Digital Double-Win

Navigating the risks and opportunities of the digital supply chain can be difficult. An executive team survival guide can help

Dr Evren Ozkaya at Supply Chain Wizard

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Today's pharmaceutical executives navigate extremely complex territory on a daily basis. The toughest quandary they face is existential in nature: how to survive and thrive in the digital economy. Digital developments present both risks – including those connected with business, security, and compliance – and tremendous upside performance transformation opportunities.

Industry headlines are forcing executives to think long and hard about their digital transformation strategies. Consider these sample, thought-provoking headlines:

- Why did CVS buy Aetna for $69 billion? (1)
- Mylan and Teva stocks rise on report about Amazon's pharmacy aims (2)
- Hearing Amazon's footsteps, the healthcare industry shudders (3)
- Big Pharma builds blockchain prototype to stop counterfeits (4)
- FDA pushes DSCSA serialisation enforcement deadline to 2018 (5)
- Pharma's digital supply chain transformation (6)

Clearly, pharma executives who want their companies to remain industry leaders need to think long and hard about their 'digital transformation strategies.' Focusing on digital improvement today will help them score a digital double-win tomorrow, especially if they prioritise improved supply chain security and performance.

Dealing with Risks

2018 will be stressful for pharma companies – especially for manufacturers and contractors – given that both the Drug Supply Chain Security Act (DSCSA) and the Falsified Medicines Directive (FMD) regulatory deadlines are in the last 12-14 months of enforcement. These markets constitute two-thirds of the world drug supply, yet multiple surveys indicate the industry will not achieve 100% compliance before the deadlines.

How to Deal with Serialisation Noncompliance

Internal and external suppliers may choose not to comply with serialisation mandates, which can cause deadline extensions or, more accurately, enforcement delays. To actively manage this, many companies assign dedicated programme or project managers to assess current risk levels and the potential impact of noncompliance across internal and external supply networks. These managers need to take a proactive approach to mitigating these risks, focusing on the highest impact/value levers at their disposal. Leveraging industry expertise in managing large-scale compliance programmes and using industry best practices to onboard and connect with trade partners can greatly reduce them. Executives should also consider the fact that some of their external suppliers/CMOs may run the risk of going out of business as their clients start consolidating volumes into fewer, more reliable strategic suppliers. Both network and consolidation strategyies are important to consider.

Managing Production Efficiency

Experiencing lower efficiency or overall equipment effectiveness (OEE) in the production environment is often inevitable when serialisation or track-and-trace systems and processes are introduced. This can be due to a variety of reasons, including added equipment, new procedures, and the potential for more points of failure. While an average OEE drop

of 5-10% is common, companies can use this opportunity to take a proactive approach to managing efficiency problems by measuring their efficiency consistently and identifying the root causes of any performance issues they experience. A published article about Par Pharmaceutical's success in managing the OEE challenge as part of its serialisation programme provides a great example of how this can be done.

Serialisation Security

Supply chain security goes beyond meeting serialisation mandates, as satisfying serialisation requirements does not automatically provide the ability to 'track-and-trace' products in the supply chain. For true track-and-trace capabilities, the aggregation of serialisation information across packaging layers (unit, bundle, case, pallet) is necessary, along with the introduction of procedures and systems to process aggregation information as products move through supply chain nodes.

Some regulations, such as the DSCSA, require aggregation for full compliance in the future, while other regulations, such as the FMD, do not. Companies serving multiple markets should consider adding aggregation as part of their global technical strategy. Many of the regulation requirements stop at the pharmacy or hospital and do not ensure that patients are provided with the right drug at the right dose.

Some countries, such as Turkey, have adopted a comprehensive approach to track-and-trace by integrating their e-prescription system into the government track-and-trace system, thereby ensuring patients receive the right drugs at all times, as prescribed by their doctors. To make sure the drug manufacturer is doing all it can to secure patient safety, it would be advisable for executives to look beyond current regulations and add additional layers of security. These might include integrating product authentication (via printing, labelling, and mobile technologies) and patient engagement technologies and processes into their programmes. Leading companies are already exploring these best practices in an effort to provide ultimate patient safety, while minimising security risks and undesirable reputational and financial risks.

Capturing Upside Opportunities

A plethora of upside opportunities have the potential to make or break a company's future survival in the evermore competitive landscape of the pharma industry.

Supplier/Buyer Collaboration

At a recent Pharma CMO Summit – a conference dedicated to serialisation compliance for pharma contract manufacturers and packagers – the Chief Financial Officer of a contract packager in New Jersey claimed his company had talked to its customers more in the past six months than in the past six years as a result of its serialisation project. Mandatory

compliance programmes actually present a phenomenal opportunity to maximise business relationships, as they offer a chance to build on and expand relationships beyond compliance requirements. Many leading manufacturers are running formal CMO serialisation programmes that provide the ability to regularly engage with their suppliers, review business and financial requirements (beyond just the regulatory ones), and find opportunities to collaborate on common value generation.

One way to accomplish this is to launch joint initiatives with trade partner networks, such as supply chain collaboration, collaborative planning and replenishment, and cost/cycle-time reduction initiatives that go beyond company borders. The intersection of companies is where the largest value potential is hidden, and the digital infrastructure (ie, the electronic highway between companies) laid for serialisation systems is an excellent way to build digital collaboration initiatives, which can also lead to improved product traceability and higher security for the supply chain. An excellent illustration of this is explored in an article describing cooperation between Johnson and Johnson and AmerisourceBergen on GS1 standards (8).

Competitive Differentiation

Some leading companies have started exploring ways of building on their serialisation system investments to improve return on investment. On the solution provider side, leading vendors have begun to focus on the value of serialisation data. The data itself offers little value, but the end-to-end nature of unit-level supply chain traceability at the item/serial-number level can provide massive business value. The ultimate end-goal for pharma executives should be to acquire data management and analytics capability

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that can provide the 'unit level profitability' metric/KPI.

This metric would enable a detailed story (history of events) to be built about every serial number as it proceeds through the lifecycle – from production to consumption. If executives could track the life story of every serial number in their supply chain, the value generated could have the power to transform the entire organisation. Imagine having the ability to identify all ineffective decision-making processes made at the unit level so as to be able to maximise the profitability of every single product, shipment, and order.

Every 'average' metric used today, in the absence of unit level visibility, actually obscures business potential. Some products lose their entire profitability when the shipment is expedited to customers, and, while the product may still be profitable on average, it may be losing much of its profitability due to unknown/untracked business decisions.

Substitution and Network Optimisation

The dynamic management of supply and demand is another important area to explore and can be useful when trying to navigate the good and bad surprises rampant in the pharma industry. During bad surprises (eg FDA warning letters or supplier issues), companies can explore ways of managing limited supply in terms of inventory and capacity in the most optimal way. During good surprises (eg demand surges due to new contracts or the receipt of warning letters by competitors), companies should be ready to capture these upside opportunities. Having network-wide data and granular supply chain visibility and capabilities to digitally collaborate with trade partners can cut the lead times to capture these opportunities and maximise the size of them. With today's typical strategic decision-making cycle functioning as part of the executive sales and operations planning (S&OP) process, making effective decisions can take months. Future pharma leaders are going to favour 'continuous S&OP' and data-driven decision-making, which will speed up this process as they eliminate weeks of slow data gathering and analysis.

Practical Digital Transformation Strategy

Future pharma industry success lies in the 'digitalisation' of the supply chain. A quote in a recent McKinsey report entitled *The Case for Digital Reinvention* says, "The biggest future impact on revenue and EBIT growth… is set to occur through the digitisation of supply chains." However, the report goes on to note that "only 2 percent, in fact, report that supply chains are the focus of their forward-looking digital strategies" across all industries (9).

Listed below are three areas critical for putting together a digital supply chain transformation strategy – the industry calls it the three Ds: data, dashboard, and decisions. If approached methodically and consistently over time, pharma companies stand to reap large rewards.

Data

- Identify organisational data gaps and leverage serialisation systems and platforms for unit-level data gathering
- Find ways to enhance unit-level serialisation data throughout the product's journey in the supply chain (eg efficiency, pricing, logistics)
- Automate collection and consolidation of data in a central analytics platform via Internet of Everything and business intelligence technologies (integrated with master data systems)

Dashboard

- Turn vast amounts of data into 'role-specific' dashboards for historical insights and trends (eg OEE performance)
- Build 'real-time' dashboards for on-the-spot feedback to all supply chain stakeholders from operators to executives for granular visibility
- Build 'predictive' models and projections to provide forward-looking visibility into the supply chain and impact of business decisions

Decisions

- Establish 'data-driven' decision-making processes to optimise business outcomes (eg from tactical scheduling to strategic network design)
- Enable data automation and turn it into 'decision-automation' for repetitive processes (eg routing, inventory replenishment)
- Build organisational capabilities (ie decision science teams) and processes to govern enhanced decision-making processes

An End-to-End Chain

While conceptually thinking about the end-to-end supply chain is important, actively pursuing local/functional opportunities for immediate impact whenever possible is vital. Companies should aim to build an end-to-end digital supply chain strategy that can leverage the best of lean and digital

technologies and processes to establish a platform of true transformation.

Most transformation does not fail as a result of technology, but because leadership is lacking (including incentives), thereby driving the transformation. Going forward, those companies showing the greatest skill, leadership, and courage in taking on the digital transformation journey will prosper the most.

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About the author

Evren Ozkaya PhD is the Founder and CEO of Supply Chain Wizard: a full-service global consulting firm specialising in serialisation and traceability as well as supply chain strategy and operational transformation programmes. Supply Chain Wizard offers products and services targeting serialisation and supply chain transformation initiatives, along with a team of consultants providing comprehensive support towards cost-effective compliance with serialisation mandates and post-go-live operational support.
Email: evren.ozkaya@supplychainwizard.com