



Life Sciences Digital Transformation

A Birlasoft Point of View for Medical Device and
Pharmaceutical Manufacturers

Introduction

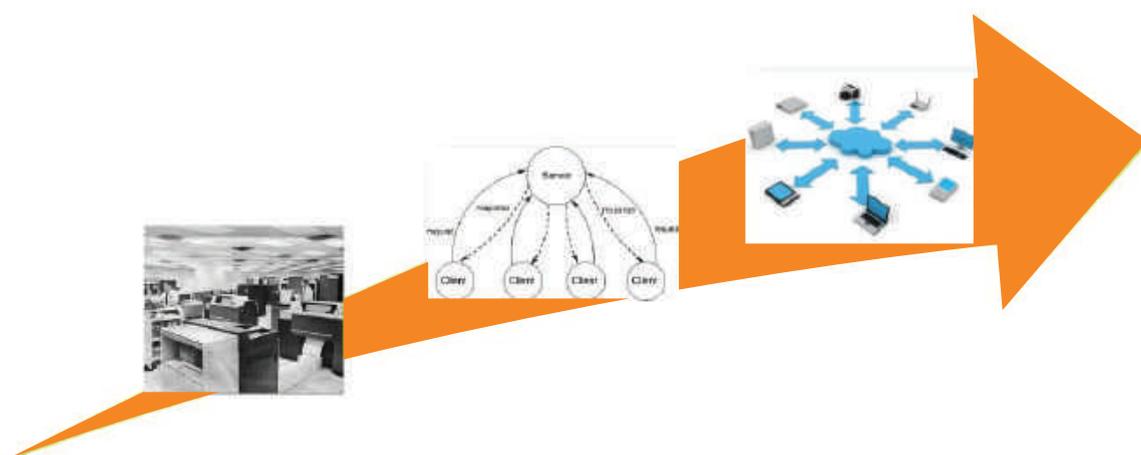
Birlasoft exclusively provides information technology and engineering services and solutions to manufacturers and distributors in a handful of vertical industry segments and life sciences is one of its primary areas of focus. Most established pharmaceutical, biotechnology and medical device companies in this space have put in place foundational ERP transactional systems and now are investing in “digital transformation” initiatives focused on surrounding those systems with “systems of engagement”. The reasons for this focus are many, but include a need to get closer to the customer through better understanding of needs and providing consistently outstanding experiences with their products, services and brand, developing new, higher margin revenue streams and realizing cost efficiencies in manufacturing and the supply chain. In this paper, we will cut through a lot of the buzzwords and jargon around digital transformation and share what we at Birlasoft are hearing and seeing in the medical device and pharmaceutical market segments, which we call life sciences.

What is Digital Transformation, Anyway?

At the moment, digital transformation, or DT, is defined many ways and with many technologies, depending largely on the industry being discussed and the technology solution(s) that an IT solution provider is positioning. To create a consistent basis for discussion, however, a concise and clear overarching definition is useful.

“ Digitizing everything & process in the world in which we live and work to provide insights to improve business operations, customer experiences and quality of life. ”

Digital transformation is enabled by what IDC has termed as the third platform, comprised of mobile computing, social networking, cloud computing, the internet of things (IoT) and big data analytics. Note that the First Platform is mainframe computer that came into prominence in the late 1950s and the Second Platform is client-server computing, leveraging the power of the PC in conjunction with mainframes, or mini-computers, which began in the 1980s.



The third platform's immense power comes from providing the following capabilities and characteristics:

Capture & Store Big Data

A massive increase in the ability to capture and inexpensively store massive amounts of all kinds of data characterized by the “3Vs” – Volume, Variety & Velocity e.g. traditional structured transactional data, unstructured text, images, videos, relationships and business logic.

Advanced Analytics

Modern analytics tools that are adept at making sense of and deriving meaningful insights from mashups of data that we are now collecting at an unprecedented rate. Traditional expectations of analytic tools providing only Descriptive (What is happening/happened?) are being replaced by new expectations to provide Diagnostic (Why did it happen?), Predictive (What will happen?) and Prescriptive (What should I do?) insights. This new style of data analysis is different from traditional Business Intelligence and is sometime called Data Discovery.

Traditional BI projects required the business users to know what kinds of questions they want to ask beforehand. The questions they wanted to ask drove the data model of the data warehouse and how the data was stored. The data model also drove what data was collected and by what mechanism. Creating this enterprise data model could be a lengthy process and in many cases resulted in a system that is slow to adapt to changes within the business.

Now, advanced big data analysis is happening bottom up. Organizations are collecting as much data as they can without knowing beforehand exactly what questions they are going to ask. This means it is no longer practical to transform every piece of data into the standard data model of the corporate data warehouse. Instead, data is stored in the form in which it was originally captured and only given an appropriate structure by the analysis process actually using it. This much more flexible approach enables more dynamic data analysis and can react much more quickly to the rapid changes within a business. Or, as Hilary Mason, former Chief Scientist at Bit.ly famously remarked, “The real innovation here is that we can ask questions and get the answer back before we have forgotten why we asked the question in the first place.”

Visualization

These tools put the power of analysis directly in the hands of non-technical business users, enabling them to access insights anywhere and anytime through mobile devices like smartphones and tablets, as well as wearables, providing real-time augmented and virtual reality views of the world around them. Modern analytical tools help us visualize complex what-if analysis across multiple dimensions in formats that are easy to manipulate and comprehend, even for non-technical users.

Digital Mesh

The proliferation of the cloud has enabled what we call the digital mesh, which means that users are no longer constrained to access data and insights on a single device. Think of how you access your social network across your PC, smartphone, or even a public computer at a library, or how you manage your travel. You can check in for your upcoming flight on your PC at home and pull up your boarding pass on your smartphone at the airport.

Use Cases in Life Sciences

At Birlasoft, we value partnering with our life sciences customers to develop technology-based solutions to enable their digital transformation journey operate in a business efficient, agile and regulatory compliant manner to lead in their respective segments and to contribute to making the world a better place. Here are some examples of work we've done together.

Smart Manufacturing – Industry 4.0

Manufacturing has evolved through four distinct eras of innovation

	Era	Operation	Connectivity	Integration	Characteristic
Industry 4.0 -of the early 21st century (today) is data driven, integrated, synchronized, adaptable and big data driven.	21st century	Cyber Systems, Data Driven	System to System, to Market	Integrated, Synchronized	Adaptable, Big Data Driven
Industry 3.0 of the late 20th is whatmost of us have viewed as modern manufacturing with the introduction of computers, robots and automation on the ship floor. This enabled fast, efficient processes and supported rapid product innovations and design changes.	Late 20th Century	Computers, Automation, Robots	Some Connectivity	Some Integration	Fast, Efficient, Rapid Product Changes
Industry 2.0 in the early Century leveraged electricity,some automation and saw the advent of assembly lines and standardization.It brought efficiency,mass production and very minimal product mix	Early 20th Century	Electricity, Some Automation, Assembly Lines	No Connectivity	No Integration	Efficient, Standardized, Min Product Mix
Industry 1.0 - brought the Industrial Revolution in the 19th century and the introduction of mechanized usually steam- powered) equipment.	19th Century	Mechanized, Manual, Steam	No Connectivity	No Integration	Slow, Non-Standardized

Birlasoft's medical device and pharmaceutical customers are increasingly embarking on programs to digitize their shop floors, to make data-driven decisions, rather than just relying on what always seemed to work in the past and static standard operating procedures stored in dusty 3-ring binders.

Predictive and Prescriptive Maintenance

On the Shop Floor

Equipment maintenance, once schedule and event driven, is now evolving into the predictive and prescriptive realm. Real-time data streams from shop floor machines (vibration, temperature, part measurements, etc.) are analyzed, sometimes using artificial intelligence (AI) algorithms to predict when a part is likely to fail, thereby enabling proactive maintenance or replacement, reducing unplanned downtime and sometimes unnecessary schedule-based preventive maintenance.

Increasingly the concept of digital twins is being employed to create digital or virtual representations of equipment. These digital twins are “brought to life” through real-time data streams coming from sensors embedded in the equipment to monitor critical parameters, like speed, vibration, temperature, historic mean-time to failure, and the full usage and repair history. Equipment across the entire organization can be monitored, compared and sometimes repaired by people and computer algorithms regardless of location proximity.



At the Customer Site

In the medical device space, predictive maintenance technology is also being applied to their products at customer sites as a means to differentiate their products, tap into higher margin revenue streams, maximize the value of their products for their healthcare provider customers by reducing downtime and radically improve patient outcomes.

Birlasoft has partnered with a leading durable medical equipment manufacturer and PTC ThingWorx on an Internet of Things (IoT) initiative with the intent to optimize, rationalize and automate maintenance of their assets installed at hundreds of hospitals and clinics. Leveraging data streaming from dozens of embedded sensors, the business will be able to:

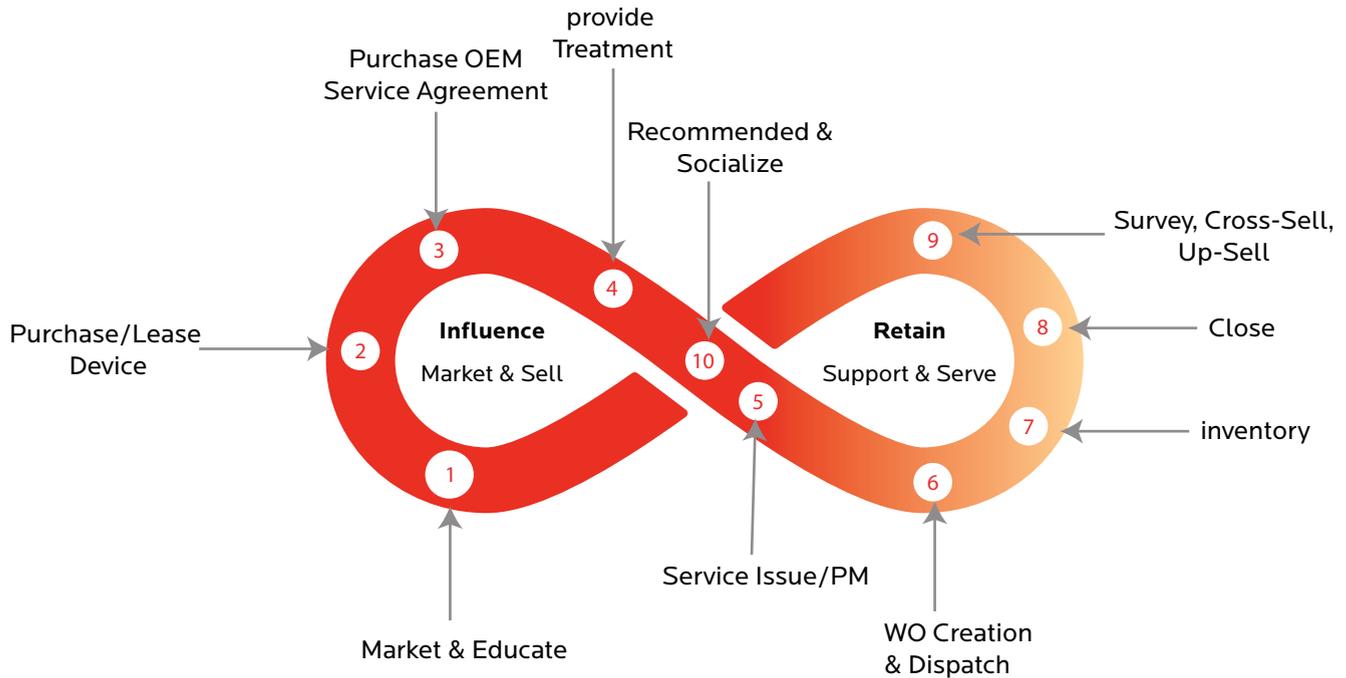
- Utilize data streaming from the devices to more accurately forecast and plan service requirements
- Deliver the right technician, parts and knowledge at the right place
- Reduce travel costs by leveraging the knowledge of remote technicians to help on-site personnel with live video sharing
- Increase end-customer return on investment and satisfaction

Augmented Reality

In 2013, Google Glass began shipping as a consumer product to selected users and in 2014 Google released the devices to the general public. In 2015, Google announced that it would no longer be producing the product. One reason for its short life was lack of a “killer application” for the consumer market. Killer business applications, on the other hand, do exist and several companies, including Microsoft, Vuzix and Epson have stepped in to bring industrial quality smart glasses to market. Birlasoft has taken a global leadership position in applying wearable computer technology for our customers’ benefit and built a platform to manage these devices and associated business processes. For more information on the Birlasoft wearables platform, please visit <https://workwear.Birlasoft.com/>

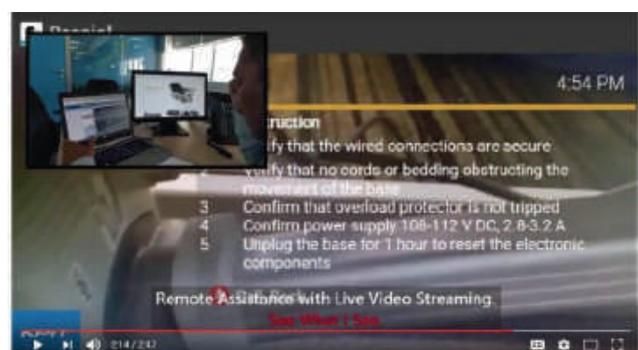
Medical Device Field Service

Rather than purely selling products, an increasing share of revenue for medical device companies is coming from product leasing, usage-based invoicing, product servicing and replenishment of associated consumables. This is called “servitization” and is rising on the priority lists of medical device OEM business leaders due to various market forces impacting this industry segment. Among these forces are increased global competition and outcomes-based payment provisions being implemented in the US and abroad.



Today’s medical device industry operates under increasingly tight profit margins and increased scrutiny of comparative effectiveness and costs of devices with similar therapeutic objectives and claims. The impact of these forces can be seen in the direction that many medical device companies are taking to pivot their business models to tap into the higher margins of providing service for their devices.

Augmented reality, delivered through “smart” glasses empower field service engineers with a 100% hands-free tool to ensure that their service jobs are completed right the first time to get that expensive, revenue-generating and sometimes life-saving device back in service quickly and efficiently. Smart glasses deliver information like a heads-up display to walk a technician through maintenance and repair checklists, images and videos from a central knowledge repository, and provide the ability to share audio and video with other, remote experts to collaboratively problem-solve. Being able to collaborate real-time with geographically dispersed knowledge workers may be the biggest benefit of smart glasses



In the Warehouse

Warehouse workers also need to use their hands and access digital information simultaneously, so the capabilities that wearable AR technology brings lends itself to increasing their work accuracy and efficiency, as well. And in highly regulated life sciences, it's imperative that the right products, lots and serial numbers are identified for shipment and production picking and inventory counting and inventory is put away in the right place. Having all the relevant information presented to the user, overlaid on their work environment and voice control to acknowledge successful completion of critical steps provides an audit trail and additional assurance that processes will be consistently repeatable,



Examples of warehouse use cases include:

- PO Receipt
- Inventory Put Away
- Inventory Picking
- Cycle Counting
- Physical
- Inventory

On the Shop Floor

Nowhere is procedural compliance, data quality and recordkeeping more important than on the shop floor. Hence, incorporating step-by-step guidance on how to do each job and seamlessly capturing actual data via a wearable mobile device demonstrates great focus on process and product quality. High definition image and video capture built into the smart glasses holds promise to digitally capture and analyze product physical quality characteristics like particle size, color, consistency, shape, component presence, etc.

Smart glasses also have a place in audits of sterile production areas. The gowning-up process is time-consuming and each one introduces a contamination risk, especially in aseptic liquid filling areas. In this use case, rather than having the entire audit team enter the area, an audit host can don the glasses, enter the room and talk live to the auditors and simultaneously share HD video, so the auditor can see everything they need to see without entering the room themselves



AR smart glasses bring value from a cost and quality perspective to any process where a person would benefit from having both hands free, but still be guided through a standard operating procedure and be able to communicate verbally, as well as with video sharing. Significant advantages that wearable AR devices deliver in industrial environments include:

- 100% hands-free operation, information delivery and collaboration
- Information delivered in the user's field of view without obstructing vision
- Enables live collaboration and knowledge sharing across geographically dispersed workers
- Neatly integrates business processes with any back-end systems (e.g. ERP, MES, WMS, field service)

Cold Chain

Just under half of new drug applications approved by FDA in 2017 require temperature control. Most of these products are extremely expensive to develop and manufacture and are often life-saving or sustaining biologics used to treat critically ill patients. Loss of product due to a temperature excursion means not only loss of product and revenue, but could result in loss of a patient's life. Traditional cold chain tracking involves embedding data loggers that travel with the product on its journey through the manufacturing and distribution chains and then downloading the data from the logger when it reaches its final destination or at checkpoints along its journey. This is often no longer adequate from regulatory, cost and patient risk perspectives. Industry and regulators are now requiring real-time tracking of multiple attributes including temperature, humidity, light exposure, shock/vibration and location, globally and also sometimes down to specific areas within a facility. Modern data loggers are now able to transmit data to a cloud repositories via the best available method, be it wifi or global cellular networks. When no connectivity is available, in cellular dead spots, on a trans-ocean voyage, or at cruising altitude of a jet liner, these devices automatically switch to data logging mode and then transmit when wireless connectivity is regained. Leveraging the power of IoT and big data analytics, Birlasoft's IntelliAsset platform captures the data from the devices in a single system visualized beautifully in near real time, alerting of changes before they become excursions and prescribing action. Birlasoft is partnering with our customers in the biopharmaceutical segment to address their increasingly demanding cold chain needs.

Conclusion

These are just a few examples of how digitally transformative technologies can be leveraged in the life sciences industries to deliver business value. Digitizing your business data is the critical core enabler for leveraging the technologies discussed here to empower employees with the information and collaborative tools they need to do their jobs efficiently and to deliver outstanding customer experiences to elevate your brand. Relying on the purely transactional systems, or even worse, on business processes managed on paper provide no ability remove barriers to collaboration, innovation and customer engagement. Birlasoft invests heavily in partnering with our customers to leverage technology as an enabler to drive business innovation and to make the world a better place. Contact us today to start the discussion about how we can help your company's transformation.

Reference Link <http://pharmaceuticalcommerce.com/clinical-operations/half-2017-fda-drug-approvals-cold-chain-products/>



RESOURCES

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Enterprise to the Power of Digital™

Birlasoft combines the power of domain, enterprise and digital technologies to reimagine business processes for customers and their ecosystem. Its consultative and design thinking approach makes societies more productive by helping customers run businesses. As part of the multibillion diversified CK Birla Group, Birlasoft with its 10,000 engineers, is committed to continuing our 150 year heritage of building sustainable communities.