Wake-Up Call:

Digitally Transform Your Pharma Supply Network **NOW**

Thrive in a World of Uncertain Customer Demand and Material Supply

tracelink.

NETWORK FOR GREATER GOOD

Executive Summary

Disruptions caused by COVID-19 exposed and amplified weaknesses that have long existed within the pharmaceutical supply chain. As the supply chain becomes larger and more complex, it's clear that efforts must be undertaken to increase agility and resilience.

But a host of obstacles—like a lack of standardized processes for resolving supply network issues, disconnected enterprise systems, and lagging adoption of digital technologies—have historically stood in the way pharma supply chain agility.

To overcome these obstacles and increase supply network agility, pharma companies need to focus on strengthening key capabilities, including visibility and awareness, real-time data access, rapid decision-making, and responsiveness.

The good news is that today, there is a better way to bring internal company teams and external supply chain partners together in real time to quickly resolve incidents, manage changes, and continually identify business process improvements that have a positive impact on the bottom line.

Multienterprise work management software provides a systematic, network-driven approach to orchestrating workflows, business rules, and information across disparate teams and companies, enabling you to build a more agile supplier network.

Agile Process Teams™ from TraceLink— the only multienterprise work management solution that runs on a network purpose-built for the life sciences supply chain—empowers pharma companies and their supplier networks to collaborate closely on critical business processes and resolve issues fast. With Agile Process Teams, you can:

- Create secure process networks and invite users from different functions from inside and outside the organization to share data and documents and collaborate on business activities.

- Track details with dashboards, due dates, accountable parties, workflow steps, notifications, shared documents, and clear communication.

- Create a single source of shared information without integration headaches.

- Measure performance, enable industry benchmarking, and identify permanent process improvements.

In addition to increasing supply chain agility and resilience, Agile Process Teams helped one global pharma company achieve **more than $100 million in annual cost savings and cost avoidance**.

Agile Process Teams enables you to digitalize shared work that spans multiple enterprises, providing greater accountability, visibility, and agility.

> **Learn more about Agile Process Teams today.**

WAKE-UP CALL:

Digitally Transform Your Pharma Supply Network **NOW**

Reduce disruptions | Drive down costs | Discover a better way
to work with supply network partners

For the pharma industry, the COVID-19 pandemic amplified problems that have existed—and largely been tolerated—for decades. Supply chain gaps and vulnerabilities have long been hidden by an increasingly unsustainable mix of high inventory levels and ad hoc solutions to manage quality, supply, materials, and production problems.

The ongoing disruptions caused by the pandemic have revealed two truths: The pharma supply chain is inherently and increasingly fragile—and steps must be taken to significantly improve supply chain agility, responsiveness, and resilience.

What's preventing higher levels of agility?

A host of challenges to supply chain agility and tighter supply network collaboration have historically stood in the way of the pharmaceutical industry's ability to be resilient in the face of disruptions. These include:

- A lack of standardized processes for collaborating with partners on supply chain issues
- A reliance on time-consuming and difficult-to-track manual business processes
- Poor supply chain visibility
- Lagging adoption of digital technologies

While investments in ERP systems, quality management systems, and other key business applications continue to serve important functional purposes, they were not designed to support shared work with supply chain partners. Disruptions caused by the COVID-19 pandemic—and the sudden global transition to virtual workforces that followed—both exacerbated and shined a light on these problems.

While there is certainly no shortage of challenges to supply chain agility, there is some good news: Today, there is clear path to creating tighter supply chain collaboration and a better way to bring internal company teams and external supply chain partners together in real time to resolve incidents, manage changes, and identify the kinds of process improvements that led one global manufacturer to more than $100 million in annual cost savings and cost avoidance.

How did the manufacturer do it? With the help of multienterprise work management software.

Multienterprise work management software enables a systematic, network-driven approach to orchestrating workflows, business rules, and information across disparate teams and companies. With multienterprise work management, you can create networks of people and processes to ensure everyone has the information they need to work effectively. Processes like tracking and resolving issues, batch record reviews, managing change controls, and quality document reviews can run faster and with less effort with the help of a multienterprise work management solution.

Agile Process Teams™ from TraceLink—the only multienterprise work management solution purpose-built for real-time pharma supply chain network collaboration—is a shared application that empowers pharma companies and their supply network partners to collaborate closely on critical business processes and resolve issues fast.

In this eBook, we'll explore the critical capabilities needed to achieve greater agility in the pharma supply chain—and explain how Agile Process Teams can help you reach new levels of supplier collaboration, so you can reduce disruptions, drive down costs, and improve on-time, in-full (OTIF) performance.
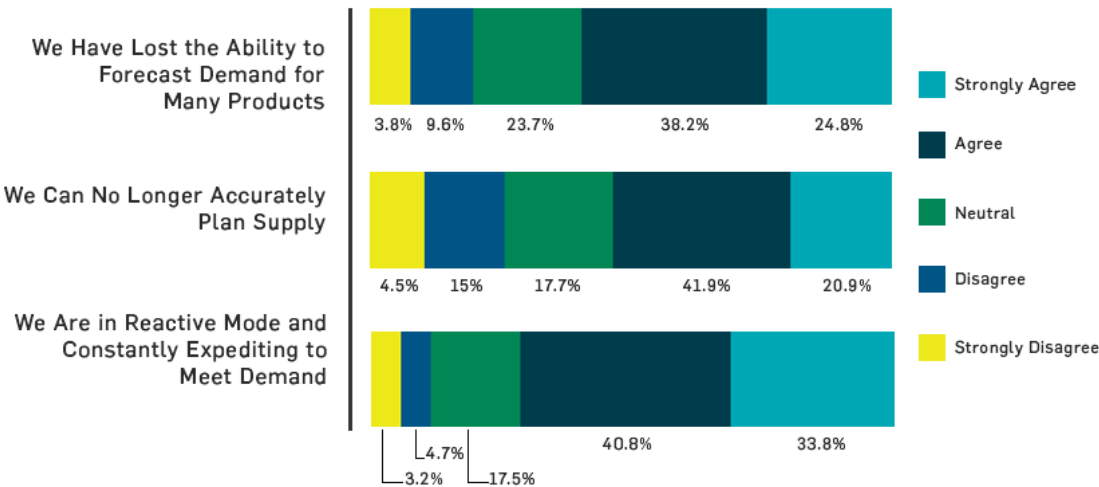
> " Achieving supply chain agility requires capabilities that will help you ensure much tighter, more transparent, and holistic relationships with suppliers, as well as structured collaboration that has not been consistently achieved in the pharmaceutical industry. "
>
> **IDC,**
> "Supply Chain Agility in the Pharmaceutical Industry," June 2020
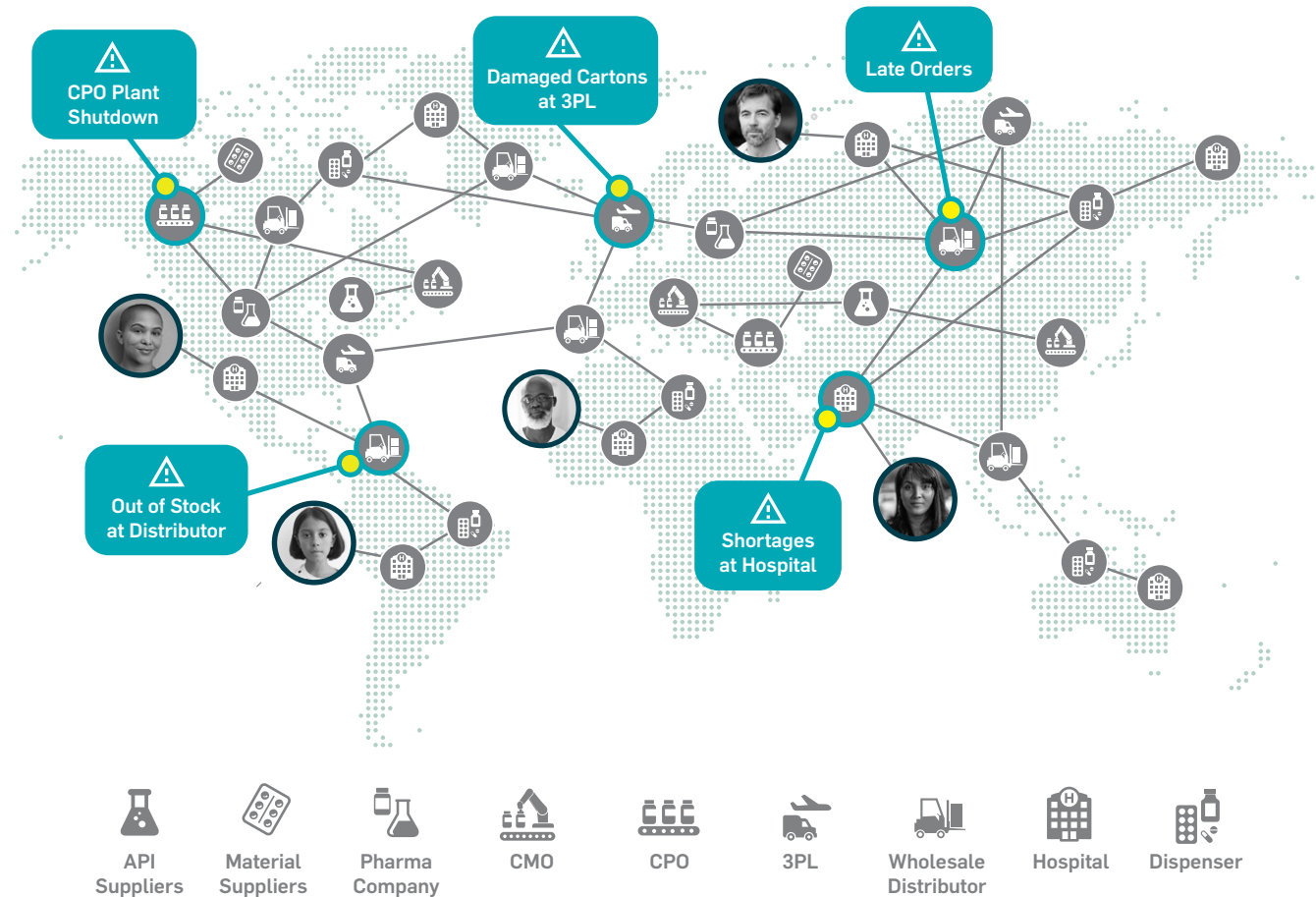
Supply Chain Planning
Please Indicate Your Level of Agreement with the Following Statements.
As a Result of the COVID-19 Pandemic...

	Strongly Agree
	Agree
	Neutral
	Disagree
	Strongly Disagree

We Have Lost the Ability to Forecast Demand for Many Products: 3.8% | 9.6% | 23.7% | 38.2% | 24.8%

We Can No Longer Accurately Plan Supply: 4.5% | 15% | 17.7% | 41.9% | 20.9%

We Are in Reactive Mode and Constantly Expediting to Meet Demand: 3.2% | 4.7% | 17.5% | 40.8% | 33.8%

Source: IDC survey of pharma supply chain executives and managers, 2020

COVID-19 revealed the value of early detection and prevention

In today's complex, interdependent global pharmaceutical supply chain, every step—from ingredient and materials sourcing, manufacturing, packaging, and quality control to storage, distribution, and dispensing—represents a potential point of failure and need for rapid response.

Raw material shortages, wrong lead times, distribution problems, quality control holds, failed inspections, lack of proper documentation, and delayed documentation are just a few of the countless daily issues that can affect drug availability and impact your bottom line.

In the past, pharmaceutical companies have tried to compensate for supply chain disruptions by maintaining excess inventory as a cost of doing business—and yet shortages are still on the rise. The pandemic further demonstrated the weakness of this approach as eight to twelve months of inventory were depleted in days—or became excess as demand suddenly shifted to other medicines and supplies. Poor real-time visibility into these demand shifts limited options and made it difficult for supply chain managers to respond to shortages, for example, by activating secondary sources of supply.

Early detection of issues is essential for supply chain agility. The sooner an issue can be identified in the supply and manufacturing process—before it becomes a disruption—the more the cost of corrective actions and the impact on customer satisfaction can be reduced. Because permanent resolutions to many issues require changes to products, materials, and processes across multiple supply chain partners, a collaborative change management process is also critical for building a more resilient supply chain.

Addressing long-standing supply chain vulnerabilities means creating a collaborative, multienterprise approach for managing issue resolution and implementing permanent changes to prevent recurring problems. In the case of a global pandemic, collaborative decision-making based on a single source of truth can be the difference between responding to a massive disruption and being overwhelmed by it.

Characteristics and capabilities of supply chain agility

> " Great companies create supply chains that respond to sudden and unexpected changes in markets. Agility is critical, because in most industries, both demand and supply fluctuate more rapidly and widely than they used to. Most supply chains cope by playing speed against costs, but agile ones respond both quickly and cost-efficiently. "

Hau Lee, Professor, Stanford University School of Business,
'The Triple-A Supply Chain', Harvard Business Review, 2004.

For decades, the term "agile" has been used to describe the trend toward more flexible and responsive supply chain operations in consumer goods, fashion and apparel, high tech, and automotive manufacturing. Agile supply chains can detect—and respond immediately to—sudden changes in demand or supply; react to unexpected disruptions promptly and cost-efficiently; and recover quickly from major shocks such as natural disasters, epidemics, and geopolitical events. Key characteristics of agile supply chain management include:

- **Awareness.** The ability to quickly detect changes, opportunities, and threats.

- **Real-time data access.** The ability to quickly find and share relevant data.

- **Rapid decision-making.** The ability to make decisions quickly using the available data.

- **Responsiveness.** The ability to implement decisions quickly.

- **Flexibility.** The ability to adjust processes and operations needed to implement a change in supply chain strategy.

- **Competency.** The ability and expertise to do things right the first time.

1) Hau Lee, 'The Triple-A Supply Chain', Harvard Business Review, 2004, https://hbr.org/2004/10/the-triple-a-supply-chain
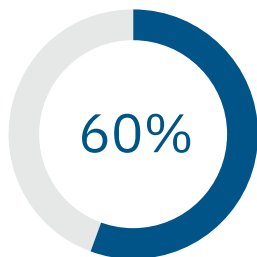
Agile supply chains can also be characterized as supporting collaborative relationships with suppliers and customers to evaluate, design, and redesign processes and prepare backup plans, including identifying and onboarding alternate supply sources and logistics providers. By sharing data on supply and demand changes continuously, internal and external teams can respond and pivot quickly—and senior managers can prioritize actions, assign teams, and monitor results.

Agile capabilities also contribute to a company's overall performance goals by enabling continuous process improvement. For a pharmaceutical manufacturer with $500M in annual revenue and $250M in the cost of goods and services, long-term process improvement can represent a significant reduction in lost revenue:
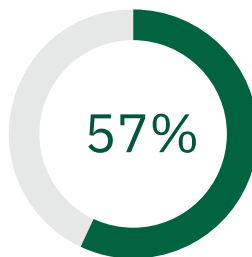
- **On-time, in-full delivery:** A 10% to 20% reduction in shipping delays can save as much as $2M per day in lost revenue.

- **Order fulfillment cycle time:** A 15% to 40% reduction in lead times can reduce work-in-process inventory by as much as $700K per day.

- **Right time, first time quality:** A reduction in defects can represent as much as $1M saved annually in expedited deliveries and express shipping costs alone.

A need for of standardized collaboration processes

To achieve the benefits of greater supply chain agility, members of the end-to-end healthcare supply chain need a more effective mechanism for collaborating with their network partners. According to IDC's recent pharma industry survey:

60%

More than 60% of pharma companies and CMOs lack standardized processes for resolving issues with upstream partners.

57%

More than 57% of pharma companies and CMOs lack standardized processes for resolving issues with downstream partners.

The collaborative infrastructure needed to build a more agile pharmaceutical supply chain has its foundation in the information-sharing networks and cloud-based solutions developed to meet product serialization and track-and-trace regulations around the world.

These solutions and platforms have also laid the groundwork for the digitalization of the pharmaceutical supply chain, replacing emails, spreadsheets, and scanned documents with standardized data formats and schemas that enable real-time data exchange as well as analytics. Extending these systems to supply chain operations is critical to the evolution of the pharmaceutical supply chain.

Using a digital platform for partner collaboration creates a more resilient supply chain that can deliver critical medicines under both ordinary and extraordinary circumstances.

Multienterprise work management:
Digitalizing the way you work with supply chain partners

How Work With Suppliers Gets Done Today

40%

STRUCTURED & FIXED

Clearly defined, repeatable processes that naturally fit into a system:

ERP – Forecasts, Orders, Acknowledgment, ASNs

QMS – Batch Records

WMS – Inventory & Supply Chain Fulfillment

CRM – Customer Orders

60%

UNSTRUCTURED & DYNAMIC

Multienterprise work that has traditionally been done manually using email, docs, and spreadsheets:

Supplier Issue Management	**Biotech Process Control**
Change Management	**Forecast Planning**
Document Review	**Efficacy Reporting**
Quality Batch Review	**KPI Dashboarding**
New Supplier Onboarding	**Supplier Due Diligence**
Clinical to Commercial	**Production Forecast**

Existing systems like ERP, QMS, WMS and CRM are designed to handle clearly defined and repeatable processes. But most work with supply network partners today is unstructured. Collaborative, cross-functional, and cross-company processes like supplier incident management, change requests, and quality batch reviews are managed using email, documents, and spreadsheets. With multienterprise work management software, supplier relationship management teams are able to:

- Bring together teams of stakeholders from across companies and departments.

- Assign tasks and track progress with pre-configured business logic and customizable workflows.

- Establish a single, digital source of truth so stakeholders across multienterprise teams can remain aligned.

- Gain full, actionable visibility into the status of processes and the performance of suppliers across the end-to-end supply chain.

- Digitalize supply chain processes and speed up the digital transformation of the supply chain.

The bottom line? Multienterprise work management software enables you to bring structure and control to previously unstructured business processes.
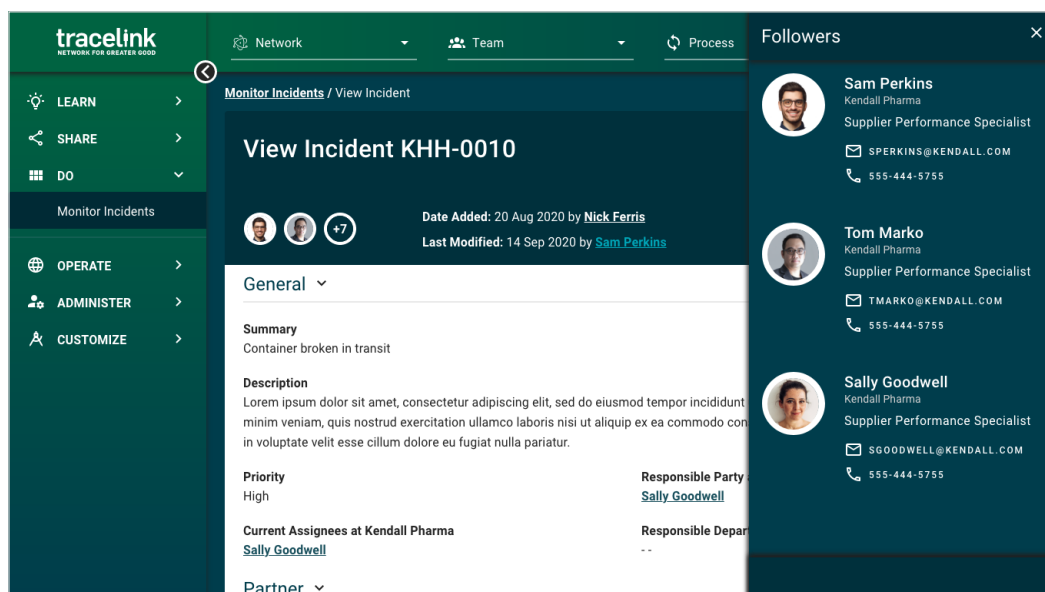
Agile Process Teams:
A better way to work with your supply chain partners

TraceLink Agile Process Teams—the only multienterprise work management solution purpose-built for the life sciences supply chain—enables you to create digital networks that connect teams representing various functions from both inside and outside of your organization to orchestrate and execute shared work. With Agile Process Teams, you can:

- Create secure process networks and invite users from different functions from inside and outside the organization to share data and documents and collaborate on business activities.

- Track the details with due dates, accountable parties, workflow steps, documents, and communication.

- Notify partners when dates are coming due or past due.

- Monitor dashboards and reports to track work in process.

- Measure performance, enable industry benchmarking, and identify permanent process improvements.

Agile Process Teams provides out-of-the-box templates to support shared processes such as supplier incident tracking, change management, and quality document review. It also enables digital collaboration across a broad range of additional supply chain activities like artwork coordination, supplier onboarding, and supplier performance management.

Creating an agile supply chain begins with digitalizing processes that are shared across network partners—and with Agile Process Teams, you can begin creating a more agile supply chain today.

Agile Process Teams for improved supplier relationship management

As the use of outsourced services has grown in the pharma industry, supplier networks have become larger and much more complex. As a result, achieving consistent supplier performance outcomes relative to benchmark goals for the delivery of products, processes, and services is growing more difficult all the time.

In other words, supplier relationship management has never been more challenging—and pharma companies need a better way to work with suppliers to address a wide range of supplier relationship management business problems. Some examples include:

PRODUCTION MANAGEMENT PROCESSES

- Production slowdowns
- Schedule changes
- Capacity problems at suppliers

QUALITY DEFECTS

- Material defects
- Out of spec
- Lengthy quarantines
- Packaging errors

SUPPLIER MANAGEMENT PROCESSES

- Supplier onboarding due diligence
- New product launch tech transfer
- Managing ecosystem of upstream suppliers
- Slowdowns in product review cycle time

Agile Process Teams is a multienterprise work management application that enables internal stakeholders and domain experts from suppliers to quickly identify, track, and collaboratively resolve all types of production management, quality, and supplier management issues.

With pharma companies and their suppliers working together in Agile Process Teams with the same data and priorities, all parties benefit from improved business relationships and greater levels of collaboration. Agile Process Teams can help you improve productivity and delivery performance and take your supplier relationship management capabilities to the next level.

Agile Process Teams for managing changes with suppliers

Changes are an integral part of the agile supply chain—and a lack of visibility into multi-company change management processes across suppliers creates supply risk and delays. With Agile Process Teams, supplier relationship management teams can leverage a shared workspace and workflow-driven processes to communicate, collaborate on, and agree to changes in schedules and priorities. Teams can also customize roles, user experiences, and workflows to create unique change request processes for a wide variety of changes. Examples include production changes, process changes, and standard operating procedure changes.

Agile Process Teams for document review management

Agile Process Teams includes out-of-the-box templates for document review management, enabling supplier relationship management teams to take advantage of workflow-driven processes for the exchange, review, and approval of all types of documents, including manufacturing instructions, quality procedures, product specs, material safety data sheets, packaging artwork, inserts for instruction sheets, and bills of materials.

Agile Process Teams for supplier incident tracking

Agile Process Teams has been proven to reduce supply chain disruptions, reduce defects, reduce customer complaints, and significantly improve the flow of medicines to patients through collaboration with material suppliers, CMOs, CPOs, 3PLs, wholesalers, customers, and internal sites. It helps manufacturers quickly identify and resolve supplier issues, initiate sustainable process improvements, and capture key measurements to understand the value of those improvements.

Global pharma company transforms supplier management with Agile Process Teams

Decreases Supply Chain Disruptions by Over 80%

Daily challenges like sudden changes in demand, material shortages, and delays in approving seemingly routine supplier change requests led one global pharmaceutical manufacturer to experience a host of problems, including a degradation of OTIF performance, a high defect rate in materials, delays in product launches, and escalations that consumed an inordinate amount of time.

To address these problems and collaborate more effectively with its suppliers, the company turned to Agile Process Teams from TraceLink. **Agile Process Teams delivered significant performance improvements that led to more than $100 million in annual cost savings and cost avoidance**, including:

68% decrease
in time to resolve incidents

Over 80% decline
in supply chain disruptions

Over 70% reduction
in defects per million

Over 80% decrease
in escalations that have to be resolved by top management

20% reduction
in time to approve quality documents, resulting in faster product release

38% drop
in incidents

While the company had sophisticated ERP, procurement, quality, and other systems for managing routine transactions with suppliers, none of these systems were suitable for resolving the various types of supply chain incidents that arise. Traditional enterprise collaboration tools offered improved communications internally but did not work outside the company's four walls and lacked support for managing structured business processes.

Agile Process Teams provided a foundation for tighter collaboration and issue resolution and enabled the company to reduce supplier business process deficiencies and quality defects and improve delivery performance. It also provides a new way to track and measure supplier performance over time to make sure they were meeting the company's goals for continuous improvement.

The company's supplier management organization initially went live with Agile Process Teams Incident Management and Change Management processes internally. Then they extended its use to suppliers across multiple company divisions. They are now using Incident Management with hundreds of suppliers to track and resolve issues such as demand changes, quality problems, damaged products, temperature excursions, and incomplete shipments.

Agile Process Teams for supplier incident management:
How it works

In addition to digitalizing change management and document review processes, Agile Process Teams allows teams and managers to track a complete spectrum of internal and external issues and incidents categorized by assessment, impact, priority, team assignment, reoccurrence, and follow up. Configurable categorization allows managers to structure initial and final response workflows detailing root cause investigations and corrective actions; helps managers track and monitor the progress of collaborative process improvement tasks; and facilitates more precise root cause analysis follow up.

With Agile Process Teams, you can launch a collaborative digital workspace where teams from across your supply network can determine workflows, share documents, and provide incident response updates in real time.
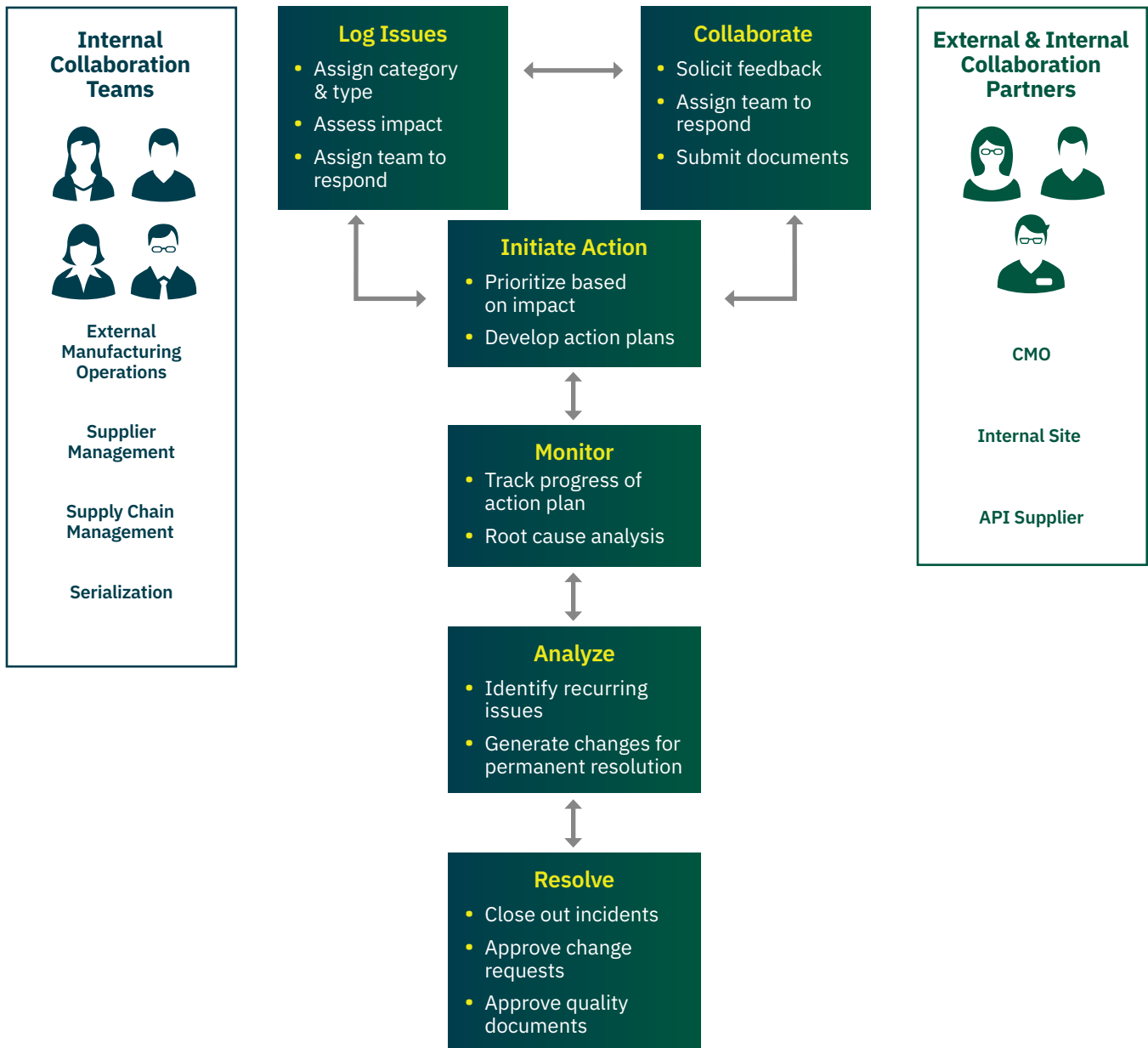

Agile Process Teams helps companies track, manage, and collaborate on a wide range of supply chain and production issues, including:

- Missing/incomplete documentation
- Out of stock
- SOP not followed
- API quality
- Late shipment
- Damaged shipment
- Out of specification
- Incorrect label/artwork
- Incorrect lead times
- Clinical supply
- Material shortage
- Invoice errors
- Customs hold
- Incorrect test results
- Inbound quality sampling issue
- Transaction/physical count
- Shipment delay
- Lack of inventory visibility
- Logistics disruptions
- Equipment failure

AGILE PROCESS TEAMS
How it Works

Internal Collaboration Teams

External Manufacturing Operations

Supplier Management

Supply Chain Management

Serialization

Log Issues
- Assign category & type
- Assess impact
- Assign team to respond

Collaborate
- Solicit feedback
- Assign team to respond
- Submit documents

Initiate Action
- Prioritize based on impact
- Develop action plans

Monitor
- Track progress of action plan
- Root cause analysis

Analyze
- Identify recurring issues
- Generate changes for permanent resolution

Resolve
- Close out incidents
- Approve change requests
- Approve quality documents

External & Internal Collaboration Partners

CMO

Internal Site

API Supplier

Create teams of internal and external experts

Every supply chain deviation, change request, and quality review affects a different cross-section of internal and external stakeholders. Agile Process Teams provides a secure, structured, and collaborative digital network that enables managers to create teams and ensure that the right team members have access to the resources they need to successfully manage multienterprise processes and issues. Similar capabilities enable managers to assign collaboration teams to evaluate, approve, and execute changes and quality reviews. Rules-based collaboration creates separate internal threads to discuss sensitive or proprietary topics inside the broader, supplier-inclusive dialogue.

Agile Process Teams replaces disconnected and ad hoc manual tracking processes with direct collaboration between cross-functional teams and supply networks. As incidents are created, categorized, tracked, and closed, historical data is captured so managers can follow up with root cause analysis and prevent issues from recurring. Agile Process Teams can reduce the number of unwarranted escalations and enable executive management to "follow" critical issues, receive alerts, and "unfollow" issues when they are resolved.

Use Case:
Material Shortage Requiring Secondary Source

SITUATION: Kate, a supplier relationship manager learns that orders for her company's most profitable product have doubled, but a key supplier can only ship 60% of a critical ingredient needed for manufacturing. Kate and her team need to quickly source the ingredient elsewhere and adjust the game plan to ensure that the orders are delivered on time, in full.

SOLUTION: Problems like these have traditionally been solved with a long and frustrating cycle of emails, attachments, and telephone messages. But with Agile Process Teams, Kate can create a digital network consisting of cross-functional team members from inside her organization and across her supplier network. From there, team members can agree on a course of action, assign tasks, share documents, track progress, and resolve the issue.

BUSINESS VALUE: Because Kate and her suppliers now have a common understanding of all the facts, information, and next steps, the issue is resolved much faster and production and shipment delays are avoided. Revenue and time to market goals are met, and costs related to managing the supply disruption are minimized. Over time, understanding the patterns of material shortages allows companies to build resilience and lower safety stocks resulting in increased OTIF, better cash conversion cycle, improved visibility, fewer disruption escalations, and improved supplier performance.

How does Agile Process Teams make your supply chain better?

Agile Process Teams delivers operational performance benefits across your organization and your end-to-end supply chain. Take a look:

Team members perform better

- Individuals can quickly assemble multidisciplinary teams from multiple companies to make better decisions faster.

- Team members also gain a digital source of the truth where they can review critical documents and see what is happening, why it is happening, and what needs to happen next.

Pharma companies perform better

- Reduce manufacturing disruptions.

- Reduce product defects.

- Reduce repeat deviations.

- Reduce cost of goods sold.

- Improve on-time, in-full delivery performance.

- Become more responsive to sudden fluctuations in patient demand.

- Achieve greater supply chain resilience in the face of disruptions like those caused by COVID-19.

Suppliers perform better

- Gain a centralized view of supplier performance across the organization.

- Benchmark performance across suppliers.

- Tighter collaboration with suppliers drives permanent process improvements that positively impact the bottom line.
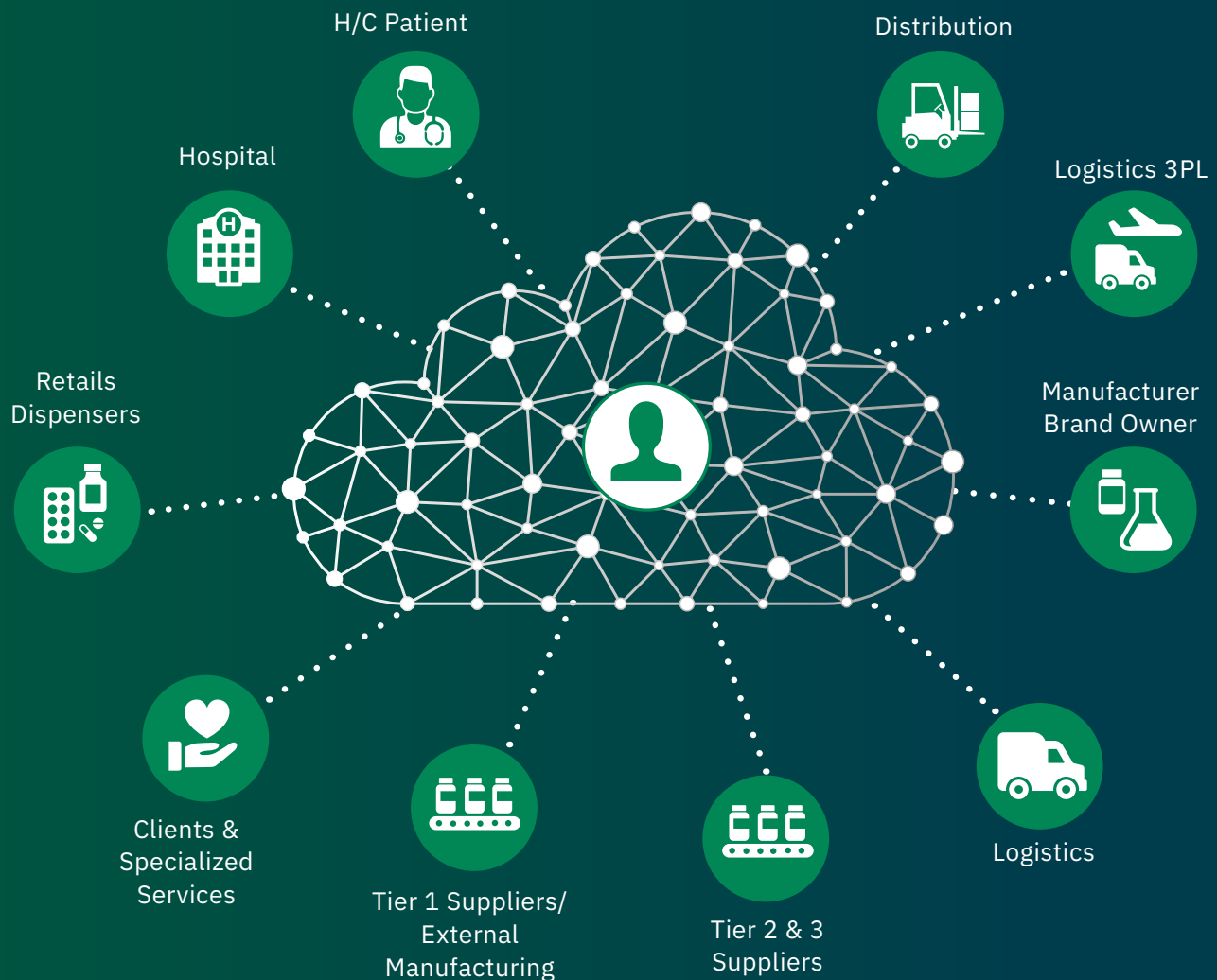
Company leaders perform better

- Gain a new source of supply chain insights for improved decision-making.

- Increase your visibility into critical supply chain processes.

> " Adopting a multienterprise work management platform has dramatically improved the overall performance of our value chain. Everyone is on the same page and working from the same digital source of truth. We don't need to look into emails and spreadsheets to see what is going on, what needs to happen next, and why something happened. We've cut our incident resolution times by 5x, and the visibility has helped us prevent issues from recurring. "

Sr. Director of IT for External Manufacturing at a large pharma manufacturer

TraceLink's Opus Digital Network Platform powers multienterprise work management and collaboration solutions that connected your entire end-to-end supply chain.

H/C Patient

Distribution

Hospital

Logistics 3PL

Retails Dispensers

Manufacturer Brand Owner

Clients & Specialized Services

Tier 1 Suppliers/ External Manufacturing

Tier 2 & 3 Suppliers

Logistics

Integrate Once, Interoperate with Everyone™ on the TraceLink Network

Agile Process Teams leverages the breadth and depth of the only end-to-end digital supply network for life sciences. With more than 280,000 trading partners on the TraceLink network, many of your customers, 3PLs, CMOs, and suppliers are already connected and verified for faster onboarding. Suppliers that already use TraceLink applications don't need to learn a new software system: They simply activate another manufacturer to start collaborating.

The TraceLink Digital Supply Network

1,450+

Direct Materials Suppliers and Partners

1,800+

Pharmaceutical Manufacturers

850+

CMOs & CPOs

870+

Distribution & Logistics

275K+

Healthcare & Pharmacy

Ready to start building a more agile supply chain?

Agile Process Teams is a powerful multienterprise work management application that enables you to digitalize shared work across different functions both inside and outside your enterprise, providing greater accountability, visibility, and agility to ensure work gets done quickly and efficiently.

Learn more about Agile Process Teams today.