One Network Enterprises™

Realizing the Full Potential of Artificial Intelligence in Pharmaceutical Supply Chains

Why AI without a solid network foundation will fail

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INTRODUCTION

Artificial intelligence (AI), in all its various forms obviously offers enormous potential value to healthcare and pharmaceutical companies, in transforming their supply chains. But without a robust strategy, proper implementation, and rigorous prioritization of high value use cases in production, most of this value is lost.

Too often, AI implementations fizzle out, with little to show in terms of business value. Or if they do deliver value in some niche area, they are difficult to scale across the enterprise and trading partners, to really transform the supply chain.

This paper explores the practical challenges for successfully implementing AI in pharmaceutical supply chains, and offers a strategy that generates high returns quickly, while minimizing implementation overhead and risk. The success of any AI solution is predicated on the centrality of a multi-tier network solution given the interconnectedness in pharmaceutical and healthcare supply chains.

COMMON CHALLENGES AND PITFALLS OF AI IN PHARMA SUPPLY CHAINS

Where do most health and life science companies go wrong when attempting to deploy AI in their supply chains?

1. Complex data landscapes and learning from both past and new data.

Trying to tackle the problem without a single integrated model therefore unable to connect the dots, i.e., not having community master data and management system. Supply chain is a heterogenous mix of partners with a myriad of data models that most often don't talk to each other. This is compounded by complex integration fabrics that makes it very difficult to trace a transaction across its life cycle.

The ability to access data outside of the enterprise or, more importantly, receive permission to see the data that is relevant to your trading community, must be made available to any type of AI, e.g., deep learning or machine learning algorithms.

High performing AI systems should be able to assimilate past trends and continually learn from new data and "incrementally adjust" the output. AI systems in supply chain shouldn't adopt a "batch" model where with every new variable or data point the entire algorithm needs a foundational shift in order to achieve a resilient supply chain.

2. Ever changing GXP compliance guidelines and regulatory landscape.

The life science industry, and particularly pharma, is heavily regulated and has strong compliance requirements. These are specific to formulations, therapy areas and geo-specific in terms of assay rules, and FDA guidelines. To make matters worse, these rules keep evolving. This requires complex text mining algorithms to figure out process implications of these ever-changing regulations.

A "Value Office" is a dedicated team focused on value. This is critical as most of the use cases are not localized to a specific silo in the supply chain, use cases are interconnected and often have multi-echelon impact around cost, inventory and service levels.

3. AI use cases beyond the back-office and hyper focus on efficiency.

While many life science companies have tried implementing AI and RPA in their back-office operations, the real value of AI manifests in engaging the users on the front end. For example, leveraging AI algorithms to predict therapies, disease occurrence prediction, and autonomous patient scheduling, as opposed to restricting AI to customer service and productivity-related use cases.

Many pharma companies fail, or are unable, to target other areas like revenue growth, patient compliance, risk, etc., and often have difficulty in establishing the business case for such areas.

4. Focusing on point outcomes without considering the propagation impact of AI-led decision making.

Most major pharma companies have, at best, isolated AI pilots in the works on select areas such as demand planning, freight optimization, vendor screening. This has led to an array of Proof of Concepts (PoC) across the various facets the supply chain., these projects struggle to scale and are unable to achieve the holy grail of supply chain: resilience. This challenge is especially difficult for the pharma industry, because its supply chains are heavily interconnected, from end-to-end and across the tiers, with complex manufacturing guidelines, and zeroing in on a set of network-wide objective functions is crucial for implementation success.

WHERE TO FOCUS FOR BETTER RETURNS ON AI

Let's cut through the clutter.

Amidst all the chatter and hype around AI applications in supply chain, life science brands need to be careful in prioritizing the right use cases, and backed with the fit-for-purpose data and tech stack, so that they can see results in months not years.

At One Network Enterprises (ONE) we interact with a wide range of life science companies, each at a different level of maturity. Yet, they all want the same thing: A set of use cases that offer the biggest return on investment.

We recommend establishing a "Value Office" a dedicated team focused on value (a function at the intersection of customer success and value engineering). This is critical as most of the use cases are not localized to a specific silo in the supply chain. Usually, the use cases are interconnected and have multi-echelon impact around cost, inventory and service levels.

The key is also to invest in the right AI models and data sets while factoring in learning curves. Here is a list of proven and high priority AI use cases in the life science supply chain that could deliver value over a shorter horizon.

LLMs can create optimized onboarding and production lead times and a customized therapy schedule that is dynamic with alerts, so it can sense and propagate issues and impacts in real time across the supply chain.

Multi-tier constrained supply planning and autonomous order promising.

Pharma manufacturing is increasingly outsourced to CDMOs. More than 60% of pharma manufacturing is owned by CDMOs who operate across multiple pharma brands, therapy areas, and formulations.

Many of the APIs and excipients are fungible and through a strict confidentiality framework that can be leveraged across customers to optimize across various objective functions such as profit margins, capacity utilization, fair-share, onset of pandemics.

Predictive analytics and machine learning models can help CDMOs better allocate scarce raw materials, schedule machine downtimes, or identify and mitigate constrained capacities. This can be done based on fluctuating demand patterns and sensing leading heuristics around patient demographics and global events that influence demand.

Predictive analytics around batch failures and predictive maintenance.

As drug formulations get increasingly customized, manufacturing processes have become more complex, and often involve multi-echelon manufacturing processes that change hands across contract manufacturing partners and suppliers. Combine this with competitive forces in the market that reduce time-to-market and batch-failures can have catastrophic impact downstream.

Gathering batch-related data at each stage and layering predictive intelligence that provides alerts around batch failures, especially for early to mid-life cycle products, is therefore of critical importance to alert brands early and provide time to react.

AI-enabled cell gene therapy-oriented drug supply chains.

The growing popularity of personalized medicines has added an extra dimension of complexity to pharma supply chains. The core premise of patient-centric supply chains is to keep the “patient” at the center and architect a value framework around her operating under compressed lead-times.

This starts from smart demand sensing with AI agents and engaging Large Language Models (LLM) that sense and translate current patient demand upstream. LLMs can create optimized onboarding and production lead times and a customized therapy schedule that is dynamic and has alerts built in, so it can sense and propagate issues and impacts across the supply chain.

Interconnected multi-party networks are of tremendous importance here, and enabled through AI they can capture vital information such as patient personas and gene-pools.

Pharma risk and resilience.

Today, AI can be harnessed to analyze historical data, market conditions, weather patterns, and geopolitical events, among other factors, to identify potential supply chain risks. But

AI networks armed with advanced LLMs help bridge the missing links across the three areas of risk detection, risk management, and risk monitoring.

instead of prepopulated dashboards, for example, generative AI can be prompted to produce risk assessments, scenario simulations, and mitigation strategies, all on demand to help planners manage and mitigate the risks proactively.

Pharma companies today struggle with both macro and micro risk in their supply chains because their supply base is increasingly global. Supplier scorecards can consider internal process parameters such as safety stock, delivery/fulfillment SLAs, as well as macro risk factors that impact the suppliers' production process.

Lastly AI networks armed with advanced LLMs help bridge the missing links across the three areas of risk detection, risk management, and risk monitoring. AI helps pharma companies carry out dynamic risk monitoring as risk scores and profiles keep changing, and therefore so must the execution and management strategies.

Today LLMs can parse the web and identify potential risk factors (after screening false positives and segregating them based on certain agreed guardrails around severity) and triangulate supply and logistics strategies thereby minimizing risk and maximizing resilience.

Pharma logistics and chain of custody.

Logistics and transportation management systems are being upended with the advancement of AI. AI-based route optimization, fleet planning, and load scheduling, can now factor in variables such as fluctuating demand, changing health and epidemic scenarios (that could cause acute demand shocks), multi-modal and packaging requirements (including cold chain monitoring).

While the transportation management systems (TMS) space has been impacted by AI, generative AI adds an extra layer of sophistication in last mile route optimization.

Generative AI can continually update and optimize delivery or pickup routes based on changing factors like traffic conditions, weather, and the priority of deliveries. This leads to increased efficiency, reduced fuel consumption and improved customer satisfaction.

Chain of custody and material traceability is another area where there are major implications for pharma, especially related to product and batch recalls.

AI-enabled networks can monitor contra-indication, adverse reactions and expiry information of certain drugs and create a recall plan and schedule based on lot genealogy data, as well as help localize the batch distribution process to lower reverse logistics costs.

For thermolabile cold chain products (vaccines and biologics) AI-enabled networks can record and analyze sensor data to earmark items within lots and batches that have suffered temperature excursions, and then plan quarantine options before the lot reaches the prospective warehouse.

This lowers logistics overheads and helps avoid discarding the entire batch. This improves material availability and minimizes waste by almost 50%.

Prioritized Value Chain Area for AI Implementation	Key Business KPIs Impacted	Key Considerations
Multi-tier constrained supply planning and autonomous order promising	• Planning Lead Time and Productivity • Optimized Product Mix • Higher production capacity utilization	• Multi-tier federated supply networks • Single Unified Data Models • Distributed BOM
Predictive analytics around batch failures and predictive maintenance	• Reduce Batch Failures and improve yield • Reduce machine down-time • Increase OEE (Overall Equipment Effectiveness)	• Integration with CDMOs and Supplier Production Systems of Record • Training ML based predictive models in complex multi-tier mfg. scenarios
AI-enabled cell gene therapy supply chains	• Demand Sensing & Patient Scheduling • Alerts and Lead Time Optimization • Supply Chain Cost vs. Service Level trade-off	• Patient Data anonymization (HIPPA compliance) • Patient and Partner Onboarding • Disease Type vs. Patient pool maps for direct engagement models
Pharma risk and resilience	• Material Availability across tiers – Early/Mid-life cycle products • Multi-Tier Inventory Optimization • FDA compliance & Product Recall	• Establishing Risk models (Exogenous & Endogenous) through multiple sources • Selecting the right Tech ensemble to bridge the gap between Risk Detection & Risk Monitoring
Logistics and chain of custody	• Freight & Global Trade optimization • Cold Chain compliance / Product Recall – quality rejection • Lead Time Optimization and Expedites	• Carrier Onboarding and data integration • TMS integration with Planning and Ordering workbench • Product serialization rules compliant to regulatory norms such as DSCSA in the USA

Figure 1: A breakdown of where value can be gained with AI in the pharmaceutical supply chain.

AI also enables pharma and biotech companies in global trade optimization by analyzing multiple factors such as tariffs, customs regulations, trade agreements and shipping costs, to propose the most efficient and cost-effective trade routes and strategies. This aids life sciences companies in navigating complex international trade networks, helping ensure compliance while minimizing costs. This is especially relevant when dealing with international supply bases and contract manufacturing set-ups located in Asia and Europe.

See the table (*figure 1* above) for a quick summary of each prioritized area, the business metrics impacted, and key considerations.

PRE-REQUISITES FOR A SUCCESSFUL AI IMPLEMENTATION IN LIFE SCIENCES SUPPLY CHAINS

Having discussed the potential limitations and the set of use cases to focus on, it's important to talk about some of the drivers for a successful implementation that offers a scalable platform for further expansion and development. By now it's amply clear that a networked ecosystem of partners with a common unified data model is foundational to any AI application to thrive and realize it's full potential.

Identify the right AI tech and Network partner

Selecting the right technology (product) and implementation partner is crucial. There are several AI products in the market across platforms, workflows, prediction engines et al. The fundamental pre-requisite for a successful AI pilot is a product

A Semi-Autonomous Supply Chain Network for Life-Sciences

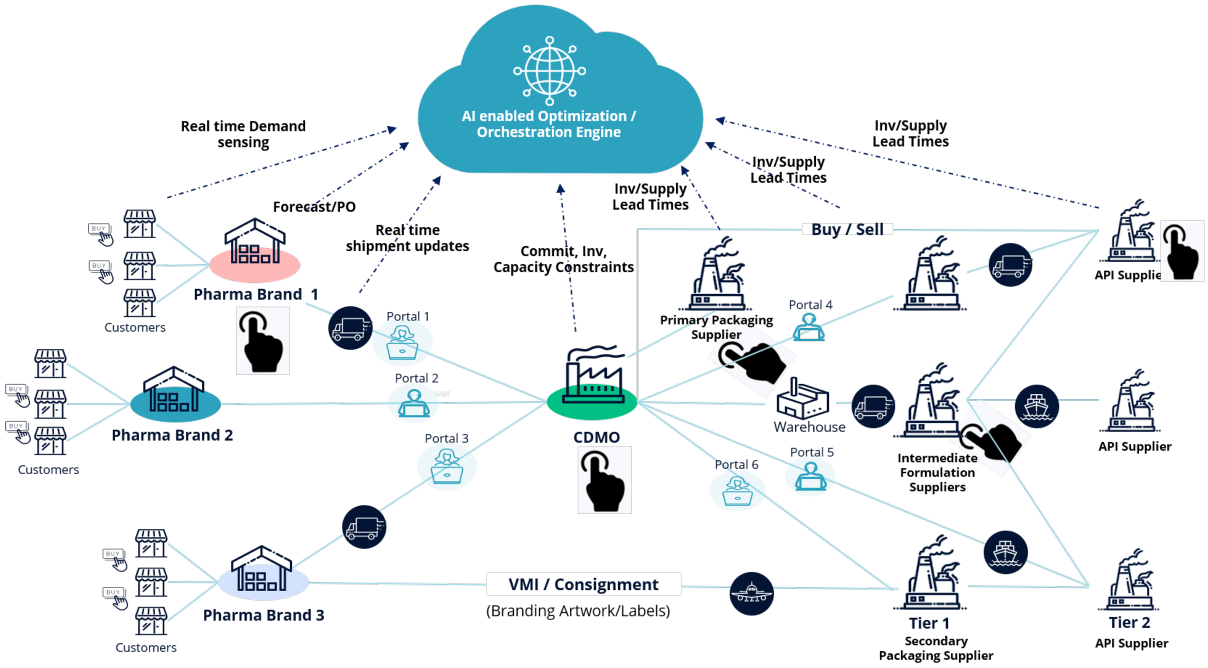

Figure 2: A Semi-Autonomous Supply Chain Network for Life-Sciences. A semi-autonomous federated supply chain network for life sciences that goes from visibility, to orchestration, to AI led optimization. All trading partners contribute with the relevant data sets accelerating the learning curves and creating value for all. Any node/hub in the network can "push the button" that optimizes across the value chain.

that enables multi-party, multi-tier network towards supply chain resilience and evaluates and responds to shocks across supply and demand tiers.

It's equally important to select a AI system that's supported by a network and imbibes data and signals from both internal and external sources into a central orchestrator that then can run real-life optimization without being just confined to internal data sources.

The technology must have a robust data permissibility framework so as to ensure it partitions confidential information and provides only the output to network partners. For example, for an AI system to do constrained supply planning across the value chain, the technology needs to be fed material/capacity constraints from all network players, which each individual party wouldn't be comfortable sharing with their downstream customers. This is very similar to how Facebook has restrictions around sharing personally identifiable information (PII) data, and how HIPPA restricts sensitive data-sharing and requires adequate permissions and guardrails. (See diagram *figure 2* above.)

Key to making the right choice, is choosing a system implementation partner with strong life sciences and pharma supply chain domain experience (as opposed to having large IT service bench). The solution integrator needs to have a good sense of pharma data models and quality frameworks to ensure any AI project fits within the regulatory guardrails. Prompt engineering in the pharma space is quite domain and function-specific, and generic LLMs can't go beyond a certain point, potentially making them a bottleneck.

Getting the Network Design Right

AI in supply chain cannot reach its full potential without a network of networks which is fundamental in data


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aggregation. However how quickly you build this ecosystem determines the payback curve. Network design therefore is foundational in dictating the use cases to go after (not the other way round).

To make this clear, if a brand has it is critical players on a network (CDMOS, suppliers, carriers, etc.) then it becomes that much easier to design any new supply chain around that ecosystem, especially when it comes to new products and therapy areas which may still leverage the same suppliers, co-manufacturers, and packers. It becomes easier for medium to large pharma companies to pivot to new and emerging product portfolios that require different SLAs, lead times and inventory norms.

Scoring early wins

Focus on establishing the business case and a value office, work around constraints pertaining to data and system integrations. The optimum release cycle we see in the market is around 6-8 months. To make this happen choosing the right integration strategy is key. The trick is to standardize data and process models and leverage "out of the box" APIs and standard EDIs that require minimal customization and maintenance.

Scoring early wins is critical to drive user adoption. User adoption reinforces the machine learning curves that in turn creates a flywheel effect of broader AI penetration across a brand's supply chain. For example, prioritizing a predictive analytics use case in cold chain logistics can be a better starting point for a pharma company grappling with high obsolescence; rather than coding Python-based supplier management or spend analytics algorithms in procurement just to catch up with peers/competitors.

Organizational change management

Change management underscores every AI implementation – both internal and external - change advocacy is critical. Internally communicating the value of AI engagements in supply chain early on is important, so that internal stakeholders can not only see "what's coming" but understand "why it's coming."

Hence, building a business case solely around efficiency and productivity can often be counterproductive and undermine the true impact of the project.

External change management is equally critical. Any slight change in data exchange and integration can be a huge change exercise for suppliers, carriers and contract manufacturers. For example, moving from csv files to special purpose APIs could mean additional IT effort on building data lakes and adapters on the partner side. This needs to be considered in the plan and timed appropriately considering their business priorities.

CONCLUSION

In summary, life science companies should be aware of the many challenges and mistakes that beset AI projects in the supply chain, and guard against them.

Establish a dedicated team and a "value office" that is informed, focused on value, and can keep the project on track.

Focus on the proven, high value use cases that AI can deliver in the supply chain, such as multi-tier constrained supply planning and autonomous order promising. And when it comes to risk management, harness data beyond the supply chain, so that AI-enabled risk assessment is accurate and mitigation strategies are more effective.

Finally, look for an experienced partner with domain supply chain expertise and a proven network-enabled AI solution. The solution should include a flexible life sciences and pharma data model, and scale across the network, to include multiple tiers and parties. It should support rapid onboarding of partners across tiers while shielding all players from complex data integration protocols through proven network level adapters.

Prioritize the early and easy wins but keep the value office focused on the long-term value. Change management is vital, both internally and externally. Ensure all key personnel at key organizations know what's happening and why it is the way it is. Be especially sensitive to, and considerate of, changes that impact trading partners.

Following these guidelines will help pharmaceutical and healthcare companies and their networks gain significant and sustained benefits in their AI journey.

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