradigm is full of challenges and opportunities.[3] SHL is currently undergoing its own digital transformation and beginning to use a variety of tools, including machine learning and predictive modelling, to leverage new advantages within our organisation.

Certainly, the advantages of following an organisation-wide, data-driven methodology are well established. Studies show that organisations following these practices can gain 4-6% increases in productivity[4] over their competitors, so it is small wonder that only 30% of the industry would consider themselves data mature.[5] Despite the success of these philosophies at places like Google, relatively few medical device contract development organisations (CDOs) and contract manufacturing organisations (CMOs) have taken the step to commit to a corporate-wide data-driven enterprise.

With much of the medical device industry built on legacy models – and with a much stronger need to include risk mitigation and regulatory oversight into the process – the sector has been slow to adapt to overcome the challenges of becoming an industry of fully data-driven design methodology (DDDM) organisations.

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Figure 1: The challenges of moving to a data-driven design methodology organisation.

UNDERSTANDING THE CHALLENGES

With so much pressure placed on the industry and with such well-established upsides, why has data-driven design and manufacture not become the norm within the space? Even with the wide acceptance that data-driven methodologies will offer many benefits, it should be noted that the transition to a true DDDM organisation is not without its own challenges (Figure 1).

First, the necessary infrastructure and organisational change requirements appear daunting.[6] Pharmaceuticals is a great example, with many companies making investments in the hundreds of millions of dollars, establishing large portfolios in analytics and transforming their IT core to be capable of handling the required data. Smaller organisations that have not yet established mature infrastructure for data analytics frequently question what sources they can use to generate high-quality data,[7] with data availability being one of their largest concerns. Frequently, they overlook opportunities both internally and externally to collect data. Many technical organisations will overlook the wealth of data being generated by their marketing and business units.

As infrastructure such as NoSQL databases becomes more common, the ability to collect and harness the ephemeral data throughout the company becomes more and more achievable. Tools such as natural language processing (NLP)[8] and unsupervised machine learning techniques offer a wealth of opportunity to begin finding value within the data already on hand in virtually any organisation.

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One of the largest shortcomings of many manufacturing and design operations is the focus on data internally. External data such as customer feedback data, patient data and external marketing data all provide vital input for all phases of the product lifecycle. Competition analysis, including through the US FDA's adverse events database, can serve as a critical function for benchmarking current product offerings to competitors.

Analysis of possible features available in the space can further support the identification of future needs. For complicated combination products such as autoinjectors, performance may be based on components provided by a variety of contractors, with no clear exchange of manufacturing and performance criteria between them. All this information can, in theory, serve a vital purpose for the technical design and manufacturing team.

Engineers should be made aware of the competitive space and patient/customer feedback on their designs so as to ensure it is incorporated into later updates or subsequent products; manufacturing should be made aware of challenges faced by the design team, as well as from product recalls related to manufacturing issues. This shows how data from later stages in product development – which is not always made available to the technical teams – can be some of the most important data for those teams to gain access to. Empowered with the knowledge of how design and manufacturing decisions impact customers and patients, organisations develop DDDM with direct impact on the market.

Beyond that, many larger organisations, thanks to low-cost Internet of Things (IoT) sensors,[9] industry-wide digital transformations and the very nature of modern work, have produced massive amounts of data during the product lifecycle. Estimates of the growth of worldwide corporate data are currently in the zettabyte range,[10] with companies increasingly turning to large cloud platforms to handle their mass data production.

> "By making data more transparent, designers gain better insight into manufacturing capability and manufacturers gain increasing insight into product function and areas of criticality."

Even with all this corporate information, surveys have found that 44% of employees do not know where to find information they need to perform day-to-day work.[11] This only goes to show that the quality of the data collected, and the tools used to gain insights into that data, are far more important than the sheer amount of data. Other surveys point to a host of issues with data being considered siloed, incomplete or resulting in insights that are not actionable.

Finally, mindset becomes the largest barrier for many organisations, no matter what size. The implementation of data-driven methodologies requires a clear change away from intuition-based decisions and a commitment throughout the organisation to drive decisions based on a company's data, even if that requires going through the necessary processes and experimentation to gather more. Organisations with the desire to become truly data-driven will need to drive the culture through the organisation from the top, using centres of excellence and internal champions of DDDM to ensure that the methodology is instilled throughout the enterprise. With these challenges, many organisations will struggle to see the numerous benefits that await fully DDDM organisations.

INTEGRATING DESIGN AND MANUFACTURING

By making data more transparent, designers gain better insight into manufacturing capability and manufacturers gain increasing

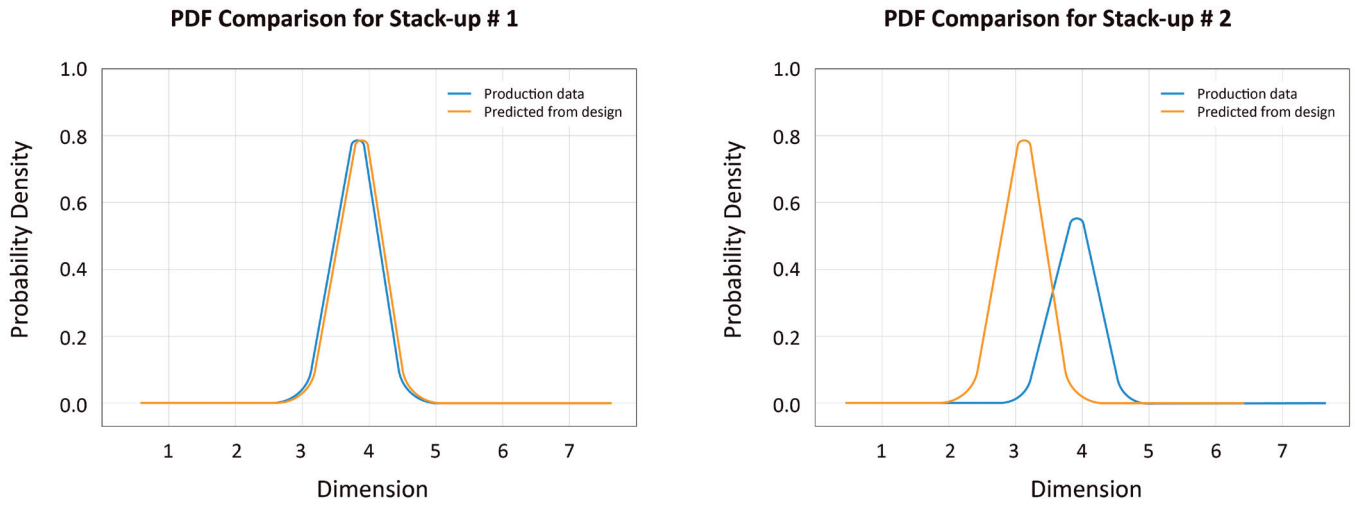

Figure 2: The overlapping probability distribution functions between manufacturing and design data for two different stack-ups.

insight into product function and areas of criticality. Data transparency indicates easier access to historical data for designers, reliable simulations and models for the testing of design decisions, accurate design output and customer feedback.

Thus, organisations with DDDM gain considerable insight and advantage. Product lifecycle management tools[12] have evolved over the last two decades to enterprise-wide solutions that combine the technical data produced in design and simulation with data from manufacturing execution systems (MES), supply chain, ERP and business informatics to allow access across a product's entire lifecycle. These systems alone will not solve the problems but the wide availability of these mature infrastructures, when combined with big data and analytics, form the basis of any modern organisation's DDDM. By creating a single source of truth, stakeholders across the organisation can more easily interact and ultimately collaborate to make products with the highest level of value to everyone.

SHL has a unique opportunity within the medical device manufacturing landscape. As a vertically integrated company that combines design and manufacturing, we are uniquely situated to see the impacts of data-driven decision making across these functions. With a variety of functions – including design, tooling, automation, moulding and assembly as well as management functions such as project management and business development – it is vital that, moving forward, SHL has a clear understanding of how these entities affect the overall structure of a product's lifecycle.

Initiatives are underway to communicate the process capability transparently to our engineers so that, when undergoing design for manufacture (DFM), activities are already aligned between those teams. More importantly, we are supporting the design process by making historical design decisions more transparent at the beginning of projects, effectively helping designers by giving them content and knowledge to work with on day one. This supports designers for future products and manufacturing when conducting investigations or carrying out their standard continuous improvement duties.

Figure 2 shows the historical process improvement when compared with the predicted process used in our engineering tolerance analysis. Furthermore, this data has potential for a variety of uses. The left image shows a stack-up of parts being produced just as the design engineers intended, while the right image shows that there is a shift from the designers' nominal value in production. Using this information, designers can decide whether certain components need adjustment to account for the manufacturing processes, while manufacturers can compare their processes to the designers' ideal. By comparing these production shifts to the original failure mode and effects analysis (FMEA), designers and manufacturers can almost immediately calculate the risk associated with a process shift.

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Models developed from historical data can form the basis of predictive analytics that analyse batches and forecast performance and quality issues. Internal MES systems can be leveraged, along with a robust maintenance programme that uses predetermined key performance indicators to ensure tools are still producing quality parts throughout the lifetime of the programme and react proactively to possible issues, allowing for preventative actions to be taken. All of this can be linked with our logistics data directly to determine impact on both supply teams and business units.

TURNING CHALLENGES INTO OPPORTUNITIES

This level of interactivity shows how the transparency of a single piece of data can yield results across multiple stakeholders. Now, with the impact understood, the organisation is empowered to make decisions that can mitigate and manage the areas where uncertainty still exists. As organisations become more empowered by data, they become more capable of reacting much faster and gaining competitive advantages across several fronts. These capabilities are also in reach for a variety of manufacturers across the industry who all stand to gain from the use of DDDM.

Data-driven design, contrary to popular belief, does not intend to replace the designer or, more frequently, team of designers in this process but to improve the starting point and design process. Does the design meet the requirements? Is the design compliant from a regulatory perspective? Can the design be manufactured with the available manufacturing process capabilities? These questions and more are very much at the

core of the data-driven design methodology and very much the questions that DDDM intends to make more transparent. Using a variety of tools, designers can link their designs directly to the requirements they are fulfilling – clearly demonstrating how their designs match the requirements.

Modern factories are required to be more flexible and agile than ever before. Especially in medical devices, where regulatory burden is high, applying appropriate risk mitigation techniques is paramount. In fact, unexpected losses due to quality concerns within the medical devices industry account for >US$4 billion (£3.2 billion) in lost revenue for the industry.[13] By using big data and modern analytics, manufacturers can gain true understandings of their processes as well as simulating and assessing the risk in making changes. Data-driven organisations can plan logistics better, adaptably shift workloads and quickly solve problems.[14–16] Fully understanding variation within the manufacturing system is now achievable and can lead to much quicker resolution of errors.

Simulations and rapid prototyping of these now linked features allows for quick feedback into the design process to validate whether specifics of the design are accomplishing their goal, at quicker rates and smaller costs than have been used in the past. Hybrid approaches that leverage model-based approaches with data-driven approaches have begun to be used, allowing for leverage of historical big data and simulated data.[17] Digital twin methods[18] fall on the far end of the simulation spectrum and encourage designers to create near-exact virtual replicas of the product, allowing for changes and parametric design space exploitation using a variety of heuristic, statistical and machine learning techniques.[19–22] This sort of transparent data sharing has been used in other industries such as semiconductor manufacturing, with foundries providing process capability information directly to designers to facilitate the simulation and yields of the design.[23]

These insights allow for more adaptable organisations, ready to respond when errors arise in their complex operations. Using increasing amounts of advanced analytics, including advanced AI methods,[24,25] manufacturers are able to model complex processes rapidly and explore change decisions to reach optimal outcomes, frequently by leveraging data that has already been collected. The other added benefits are that this level of insight into process also allows for automated optimisation algorithms to find unexpected cost savings in materials, energy and other logistic areas, sometimes drastically improving operations management.

CONCLUSION

It should be apparent that modern organisations will have to continue to adapt to the use of big data and analytics while continuing to drive change towards an objective DDDM. As SHL undergoes its own digital transformation, the advantages of leveraging different types of data are already beginning to confer advantages to our own process. Organisations that undergo these changes will reap benefits and gain significant strategic advantage while gaining an insight into their processes that can be enjoyed across the entire organisation.

ABOUT THE COMPANY

SHL Group is a world-leading solutions provider in the design, development and manufacturing of advanced drug delivery devices such as autoinjectors, pen injectors and advanced inhaler systems. It offers a full range of in-house core competencies and services in the fields of medtech and patient care. With >4,000 employees worldwide, SHL Group consists of several distinct group companies: SHL Medical designs, develops and manufactures advanced drug delivery devices for leading pharma and biotech companies across the globe; SHL Healthcare develops and manufactures equipment solutions for home, hospital and long-term care use; and SHL Technologies provides contract manufacturing and engineering services for the production of complex medtech products.

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Frederick Gertz is the Manager of Data and Process Innovation at SHL. His focus in the company is on facilitating data-driven methods across the organisation and providing unique insights from data using a variety of techniques, including artificial intelligence and deep learning. Prior to SHL, Dr Gertz worked in the medical device start-up space where he focused on bringing novel processes and techniques, including machine learning, into the biotech industry. He holds a PhD in Electrical Engineering from the University of California, Riverside (US) where his research focused on biophysics and spintronics.

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