The path to digital success in Pharma and Life Sciences

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Every day, organisations in Pharma, Life Sciences and Healthcare are giving their best to deliver treatments to patients in need. The flow of medicinal products and services results in a financial flow that is further complicated by important stakeholders such as health insurance companies, employers, governmental organisations and interest groups. Both flows require and cause a vast amount of information. In addition, the extensive regulations in Pharma and Life Sciences require additional flows of information for reporting and control. The COVID-19 crisis is pushing all these flows to their limits and thereby exposing vulnerabilities. In this article we focus on the information flow and how digitisation, digitalisation and digital transformation can help to fight today's and tomorrow's challenges.

What is digitisation, digitalisation and digital transformation?

Information can be considered as the combination of data and its interpretation. Information is used to make business decisions and is rarely used in isolation. Good information is actionable, unbiased, fit for purpose. A successful flow of information gets good information to the right people in a timely manner. For all this, organisations rely on people, processes and data.

Data used for interpretation needs to be of a sufficient quality[1]. To achieve a certain degree of standardisation and consistency, processes are designed to produce, capture, analyse, store, archive or destroy data. Well-designed processes contribute to the trustworthiness of data, but the most important factor in that regard are the people involved. People design the processes, interpret data and eventually act upon it.

Digitisation, the large-scale transformation of data into a digital format, enables the spread of data on a global scale and at the (near) speed of light. Storage of digitized data is cheap and easy, therefore digitisation tends to explode the volume of data to be managed. To tackle this issue, software tools are deployed to support the processes that are involved to manage all that data. This is called **digitalisation**, i.e. the transformation towards software tool-supported processes.

Digitisation and digitalisation also change the relationship people have with data and information. 'Knowing facts' is replaced by knowing where to find the correct data and how to interpret it, or, who to contact if lost. Because of digitisation and digitalisation, availability of data has become abundant, therefore the processes and people involved are gaining importance. The idea of owning or paying for volatile data is replaced by acquiring skills and guidance on where and how to access or find it. This also means that, if the value proposition in the business model of your organisation can be digitised, the business model should be redesigned to match the new relation with data. This is called the **digital transformation** and already exists in the music, movie and book industry. Many organisations have completed a digital transformation to some extent for non-tangible services. Even more companies are actively looking for new ways to do so.

1 DAMA International, DMBOK 2nd ed., chapter 13. Technics publication, NJ, USA, 2017

Should organisations engage in digitisation, digitalisation and digital transformation?

In brief: YES! Here is why:

Lots of benefits are associated with digitalisation of operational processes. First of all, more control can be exerted as there is more and detailed data captured on the execution of processes, sometimes even in real-time. As a result, full checks and audits can be automated and performed more thoroughly and more often. This results in less deviations in production, capturing errors earlier, getting the right product to the right people at the right time, less risk for patients, less recalls, etc. Secondly, processes will run more efficiently and can be measured more accurately, supporting detailed analysis for monitoring and continuous improvements.

Although a considerable effort is needed to make a digitisation or digitalisation project a success, the mid- and long-term benefits in efficiency outweigh the initial efforts. Main business areas in which efficiency gains are possible are listed in 'Areas impacted'. Being an early adopter might give you a competitive edge.

Apart from the benefits, some services and information are moving from a 'nice-to-have' to a 'must-have'. Both the market and governments require additional info that would depend upon an enormous effort to provide when using non-digitized processes. For example, end-to-end real-time traceability, outcome based medical dossiers, instantly customised summaries of data, etc. are becoming the norm.

When should companies be thinking digital?

Digitisation, digitalisation and digital transformation is already high on most companies' agendas, either because of obligations for compliance, optimisation reasons or in order to serve patients better. However, the cultural shift to 'think and act digital' is often not achieved. Case in point are **digitalisation** projects that are run in isolation: dedicated teams, technology focused objectives and key results, little strategic support, etc. Friction with affected departments is abundant and the full potential might not be achieved.

A digital transformation, at which the cultural shift is completed throughout all levels in the organisation and reflected in the business model of the organisations, is somewhat further down the road. The speed at which this will unwind further in pharma is difficult to predict. Some hurdles, such as the legal framework and data input, might hold back the implementation, although lots of progress is made on the legislative side in the earlier years. The main blocking reasons, however, are data literacy and reservations about the unknown. The – sometimes abstract – topics, technologies and processes are often outside people's comfort zones, resulting in resistance to change. This data illiteracy might improve over time because of natural workforce turnover and observational learning[2], it can be accelerated with clear guidance on how to link the digital world with real life[3]. The Hemingway 'law of motion' might be applicable here: "Gradually, then Suddenly". At first, change may take much longer than everyone expected, and then suddenly, change is happening much faster than anyone could have ever imagined.

> "Gradually, then suddenly
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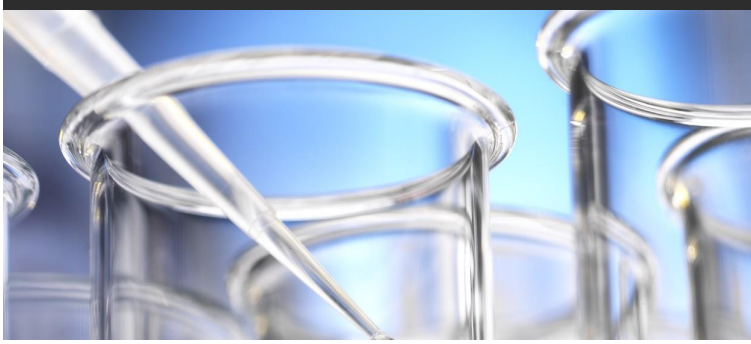
> Adapted from 'The Sun Also Rises', Ernest Hemingway, 1926



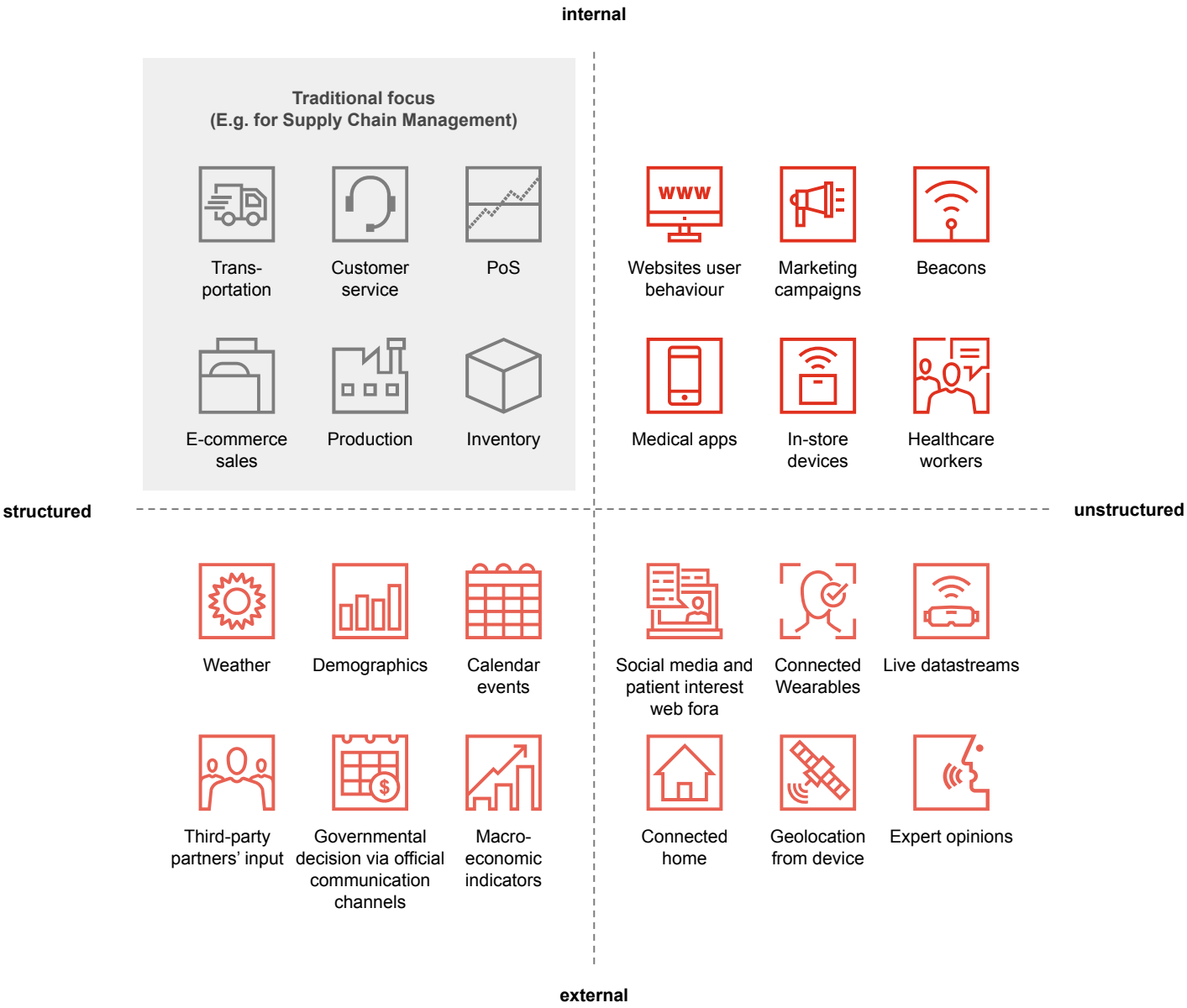
2 Yi, Mun & Davis, Fred. (2003). Developing and Validating an Observational Learning Model of Computer Software Training and Skill Acquisition. Information Systems Research. 14. 146-169. 10.1287/isre.14.2.146.16016.

3 Data and Reality: A Timeless Perspective on Perceiving and Managing Information in Our Imprecise World, 3rd Ed., Kent W. and Hoberman S., Technics Publications, 2012

What does it mean for Pharma and Life Sciences?

The goals of the pharma and life sciences industry are still to develop and deliver treatments, but the way to achieve them does. The volume of data to be managed increases and the nature of data changes. Data characteristics such as accuracy (e.g. consistent spelling), correct formatting, definitions and structure are becoming more important in a digitised world. For specific advanced applications, new technologies[4] allow organisations to capture and use data on a level of detail and scale not possible before. Figure 1 gives an overview of some of these types of data and their sources in a pharma-supply chain context.

▼ **Figure 1:** Illustration of data classification framework, applied for pharma and life sciences. Adapted from: Philipp Berttram, Judith Schneider and Marc Münch, 'The magic of predicting demand from data', Strategy+business, Jan, 2018



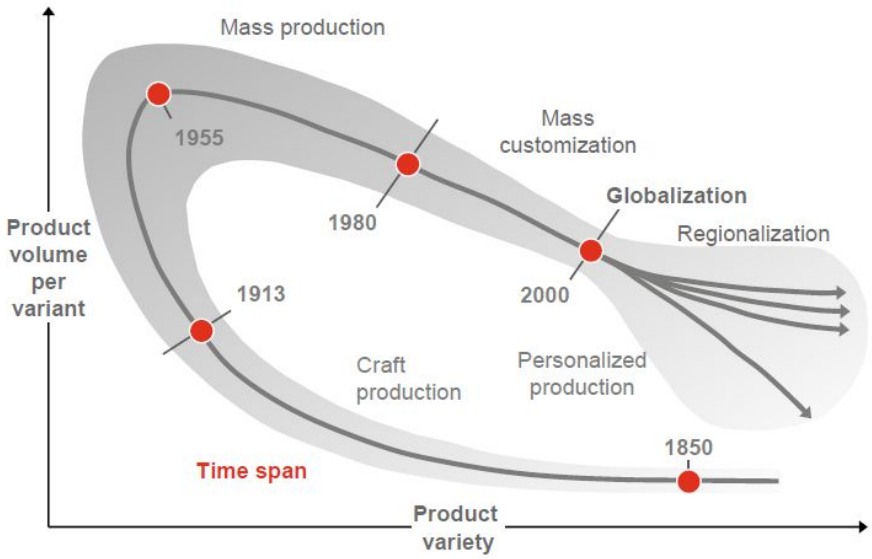
4 Industry 4.0, Essential 8: Your guide to the emerging technologies revolutionising business now, Scott Likens for PwC, [https://www.pwc.com/gx/en/issues/technology/essential-eight-technologies.html]

For the pharma industry, technologies such as virtual and augmented reality, 3D printing, blockchain, artificial intelligence, robotics and drones could revolutionize the ways of working for pharmaceutical companies. To manage this data, new data is summoned. The adage “it takes data to manage data” is certainly applicable here, mostly in the form of meta-data, i.e. data that provides information on other data, e.g. when something was saved or who reviewed a data element. Some of this data that has no connection to - or only remotely - real-life concepts, e.g. non-meaningful primary keys in databases, are introduced, even in non-technical environments. This might seem scary for people who are not used to working with these abstract concepts, that is why enough attention should go to get everybody on board, e.g. by building ‘business information models’ and training programmes to improve data literacy. These initiatives always pay off in the longer run.

For processes, there is more reliance on software tools to execute processes rather than human actions. This allows higher volumes of data to be processed in a more standardised way. Using tools also allows more control and faster flows of information, which benefits the service and decision-making processes. However, it does require a different skill set from the people supporting these processes and, even more important, on how the processes are designed and executed by these tools. To successfully (re)design processes that are supported by tools, both a thorough understanding of the technical aspects as well as a good understanding of the business needs and current reality is needed. The most successful teams for implementing tools to support business processes are teams with a diverse skill-stack, including technical skills, business acumen and a strong leadership to safeguard purpose and direction.

The impact of digital transformation on business models is embodied in a few trends that are unfolding today. A general trend towards ‘mass customization’ is unfolding in production environments, see figure 2. Pharma usually follows these trends albeit with a few years of delay. In parallel with the flow of medicinal products to patients, also more information and services are provided to them, thereby improving therapy adherence and eventually the success of treatment. Moreover, information about the patient also flows back. This information is personal in nature, causing some points of attention regarding privacy (see GDPR regulation), but also allows a more personal treatment. Industry 4.0 technologies (e.g. wearables, online consultations, therapeutic drug monitoring, etc.) enable data flows to be continuous and automated, thereby making the continuous monitoring of certain indicators cheap and easy. Because of the low threshold, healthy people have the ability to also monitor key health indicators to assess their lifestyle. This phenomenon is not new, but can be applied and quantified on a large scale which causes a shift from curative to preventive healthcare. The centre of focus is the patient rather than the disease[5]. The focus of pharma companies transformed from a drug developer/manufacturer into a provider of a treatments. They are expected to collaborate more closely with the other health stakeholders such as patients, physicians, hospitals, regulatory authorities, governments and healthcare financing organisations, all which in turn, is possible thanks to a digitalised way of communication. More structured data in digital formats is expected from pharmaceutical companies regarding real world monitoring, traceability and control, preferably monitored continuously. More emphasis is put on the benefit for the society. QALYS[6]. This proof can only be provided when the correct data is captured, and the information flows are well-managed.

Figure 2: General trend in production which (usually followed by the pharma industry). Source: Yoram Koren – The Global manufacturing Revolution



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6 Weinstein, Milton & Torrance, George & Mcguire, Alistair. (2009). QALYs: the basics. Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research. 12 Suppl 1. S5-9. 10.1111/j.1524-4733.2009.00515.x.

Main Business Areas impacted

Supply chain:

Digital transformation of the supply chain function is trending in most modern pharmaceutical companies. Planning departments receive relevant information from all shackles in the supply chain. If they succeed in managing this vast flow of information, a 'control tower setup' can be installed where decisions across the supply chain are made in real time over all levels of detail, thereby achieving a 'fully connected planning'. Supply chain planning information such as production planning and stock at hand is shared with verified suppliers and is integrated in their supply chain planning processes in order to ensure a reliable flow of goods. In production, **3D Printing** (3DP) - has the potential to diversify the pharmaceutical forms, including vaccines [7] and to quickly shift form, shape and appearance of solids. Together with **Robotics**, the production processes will be quicker and potentially portable[8]. **Blockchain** technology facilitates full supply chain visibility and traceability. In combination with **Internet of Things** concepts, such as smart packaging, quality assurance throughout the transport chain can be improved.[9] [10] Delivery of urgent medicine might happen via **Drones**[11]. Finally, **Artificial intelligence** (AI) is already used to help predict the course flu epidemics and accelerating research, specifically the *'in-silico'* phase[12]. For the end user, technologies such as **Virtual Reality**, a simulation of a 3D image or complete environment where a user can interact in a seemingly realistic way, can help kids overcome the fear of immunisation[13]. **Augmented reality**, the addition of the physical world via a data, graphical, or digital overlay of information or visuals, helps patients by visualizing how drugs should be used[14] resulting in a higher treatment adherence. Information on the use and effectiveness can be monitored using wearable devices.

Quality:

In Pharma and Life science industries, stakes are high as human lives are at risk if the product is not of the highest quality. This caused the pharma industry to be one of the most regulated industries. Full control, visibility and traceability were always the norm in Pharma; digitisation of operations allowed these requirements to be fulfilled instantly. This instant traceability, instant visibility and instant control is becoming the new normal, both towards governmental organisations as towards customers. In addition, as supply chains are globalized, the teams ensuring quality are also global. This requires a reliable and performant flow of information, something that only can be achieved when this information flow is digitized and supported by cloud based solutions.

Another challenge for quality departments in Pharma is the changing regulatory landscape. Not only is there the need to adapt fast to changing regulatory requirements, the different landscapes need to be aligned with each other. This is already recommended in order to facilitate collaboration between different regions but is an absolute prerequisite if one wants to support the quality function by globally implementing tools and platforms. Alignment is needed in terms of definitions, data structure, semantics, baseline concepts, granularity and logic. If this can be achieved, software can help a lot to achieve full control efficiently.

Nevertheless, human interpretation and decision making will remain necessary, at least in the short and mid-term. But, a digitalised quality function will be better informed on the internal state of business and thereby make better informed decisions more efficiently. Consequently, the role of people involved in quality will shift from a content-focused 'check and approve' role, to a more data process-focused 'design and control' role. Content-focused work is then reserved for exceptions and changes.

One of the main reasons for the need for human intervention is that legislation is written for humans, not for machines, and is sometimes open to interpretation. The need for more structured and 'digitisable' guidelines has been voiced and most governmental organisations have included this in their strategic agendas.[15] [16]

Research and Development:

The discovery phase of drug development is transitioning into an *in silico* event rather than in a wet lab. Artificial intelligence, powerful modelling algorithms and an advancing knowledge in the molecular, biochemical reactions at the basis of pharmacological effects allow prediction of safety and efficacy[17]. In addition, the knowledge of the human genome allows treatments to be targeted at more specific groups of genetic defects, especially for rare diseases, for which 80% have a genetic origin.[18]. In the future, tailor made medicines might be introduced.

Because of the more elaborate discovery phase of drug development, the pre-clinical and clinical trials will have more chance of success. On the other hand, requirements are tending to become more stringent rather than more relaxed regarding safety and efficacy. In addition more data is captured during the trials, key to success is to handle[19] and interpret the data and all this in full transparency as the data integrity standards remain the same.

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9 This startup uses blockchain tech to make sure your vaccines are safe, By Michael Tegos, Sep 1, 2017

10 IoT-enabled Smart Fridge helps manage vaccines and saves lives, By Barb Edson, Aug 16, 2016

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Common Pitfalls

Running successful digitisation and digitalisation projects in a digital transformation exercise is not an easy task. Many hurdles need to be jumped over to reach success. A heads-up on the most common hurdles will help to prevent them from becoming obstacles.

Vision and Strategy not aligned with regulatory constraints

A vision and strategy are critical at the onset of projects. Digitalisation projects are often part of a broader digital agenda and follow a digital strategy. This strategy is aligned with the overall organisation strategy and sets out the chalk lines for any project with a digital impact. In pharma and life sciences industry additional constraints are imposed by the (local) regulatory framework. For innovative projects, including digitisations, digitalisation and digital transformations, regulators are often collaborative in the ideation. Key is to also be collaborative during inspections. For specific projects, the overarching strategic decisions will help to answer the 'why' question and high-level on the 'how' and 'who'. It will help to focus on right areas, set priorities right and to align goals with the overall organisational strategy and (regulatory) constraints. More importantly, a good implementation of the overall vision of an organisation into a specific project provides meaning to that project, creates a sense of urgency and will serve as a source of energy for the people involved. Having regulatory constraints not included in the strategy might create challenges that are significant energy drainers.

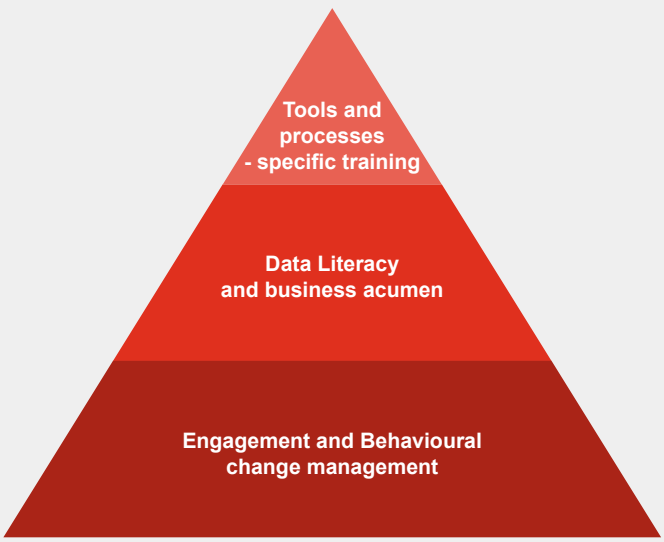

Figure 3: Fundamental focus areas when implementing data processes and tools

Ignoring the people and business sides of digital projects

Digitisation and digitalisation projects have a strong technical aspect to them. However, technology is the means to achieve the business goals, it should never be the goal on itself. In addition to the technological aspects, processes and people are just as important. People working with the technology need a certain degree of data literacy before starting with the training. If the data literacy[20] and business acumen is lacking, then this needs to be built from a strong engagement and the required behavioural change needs to be actively managed to steer towards the desired behavior changes. See figure 3. Part of the solution to avoid this is the role of data stewards. People with a sound understanding of the business processes and enough technical knowledge to ensure a proper use of the tools to support the business process but also to translate business needs with the system owners.

Trading off control for convenience

Keeping control while not relying too much on systems is a double-edged sword. On the one hand, it is tempting to engage in a 'one-size-fits-all' approach, leaving everything up to the mechanics to run a process. There is a risk that the process turns into a black box, where nobody has the full overview on how business decisions are made. On the other hand, having less manual work is usually one of the main goals of digitalisation projects. A good practice is to design quality gates into the processes that keep critical decisions in a glass box and do not penalise efficiency.

Toxic scope creep

During digitalisation projects, more often than not, latent issues might resurface, these need to be tackled sooner or later. Consideration should be made to investigate what the root causes are and, more important, what the impact is on the project. For example, suppose that the implementation of new supplier management software cannot function correctly, because the supplier master data is not of the required quality. Approaches that are usually taken are 1) Put implementation on hold until master data is suitable, 2) Start up a parallel project to address the master data issue or 3) Resolve the data issues after implementation. Either way, the scope has increased. In most cases, an enlarged scope is justified, in some cases however, it is not, and can be toxic for the project. Reasons justified scope creep are usually a lack of proper project planning. In some cases scope creep does not add value for the project nor company, in that case we talk about toxic scope creep. Toxic scope creep can be caused by: conflicting agendas, no alignment between strategies, stakeholders that use a project to force realisation of another agenda (which is not aligned with overall strategy and vision). Signs to look out for are: 1) Inflating issues ("the world is doomed if we do not get this resource"), 2) Bargaining: if you need A for your project, then give B for mine, 3) Improper escalation: bilateral meetings and agreements.

20 The ability to read, understand, create, and communicate data as information. Knowing and applying (internal) conventions such as definitions, data modelling concepts, data structure and data governance

Common Pitfalls

Lack of business information model

Before any digital solution for a real-world problem can be implemented, the real world needs to be understood and stripped from the context, subconsciously applied to define concepts in real life use. All stakeholders need to align on that understanding. Definitions of concepts and the relations between them from the business information model and is the basis for the technical solutions (logical and physical data models).

In pharma and life sciences, understanding reality in well defined concepts and relationships is a challenge. This is because nuances in definition can change over time or, concepts (defined by regulators) are ambiguous or are interpreted ambiguously.

Furthermore, pharma and life sciences have a specific context, therefore, specific concepts are not easily aligned within general-purpose software or application in other parts of the application landscape.

Investing time and effort in a good business information model will help training of people, and is key for proper use and setup of new tools.Furthermore it will help to cope with technical changes as business information model is independent from a physical and/or technological data model.

Conclusion

Digitisation, digitalisation and digital transformations are today's new normal and are critical in solving important issues in all the areas of the pharma and life sciences industry. Many organisations have digital high on their agenda but many hurdles are encountered and are not always handled in the best possible manner. In addition, the potential impact and industry-specific challenges regarding compliance and risk, increases the stakes for successfully implementing digitisation, digitalisation and digital transformation projects. In the text, many examples are referred to illustrate the different ways in which digitisation,digitalisation and digital transformation are happening today, what challenges they address and which new challenges this brings along.

Common pitfalls such as the vision and strategy not aligned with regulatory constraints, can be mitigated by proper planning and inclusion of key stakeholder early in project. Ignoring the people and business sides of digital projects should can be avoided by investing in data literacy skills and advocating data stewardship. No tradeoff between control and convenience should be made, toxic scope creep can be avoided by identifying early signs. Finally a lack of business information model is critical as it reflects the understanding of reality in a way that makes sense from a technical perspective.

Digitisation, digitalisation and digital transformations are part of every aspect of today's business reality. By applying old ideas such as collaboration, good understanding and planning to these new trends, issues can be avoided and your digitisation, digitalisation and digital transformation project will be a success.

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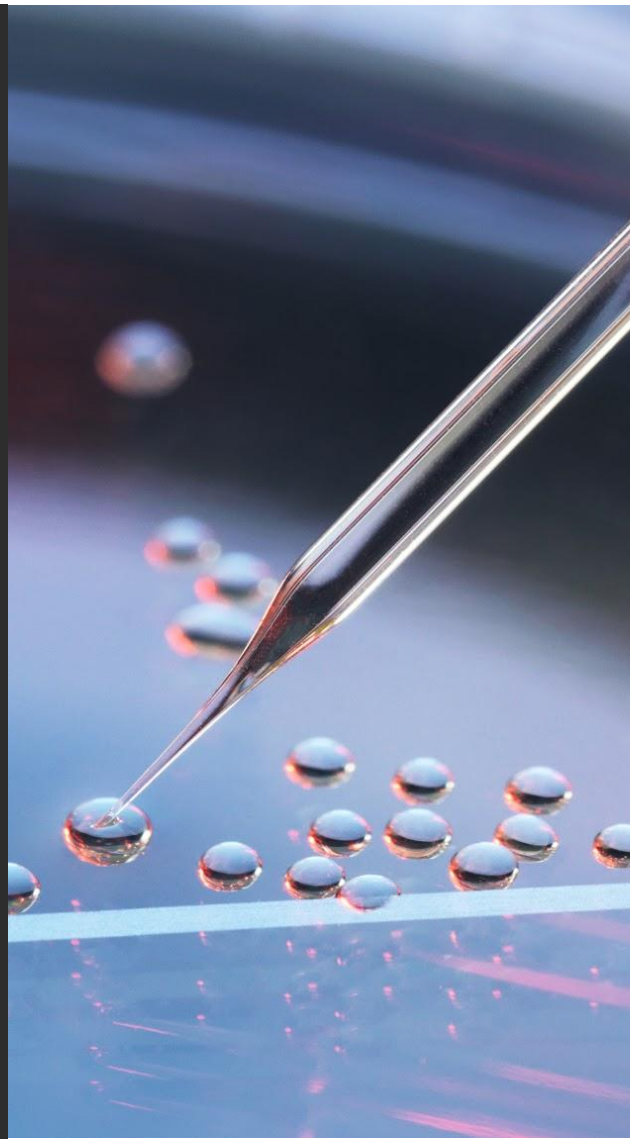

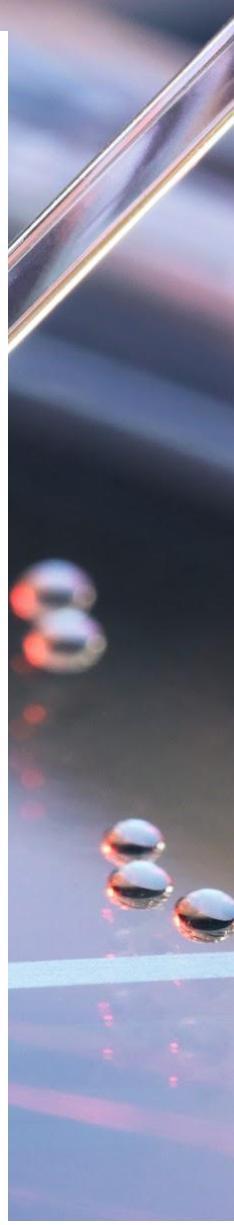

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