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All Roads Lead to Digital Transformation in Life Sciences

How the life sciences sector can embrace new technologies to reimagine business models and push growth

There are several benefits to digitizing the life sciences sector – including easier market penetration (17%), smarter business models (23%), business process efficiency (23%), and brand innovation. But with 1 out of 5 companies still uncertain about digitization, is the industry leveraging technology meaningfully? How can cloud, AI/ML, Analytics, IoT, AR/VR, and Blockchain transform the future of life sciences, enabling new business models like servitization and easing regulatory compliance? We discuss these various threads of the conversation on digitization in life sciences, with Birlasoft's ten best practices for the Life Sciences and Medical Devices sector.

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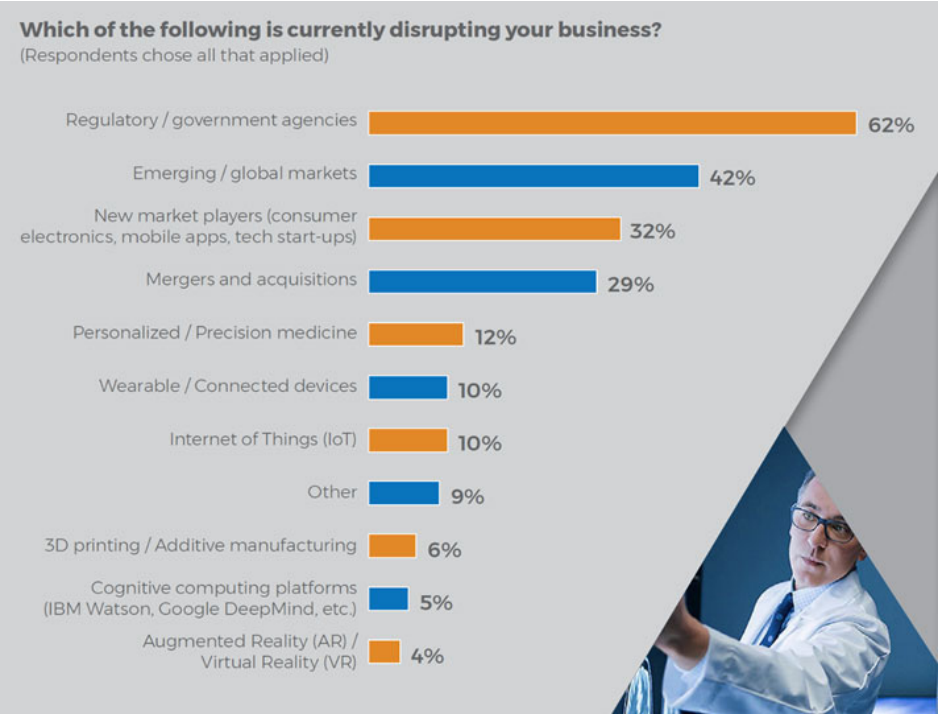
Introduction

The life sciences sector is at a strategic crossroads, where a smart approach to digital transformation could unlock immense long-term benefits. On one hand, advancements in Cloud, Artificial Intelligence (AI), its component technologies like Machine Learning (ML), and Natural Language Processing (NLP), the Internet of Things (IoT), and Blockchain make it possible to modernize legacy operations at scale. Life sciences companies can now aim for superior experiences for customers and patients, taking advantage of service-based delivery or servitization to complement existing revenue streams.

On the other hand, research suggests that the life sciences sector has largely been lagging other industries like telecom, retail and automotive in unlocking the full potential of digital technologies. These companies predominantly operate at less than optimum, given that one out of five still sees digital disruption as a threat. However, a PwC study also found that companies are acutely aware of the need for digital transformation and its benefits. These include easier entry into new markets (17%), refreshed business models (23%), faster/more efficient business processes (23%), and brand innovation (37%).[1]

As life sciences companies face disruption from a variety of forces, we are witnessing a period of both challenge and change. According to an Axendia research study titled Driving a Culture of Quality Within the Medical Device Ecosystem[2], 62% of companies ranked regulatory/government agencies as the biggest business disruptor followed by emerging / global markets (42%), new market players (32%), and M&A (29%). To stay on the winning side of this crossroads and guide their organizations, business leaders must consider the many facets of digitization and how they impact the as-is landscape.



Source: An Axendia Medical Device Research Survey - Driving a Culture of Quality Within The Medical Device Manufacturing Ecosystem
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The Rise of Servitization in Medical Device Manufacturing

The healthcare industry has always operated on a service-based model when it comes to interacting with and delivering to the end-customer or patients. Servitization brings a similar approach to other parts of the healthcare and life sciences value chain – specifically, the medical devices manufacturing sector. Under this model, medical device Original Equipment Manufacturers (OEMs) no longer follow a sell and retire philosophy. Just like Software as a Service consumption in the digital world, servitization repositions each piece of medical equipment as a component of a larger service offering. This has several benefits:

- Recurring revenues from customers who "subscribe" to the equipment
- Additional revenues from maintenance, extension, integration, and consulting services
- Customer demand for the procurement of consumables (e.g. catheters, tubing, mouthpieces, batteries, sterilization devices, etc.) related to therapeutic medical devices
- Greater freedom in product innovation as inventory becomes dynamic
- Accurate data insights on product usage, as the product is leased and not sold

Several industry pioneers have already gone down the servitization route. For instance, GE Healthcare – a global manufacturer and distributor of sophisticated medical devices – adopted servitization in the early 2000s. Since then, they have made forays into remote equipment monitoring and even maintenance support for other manufacturers' devices[3].

Digital transformation is a primary driver for servitization in the life sciences industry as companies would need IoT sensors to remotely monitor equipment, advanced data analytics to predict customer needs, and a next-gen process backbone to support enterprise resource planning, service transactions, and service delivery. Studies suggest that life sciences may be ahead of other industries in this regard, with 22% of medical device manufacturers operating in a fully servitized environment against the 4% cross-industry average[4].

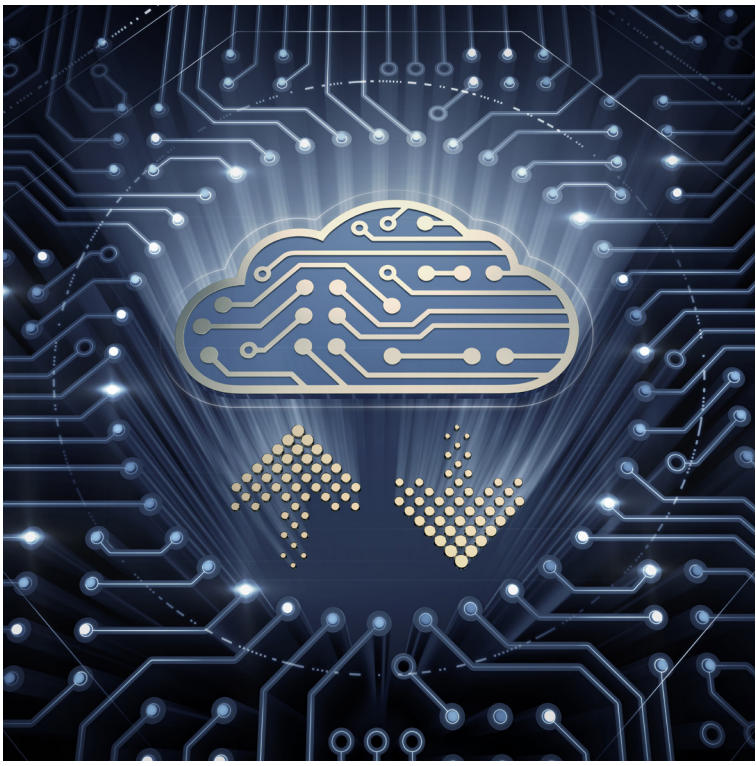
The Cloud Becomes the New Normal

In our experience at Birlasoft, companies in life sciences, pharma, and medical devices were skeptical about cloud adoption as recently as 18-24 months ago.

But there are clear signs of change as of 2020. The cloud would dramatically reduce the infrastructural burdens on life sciences companies, allowing them to focus on innovation and business growth instead. It would also make advanced capabilities like IoT, advanced cognitive technologies, and blockchain that are built into leading cloud platforms, more readily adoptable to enable digital transformation advancements. Further, public cloud technology is now becoming more affordable – making cloud adoption both a sustainable and secure choice. Underlying this trend, UK's National Health Service (NHS) moved critical systems to VMware Cloud on Amazon Web Services (AWS) last year[5].

2020 has continued to witness an uptick in cloud adoption, particularly impacting healthcare information systems. Approximately 39% of healthcare information technology workloads are already on the cloud, and nearly 50% will be moved to the cloud in the coming months. In fact, 8 out of 10 healthcare stakeholders agree that cloud adoption is a strategic priority for 2020[6]. Apart from infrastructure cost benefits, it would democratize access to key data (with the requisite security controls in place), making it easier to conduct audits and reporting activities.

Medical device companies could leverage cloud-based Manufacturing Execution Systems (MES) to orchestrate operations across distributed plants and delivery centers. Scalability will increase, while companies would be able to eliminate much of the process complexities that exist in today's life sciences manufacturing landscape



Thriving in a Challenging Regulatory Environment

The life science industries have always been under more regulatory pressure than other sectors for two reasons.

- It is responsible for the production, distribution, and maintenance of potentially life-saving goods and services where even a minor dip in quality is impermissible. As a result, life sciences Quality Management Systems (QMS) are subject to stringent regulations from a multitude of global regulatory agencies.

- It deals with a large volume of Personally Identifiable Information (PII) that comes with its own data collection and governance rules/mandates. Privacy is of the utmost importance when handling patient data, at the same time, ensuring timely access to concerned stakeholders across locations.

Some of the key regulatory requirements for life sciences right now include:

01 US FDA guidance on cybersecurity

The US Food and Drugs Administration (FDA) provides specific guidance to help medical device OEMs design and maintain products to be secure from cyber-attacks. According to this, manufacturers must regularly monitor and assess their cybersecurity posture for early detection of any vulnerability. And, if a vulnerability appears as prone to becoming a risk, the FDA is entitled to issue a notice called "a safety communication" – 9 of which have gone out since 2013[7].

This means that OEMs must be ready to monitor their threat landscape in near-real-time, isolating any anomaly before it can escalate. Failure to do so can result in product redesign, product recalls, and even loss of life.

02 EU MDR /IVDR

European Union's (EU) Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) is relatively new, originating in 2017 and requiring conformity by 2021 and 2022. The mandate lays down guidelines for expanded clinical evidence requirements, intensified supervision, and changes in regulatory oversight. EU MDR/ IVDR consolidates and replaces three earlier directives, which is why life sciences manufacturers must realign their product certification processes and ramp up post-market surveillance. Along with the US FDA's Unique Device Identification (UDI) regulation, it is a massive product data management challenge for medical device OEMs.

03 Health Insurance Portability and Accountability Act (HIPAA)

Under US HIPAA law, healthcare organizations must stay compliant when collecting and storing patient data for insurance purposes. It has a dedicated Privacy Rule wherein the government regulates the use and disclosure of Protected Health Information (PHI). At any given time, a patient can request an alteration in their PHI, which means that companies need requisite systems to find, retrieve, and modify data. Companies offering technology solutions that deal with HIPAA-relevant PHI must have a Business Associate Agreement or BAA in place. This is an agreement that their solution/services will comply with the technical and procedural HIPAA regulation that the customer will be held responsible for.

04 21 CFR Part 11

Part 11 of Title 21 of the Code of Federal Regulations provides a uniform, enforceable, baseline standard for accepting electronic signature and electronic records and provides a level of confidence that records maintained in accordance with the rule will be of high integrity. In other words, any digital record-keeping initiative involving regulated data in life sciences must ensure 21 CFR Part 11 for compliance.

05 ISO 13485:2016 / ISO 14971

ISO 13485:2016 discusses how life sciences companies can and should leverage their QMS to stay at par with customer expectations as well as regulatory requirements. By meeting these ISO standards, companies can mitigate risk and ensure that they can confidently roll out products and services without fear of preventable non-compliance. ISO 14971 also delves into risk management, but this is specific to medical device manufacturing. Life sciences leaders will be the ones that obtain both these certifications and can achieve maximum business continuity across all of their service locations, in the EU, the US, and elsewhere.

These five regulations are representative examples from the EU and the US, but there are similar and divergent variants from other global regulatory agencies, so we are currently experiencing a fragmented regulatory environment in life sciences. Research suggests that this could change soon – according to a recent report, bodies across Canada, the US, South-East Asia, Australia, and the APAC will work towards harmonizing regulations by 2025[8]. Technology will play a significant role in this, allowing companies to transform their compliance mechanisms at scale and at speed.

AI Contains Compliance Risk via Smarter Data Management

A cross-industry study of regulatory management suggested that current approaches are overwhelmingly dependent on human effort. Teams are stretching themselves beyond optimal, due to new regulatory requirements (53%), and growing product lines (49%). Expectedly, an overwhelming 90% would welcome technology intervention to reduce workloads and shrink/eliminate the chances of human error[9].

This is where AI and its component technologies like ML and NLP could play a role. Many compliance activities are iterative,

such as scanning documents for words and phrases, sending notices to necessary stakeholders, generating compliance reports, and exporting data for internal audit logs. AI could help to automate a lot of this, freeing human effort for more value-adding activities. The benefits here are multifold: reduced risk of non-compliance, better utilization of human resources and leveraging the power of cognitive technologies to spot hidden patterns and insights in large data sets that would be missed by human brains.

AI is already in action at several health sciences organizations around the world – for instance, the premier US institution, John Hopkins University. John Hopkins leverages AI to build an extremely accurate privacy analytics model, automatically reviewing patient data access points, and detecting any instance when an Electronic Health Record (EHR) was vulnerable to a privacy violation. Apart from this, John Hopkins used NLP to generate a short note for healthcare employees who need to submit tickets to a compliance officer[10].

There are several potential use cases like these for AI, in compliance management, by automating data governance (less exposure to human individuals), ramping up data analysis capabilities, and reducing audit/investigation timelines. But to gain from this, life sciences organizations must first strengthen – in some cases, transform – their digital infrastructure to achieve AI technology readiness.

Another Promising Use Case for AI: Pharmacovigilance

Pharmacovigilance, also known as drug safety, involves the life sciences industry's responsibility for monitoring the reception and effects of their therapeutic products in the market. Proactive pharmacovigilance can reveal useful insights on market demand, treatment impacts, and hidden safety signals that go into future drug discovery cycles. This helps to speed time-to-market for new drugs in the long term, building a robust repository of market and patient data and of course, serving to protect patient health and safety.

Not surprisingly, pharmacovigilance is highly labor-intensive, involving strategic thrust from business leaders as well as a massive orchestration of individual and team effort at the grassroots. As with many highly manual and repetitive business processes, pharmacovigilance stands to gain significantly from AI. A 2019 study found that it is quite feasible to use AI for the extraction of adverse-event (AE) source documents and evaluate case validity. Right now, processing AE cases is among the biggest cost drivers in pharmacovigilance – AI could change this for good[11].

The utilization of AI for pharmacovigilance is inconsistent at present – slightly more than 50% of life sciences organizations say that they are at a "beyond nascent" state of adoption, indicating plenty of room for innovation[12].

The Need for Integrated and Comprehensive RIMS

Increasing regulatory complexity coupled with siloed information across the life sciences value chain makes it imperative to relook at existing regulatory information management systems (RIMS). Globally, the industry spent $797.2 million on RIMS in 2018, with a projected growth of 13.7% CAGR to reach $2442.9 million by 2027[13]. This is not surprising, keeping in mind the dynamic nature of laws, standards, and industry regulations in life sciences.

However, our experience at Birlasoft suggests that only 20% of biopharma companies are maturing digitally at a pace adequate to achieve the necessary transformation in RIMS.

This leads to several lost opportunities – for example, real-time data flows within QMS platforms could improve agility, feeding timely information into RIMS for up-to-date reports and audits. A next-gen RIMS solution would go beyond core regulatory process management. It would automate submission management so that life sciences organizations could easily compile and validate their regulatory submissions against all local, national, and global mandates. It would establish a single pane of visibility for all stakeholders, with AI/ML intervention to reduce human effort wherever possible.

We have developed global product registration (GPR) solutions built on several leading product data management solutions to help a medical device company manage its product licenses and registration data[14].

Towards a Superior Customer Experience

In the last few years, life sciences and healthcare have become increasingly patient-centric. Patients are now more willing to share their data if it leads to better outcomes. A recent survey found that at least one-third of patients would share their health data in emergency scenarios, and 40% would share their personal health data collected via medical devices with a device developer[15].

Given this imminent rise in expectations, life sciences companies can leverage emerging technologies like AI, IoT, and augmented reality/virtual reality (AR/VR), to transform customer experiences.

- **AI predictive analytics to anticipate OEM customer needs**

Device information can feed into an AI-enabled predictive analytics model to plot demand patterns and forecast future behavior. This will help OEMs – particularly those engaged in servitization – anticipate equipment repair and deploy personnel. 6 out of 10 participants in Axendia's research on The Impact of the Internet of Medical Things (IoMT) on Patient Outcomes[16] expect that using smart and connected devices they will increasingly link to networked data and analytics in products. IoMT connected devices will improve patient care by providing the health care industry with better aggregated information to continually improve products and services.

- **IoT sensors for customer behavior monitoring**

According to Axendia's research[17], 42% of industry respondents expect to rely on sensors to improve up-time and schedule preventative maintenance. IoT for end customers (e.g., smart medical devices and wearables) can help find previously hidden insights on customer behavior, as well as latent healthcare needs signals. IoT sensors could also transform the OEM service delivery landscape, continuously collecting data from the medical equipment usage environment.

- **AR/VR for more responsive support and effective treatment**

Outside of gaming and entertainment, healthcare is the #1 industry for AR/VR applications. Life sciences OEMs could equip their field workforces with AR/VR assistance, minimizing their product mean-time to repair and enhancing customer satisfaction. AR/VR has incredible potential for revolutionizing life sciences, through 3D visualizations of chemicals and human anatomy.

IoT and Blockchain Come Together to Power Tomorrow's Pharma Cold Chain

A cold chain failure poses severe threats to pharmaceutical companies, greatly increasing the risks of delivering potentially unsafe treatments. Last year, a research paper noted how a cold chain breach in a Sydney hospital affected 1100+ new mothers and babies, calling for stronger surveillance and always-on, automated monitoring[18]. A combination of IoT and Blockchain could address this by:

- Continuously gathering cold chain data as per preset parameters to detect anomalies
- Maintaining an immutable and extremely reliable data fabric for cold chain maintenance

A similar use case is currently in action in the food industry, which also deals with perishable products. A coalition of global giants, including Walmart, Unilever, and Nestle, are leveraging Blockchain technology to monitor their products' temperature conditions in a connected cold chain environment[19]. Most existing cold chain monitoring mechanisms make use of rudimentary digitization, often USB connectivity to relay shipment data. IoT replaces this with near-field communication (NFC) to transmitters which would work over Wi-Fi, cellular, low energy Bluetooth, and satellite, enabling remote data collection at regular intervals. Once stored on the Blockchain, this would reflect product temperature at source, en-route, during delivery, and across all milestones in-between for absolute authenticity.

Best Practices for Accurate, Flexible, and Efficient Medical Device OEM Operations

As the regulatory burden grows and customers expect increasingly more from their healthcare providers, the onus is on medical device OEMs to conceptualize, design, produce, and deliver game-changing products. And across this journey, companies must stay cognizant of the regulatory mandates in place at that time and as applicable to the intended consumer audience. Meanwhile, industry leaders are moving into new business models such as servitization, providing stiff competition to other players.

To succeed, therefore, OEMs require a full suite of digital technologies in conjunction with a smart implementation strategy.

01 Integrate real world data (RWD) into analytics to drive actionable insights

Siloed information at various points of the life sciences value chain must come together to provide a holistic picture of new product development and deployment models. Companies can use IoT to monitor production lines in real-time, integrating the supply chain to unlock coherent business insights.

02 Use predictive analytics to eliminate supplier inefficiencies

Supplier analytics will study performance parameters for the entire supply network, spotting trends, and classifying OEM partners. This will allow medical device companies to select the best-fit supplier for a production cycle.

03 Modernize Manufacturing Execution Systems (MES)

This continues to be a huge, largely unmet need for the industry. For example, one of our large, global medical device manufacturing clients runs 50+ plants around the world, but less than 20 use a modern digital system. The majority relies on spreadsheets to manage their manufacturing processes. A next-gen MES will be compatible with real-time data streams pouring in from connected, smart machines. Companies could even couple this with AR/VR platforms to visualize the manufacturing landscape as a digital twin to safely optimize production configurations.

04 Automate scheduling and maintenance where possible

Automated workforce scheduling and predictive – not event-triggered – medical device maintenance can improve customer satisfaction, generate recurring revenues, and improve treatment results. To do this, companies need AI-led predictive analysis and process automation.

05 Build a single source of truth

Unifying visibility across the life sciences value chain would enable deeper drill-down into datasets and, consequently, more accurate insights. This would allow companies to flexibly move production to any plant location, which is critical in today's environment where entire countries can be taken offline by a global natural disaster, like a pandemic. It is essential to unify plant monitoring, process controls, process optimization, and regulatory compliance environments for anytime, anywhere visibility.

06 Modernize warehouses via robotic process automation (RPA)

A smart and agile warehouse can bring down device rollout timelines and improve customer service, without compromising quality or compliance. RPA can assist in picking, sorting, storage, retrieval, loading, and unloading – tasks that are manual, repetitive, and labor-intensive. Companies would be able to reconfigure warehouses in an agile manner, as per product, business model, market, and regulatory requirements.

07 Switch to IoT and RFID-enabled contactless tracking

IoT and RFID technologies can empower data transfer without any human-to-human or human-to-computer interactions. Fortunately, most of the technology for this is already in place, such as GPS, Wi-Fi, and Bluetooth connectivity at medical device plants and warehouses.

08 Implement pricing analytics for a competitive edge

Historical data can provide useful action-points around pricing, demand, and possible supply variations. Life sciences companies can use this to improve inventory planning, negotiate better prices, and reduce production pressure during peak demand periods. What's more, a medical device OEM could potentially track leased-out equipment in real-time to forecast demand and preemptively optimize replenishment and usage-based invoicing workflows.

09 Crisis-proof the supply chain

Regulatory pressures and unprecedented crises could block access to integral parts of one's supply network. To mitigate these risks, medical device companies can use advanced analytics to provide insights about which suppliers may be at risk of failing and keep a database of more reliable alternate suppliers–along with the agile processes needed to make the switch.

10 Stay ahead of compliance with preemptive data management

Regulatory compliance is central to crisis-proofing a life sciences organization, particularly medical device OEMs. Preemptive data management will ensure that there is a single pane of glass, with clear accountability for data changes, visibility into data exposure requests, and pre-approved data utilization. This would pave the way for faster production and delivery, taking advantage of emerging demand.

Digital Transformation for Life Sciences, Medical Device and Pharma

At Birlasoft, we recognize the immense potential of digital transformation of key business processes in the life sciences sector through:

Capturing and storing Big Data, characterized by the 3 Vs of volume variety, and velocity

Advanced analytics providing descriptive, diagnostic, predictive, and prescriptive business insights

Visualization to put the power of insights in the hands of non-technical users, coupling technology with the life sciences business understanding

A fully connected ecosystem or “digital mesh” owing to the proliferation of the cloud, giving life sciences companies access to data residing anywhere on the value chain

Our medical device and pharma customers are increasingly embarking on digitization programs to modernize their shop floors, supply chains, customer experiences and back-office processes, paving the way towards data-driven decisions for a dynamic future. We support them through the best in digital technology platforms and solutions, with expertise in key areas such as IoT, analytics, mobility, AR/VR and the cloud, among others. We also partner with industry leaders such as Oracle, SAP, and PTC to holistically support our customers’ digitization initiatives.

To know more, please email us at contactus@birlasoft.com

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contactus@birlasoft.com

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-dollar diversified The CK Birla Group, Birlasoft with its 10,000 engineers, is committed to continuing our 158-year heritage of building sustainable communities.