The Pulse of Life Sciences Supply Chain

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Global life sciences market overview

In years to come, the global life sciences market intends to put more emphasis on restructuring the industry, getting stakeholders ready to seize the many opportunities the pandemic has revealed and accelerated. Forward-thinking businesses aim to adopt a "Digital First Approach" mentality in the coming year and evaluate how these technologies may enhance human capabilities and modernize the execution of procedures.

As a result of new and evolving technology advancements, the healthcare industry is gearing up for disruption with more sophisticated electronic medical records (EMRs), wearable health care devices, next-generation sequencing, immunotherapy, gene therapy, breakthroughs in genomics, real-world evidence (RWE) studies, advanced data analytics and more.

The fact is that the world of regulatory compliance is ever evolving, and the need for customized products is raising R&D expenses and efforts. The demand for better healthcare has significantly changed over the past couple of years, which has inversely changed the way clinical trials are run.

Technology-driven innovation has grown exponentially, and McKinsey estimates that using such innovation to deliver individualized care may generate between $350 billion and $410 billion in annual value. And there is no denying fact that clinical trials and medical devices have quickly imbibed these innovations with oximeters, e-Consent forms, and tablets used for data collection.

Technology-driven innovation to generate between $350-$450 billion in annual value

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Emerging supply chain trends in life sciences

Modern life sciences organizations understand the technological forces that surround them and look for ways to harness them for the benefit of consumers and patients alike. They are gearing up to adapt life science-specific technology trends most likely to disrupt over the next 18–24 months. Let's check out trends that may be most relevant and could have significant effects on life sciences and healthcare businesses, from the rise of strategy and technology becoming inseparable to the fast-eroding line between the real and virtual worlds.

Life science-specific technology trends to disrupt over the next 18-24 months

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Emerging supply chain trends in life sciences

To increase agility, more life science enterprises are growing smart factory capabilities. Biopharma and MedTech firms are investing in fully digitizing and integrating manufacturing information technology (IT) and operational technology (OT). They are attempting to increase performance, reduce cyber risk, and alter infrastructure and culture.

Life sciences organizations employ data-driven technologies—like artificial intelligence (AI), machine learning (ML), and the Internet of Things (IoT). They are focusing on improving visibility and performance capabilities by seamlessly linking and integrating their heterogeneous production systems and processes.

The life sciences industry has already embraced cloud processes for scalability, but industry-specific cloud-enabled data, ecosystems, and services are the next frontier. Leading enterprises are improving their cloud and data strategies to fuel R&D, commercial functions, and patient engagement.

Life sciences organizations are beginning to address repetitive work by automating processes across the board, using technologies including AI /ML. Expect to see more companies not only automating processes inside their organizations but amping up automation to deliver precision experiences for patients and partners too.

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Emerging supply chain trends in life sciences

Nowadays healthcare companies are conducting clinical trials enabled by remote monitoring or virtual patient check-ins. With medication companion applications or digital therapeutics, they are trying to enhance treatment regimens supplemented by wearables or medical devices like glucometers and medication distribution devices.

Blockchain is fundamentally a living list of linked digital records—a distributed ledger—that permanently stores updates via a consensus among those who share it. Without the need for a central repository, all records of the detailed transactions are embedded in the information itself.

Modern analytical platforms are being used to easily process information from different sources and store it in one place. This enables you to perform self-service analytics and make informed decisions using real-time data. The use of big data analytics in healthcare has a lot of positive and life-saving outcomes in a smart and fast way, such as EHRs.

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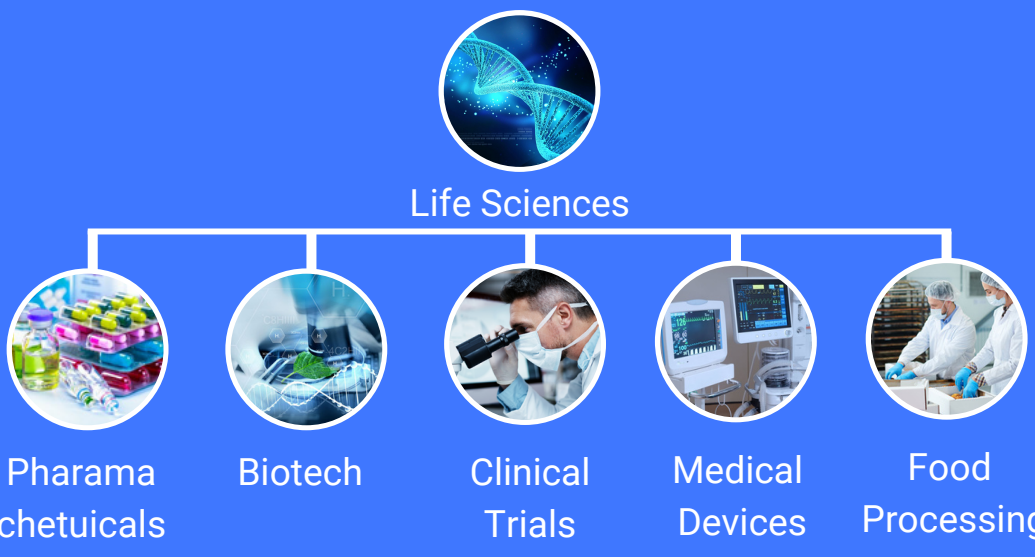
Keeping life sciences supply chain risks (challenges) at bay

In the long run, only businesses that are keen to adapt to changes and enhance their strategy will be successful. Rising shipping rates, port congestion, product shortages, and geopolitical tensions are just a few of the challenges making it more difficult than ever for life-sciences companies to maintain reliable supply chains.

With the increasing changes in the business environment, they have to supply high-quality products, deliver fast responses, and make their dynamic competencies better. As the industry evolves away from conventional models, advanced manufacturing techniques are required to achieve profitability goals.

Also, new regulations are challenging current pricing norms and forcing businesses to adopt more cost-effective manufacturing techniques. Particularly, the pharmaceutical and healthcare industry is facing the same challenges that many other industries have experienced in the past.

Apart from this, there is a greater focus on addressing issues like cost and pricing, clinical and operational innovation, customer and consumer interaction, and regulatory compliance that have plagued life sciences companies for decades.
There are new challenges companies must tackle to remain successful within the competitive world of life sciences.



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Pharmaceuticals:

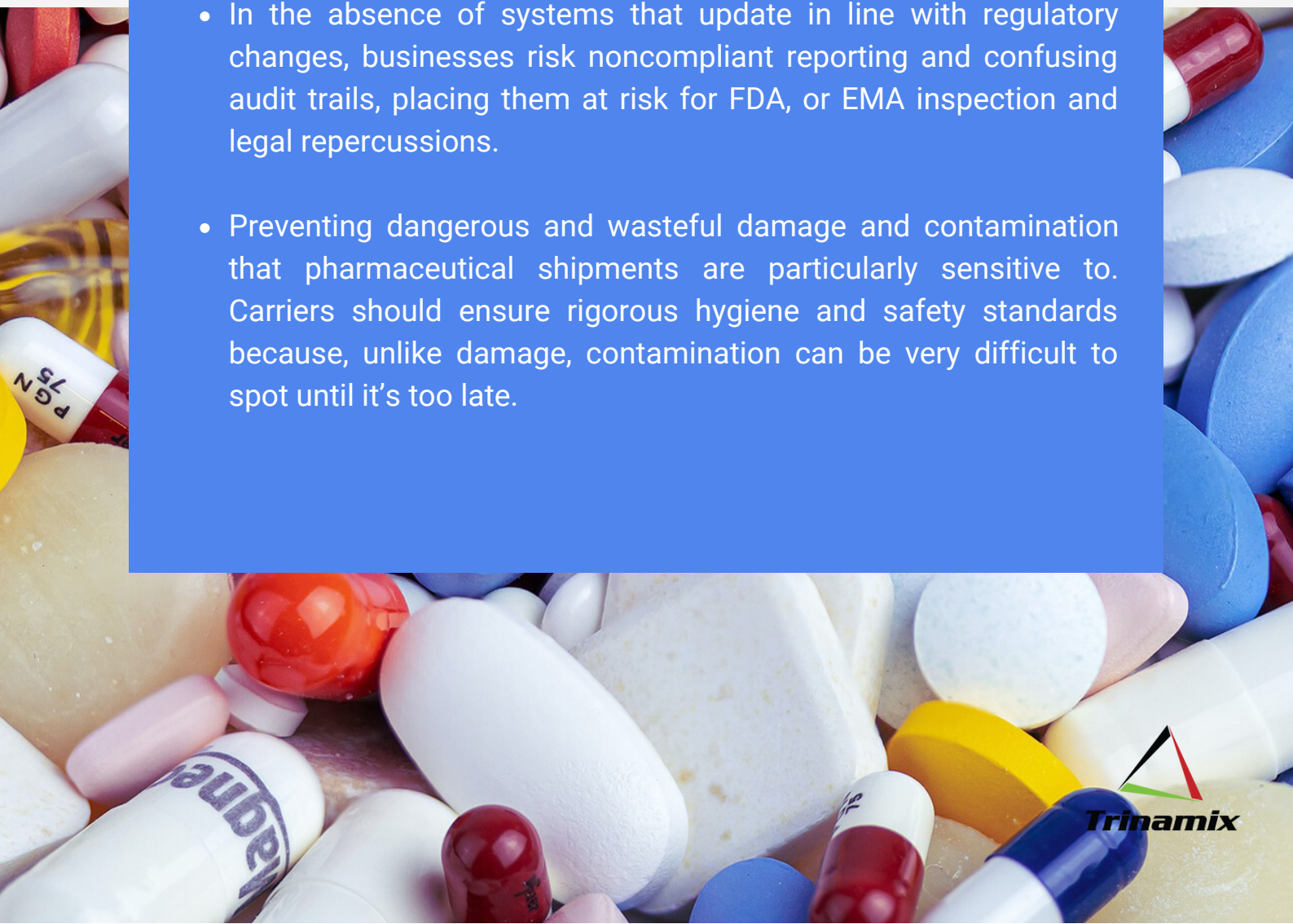
- Risk of On-time In-Full (OTIF) failures, and failure to optimize inventory levels, and adapt just-in-time inventory model, especially when they have cold chain distribution.

- Unidentified inventory tracking causes error and confusion, leading to a reduction in supply chain visibility and difficulty to meet unique device identification (UDI) standards for packaging and labeling of items.

- Striking a perfect balance between overstocked and underprepared. Pharmaceutical companies must develop a fine-tuned approach to supply and demand forecasting.

- In the absence of systems that update in line with regulatory changes, businesses risk noncompliant reporting and confusing audit trails, placing them at risk for FDA, or EMA inspection and legal repercussions.

- Preventing dangerous and wasteful damage and contamination that pharmaceutical shipments are particularly sensitive to. Carriers should ensure rigorous hygiene and safety standards because, unlike damage, contamination can be very difficult to spot until it's too late.



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Biotech:

- New therapies increase supply network complexity with the challenges of producing and distributing medicines.
- Importing challenges because of supply chain stressors, such as tariffs placed on numerous foreign goods.
- Striking a perfect balance between overstocked and underprepared. Life sciences companies must develop a fine-tuned approach to forecasting supply and demand.
- Shipping and transportation, bottlenecks at ports due to warehouse staffing issues, and a lack of truckers to transport goods further increased the supply delays.
- Increased focus on supply chain security and evaluating the measures that they are taking against ever-evolving cybercrime tactics.
- Every aspect of biotech logistics spending must be vigilantly monitored and controlled. This requires special precautions, which drives costs up.
- Regulators are stepping up their compliance oversight and enforcement activities as the speed of regulatory changes and new regulations are expected to continue.

Clinical Trials:

- Legacy systems are operating in silos – as data does not update seamlessly across all procedures, their entire operations rely on obsolete, contradictory, and erroneous data to make critical choices, delaying innovation, and time to market.

- Supply chain in the complex environment is driven by the impact of intellectual property, tax structures, and changing market access needs, as well as a growing reliance on third-party business partners, increasing effective governance, and better risk management.

- Unable to meet timelines due to inefficient management, time-consuming data entry, poor communication technology, or unorganized processes, hence time to market extends.

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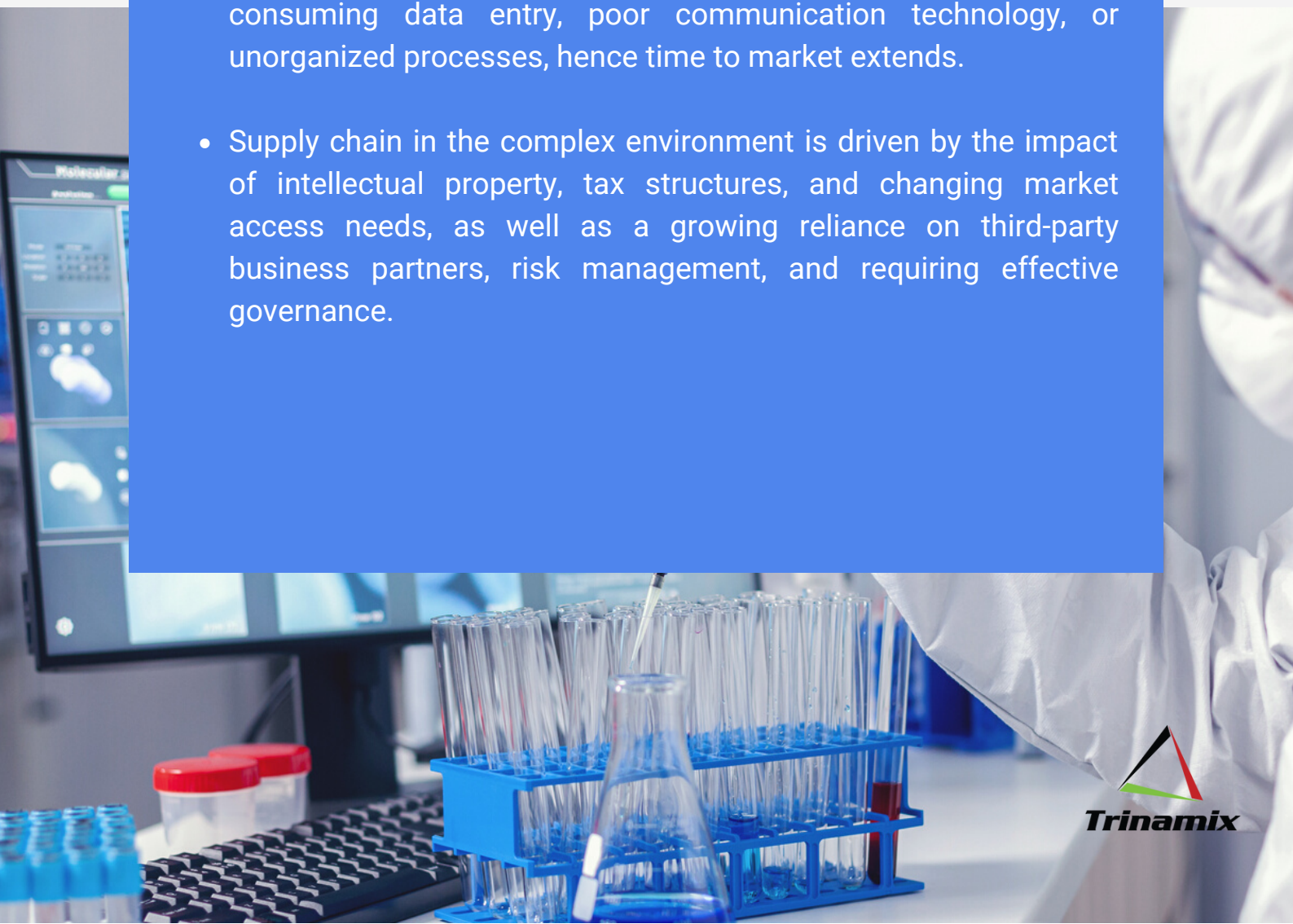


Medical Devices:

- The growing usage of software in devices exposes users to cyber-attacks and data privacy concerns. From assessment to deployment, solutions and services are tailored to adhere to GDPR, MDR, UDI, GxP, and HIPAA compliance.

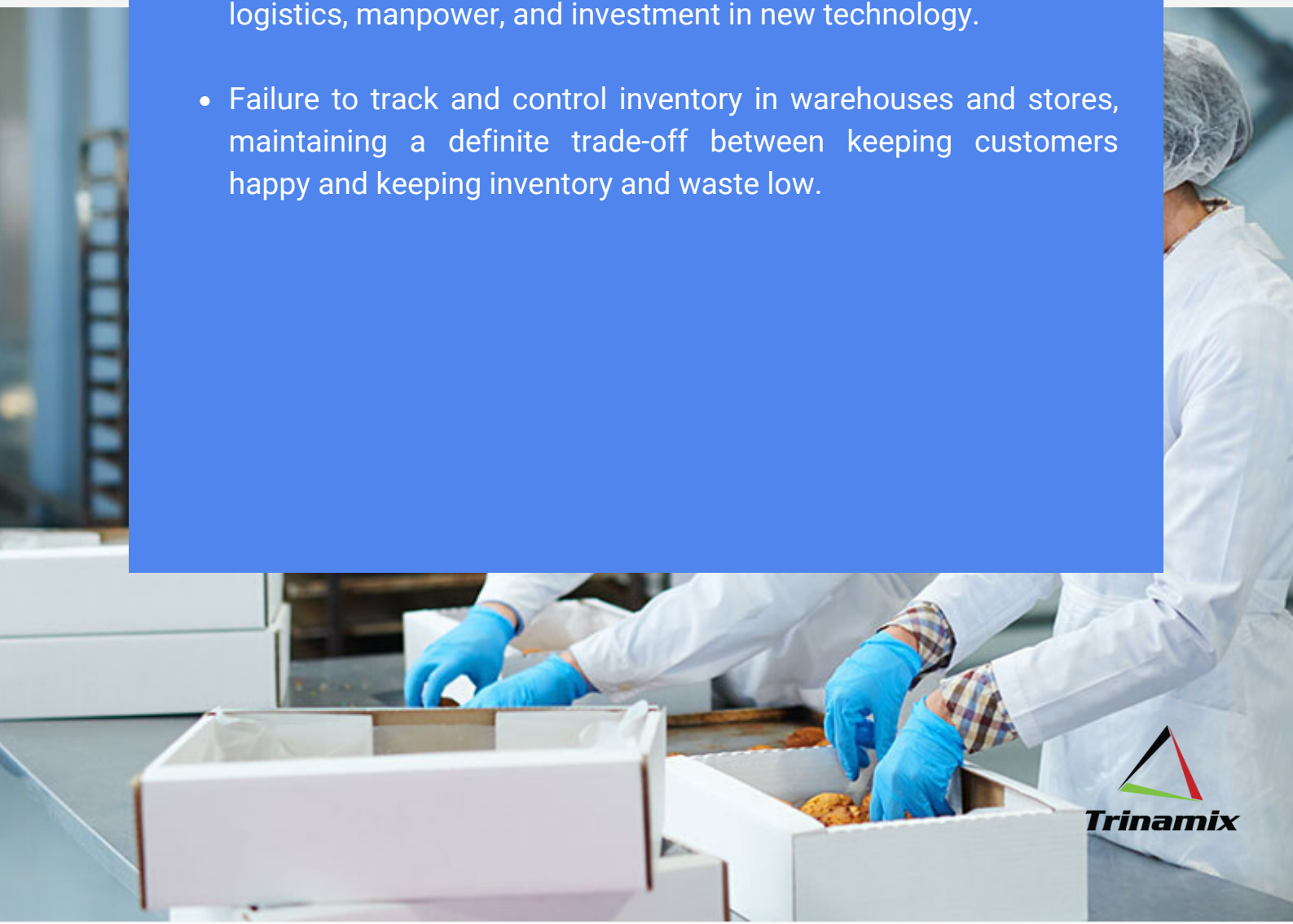
- The complexity of new product types and therapies are more diverse and have shorter product lifecycles, and there is a growing emphasis on outcomes and new models of healthcare delivery.

- Unidentified inventory tracking causes error and confusion, leading to a reduction in supply chain visibility and difficulty to meet unique device identification (UDI) standards for packaging and labeling of items.

- Implementing changes within the existing regulatory framework, and the management of regulatory and technical change presents a significant cost and operating challenge for life sciences companies.

Food Processing:

- The supply chain and food system are often fragmented with unique logistics needs, information-sharing policies, and government laws.
- Today's food shippers and receiving customers want traceability that not only meets expanding food safety regulations but also meets the need to offer consumers with peace of mind.
- Poor communication between supply chain participants, still many challenges involving a lack of communication that plague the industry.
- Rising supply chain costs due to energy and fuel costs, freight and logistics, manpower, and investment in new technology.
- Failure to track and control inventory in warehouses and stores, maintaining a definite trade-off between keeping customers happy and keeping inventory and waste low.



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The increasing importance of validation and regulatory organs in life sciences

Food and Drug Administration: The FDA defines validation as a process required to establish documented evidence that provides a high degree of assurance that a specific system, equipment, computer system, or process, should consistently meet the requirements and its intended use.

In the life sciences industry, all systems, computers, equipment, and processes that have GxP impact require validation. Organizations that use computer systems in FDA-regulated environments need to be evaluated and maintained in such a way that their performance matches the end-user expectations.

Validation ensures that computer systems that are being used to maintain Part 11 records do so with accuracy, reliability, integrity, availability, and authenticity. Although validating systems against 21-CFR-Part 11 might be resource-intensive - it’s mandatory for all life sciences companies.

The FDA intends to raise the standard of products, stop non-value-added operations, and concentrate testing in high-risk areas. By concentrating on the software's impact on product quality, patient safety, and quality system integrity, they hope to cut validation costs and time. Instead of using automated solutions to check that the product is being used as intended, testers frequently spend time making sure their protocol is error-free.

The FDA’s new approach to CSV, Computer Software Assurance (CSA), is a revolution in computer system validation, because it places critical thinking at the center of the CSV process, in place of a conventional almost one size fits all approach.

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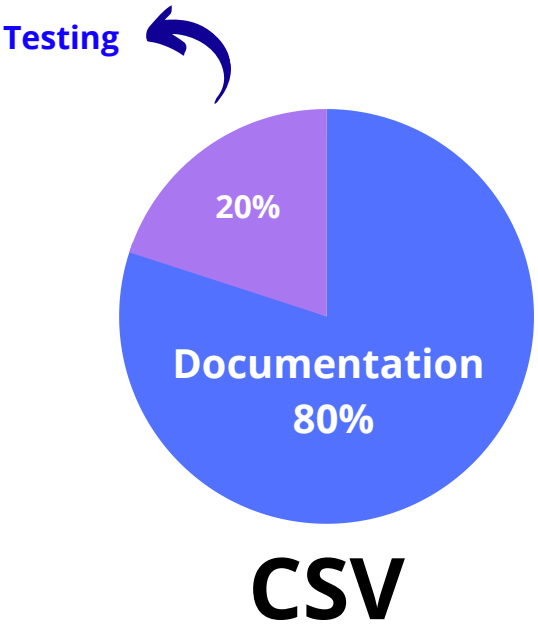
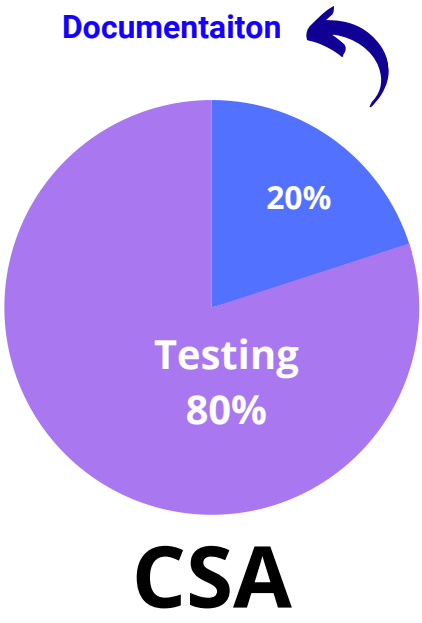


CSV



CSA

CSV	CSA
Focus on creating documentary records for compliance	Focus on testing for higher confidence in system performance
"Validate" everything (and miss higher risk areas)	Risk-based "Assurance", applying the right level of rigor for a given level of risk to patient safety and/or product quality
Ignoring previous assurance activity or related risk controls	"Take credit" for prior assurance activity and upstream/downstream risk controls
	Focus on testing, not scripting. Using unscripted testing for low/medium risk components

Customers must first define clearly how their business will gather and evaluate objective evidence for all testing procedures to satisfy the FDA. They would ensure that their objective evidence is founded on what occurred during testing, including what the tester saw.

The ultimate objective is trust – trust in their validation efforts by their system users, by your customers, and of course by the FDA. With legally and scientifically sound objective evidence, they will be confident others will be able to trust your data, its origins and documentation, and the ultimate results of their systems

Results of non-compliant - FDA

While completing Computer System Validation (CSV) might be time-consuming, failing to do so results in formal warning letters from FDA investigators, who frequently cite difficulties with "intended use" and other sections of **Title 21 C.F.R. 820.70. (i).**

The cost of non-compliance is respectively higher than the cost of compliance, including reputational damages, fines, and impact on patients.

The FDA has the authority to issue a Notice of Non-compliance to a responsible party for failure to comply with certain requirements, including:

- Failing to submit required clinical trial information
- Submitting false or misleading clinical trial information

FDA also has the authority to issue a Notice of Noncompliance to a submitter who has failed to submit or knowingly submitted a false certification to the FDA.

European Medicines Agency: The EMA (European Medicines Agency) is equivalent to the US Food and Drug Administration (FDA). As discussed and agreed upon by the GCP Inspectors Working Group, they direct the forms of questions and answers (Q&As) on good clinical practice (GCP).

They have prepared and published a notice for sponsors of clinical trials (CTs) to emphasize the requirements for the qualification and validation of computer systems used for managing CT data. In accordance with this notice, EMA has also updated questions 8 and 9 on this page, which provide additional information on computerized systems.

Results of non-compliant - EMA

Failure to document and therefore demonstrate the validated state of a computerized system is likely to pose a risk to data integrity, reliability, and robustness. The GCP inspectors may advise the CHMP not to use the affected data in the context of an MAA due to the crucial nature of the data in question.

FDA, EMA

Ability to provide FDA, EMA, and other regulatory organs with all the needed documentation

COMPLIANCE, NON-REGULATORY

Reduce compliance risks, legal liability, and non-regulatory loss

LABOR COSTS, SYSTEM EFFICIENCY

Reduce labor costs and maximize system efficiency

MONEY, TIME

Save money and time by discovering defects before a system goes live

Benefits of Computer System Validation

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More regulatory organs:

National Institute of Standards and Technology (NIST)

Solutions that provide measurement traceability, enable quality assurance, and harmonize documented standards and regulatory norms are offered through NIST's portfolio of services for measurements, standards, and legal metrology.

Good Automated Manufacturing Process (GAMP 5)

GAMP is a system for producing high-quality equipment using the approach of prospective validation following a life cycle model. This has been specifically designed to help suppliers and users in the pharmaceutical industry.

Creating a future-proof MedTech supply chain

In the last few years, MedTech companies might think that they have learned a lot about their supply chains. However, the situation, like the pandemic has exposed vulnerabilities in both supply-chain infrastructure and its performance, leaving many reflecting on “What steps they could have taken earlier to save themselves from submerging the unprecedented crisis.” The next phase of a pivoting healthcare supply chain needs to take a leap step toward the digitalization and automation of existing processes and concepts.

What do supply chain transformations look like?

Personalized products and services

A new phase of hyper-personalized offerings, such as precision treatments based on an individual’s cells or genes. To ensure this, they will face challenges related to operational complexity, regulatory burden, scalability, and high COGS.

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Platform-enabled business models

Digital ecosystems will support healthcare customization and the rise of Me-Commerce. Offering patients straightforward and equitable access to products and services, these interconnected digital platforms will facilitate trade-offs along the end-to-end healthcare value chain.

Digitally powered operating models

Life sciences professionals will move toward an agile and faster-operating model, leveraging the most out of AI/ML. They will further evolve their business operations to be highly automated, remote, and modular, while mitigating workforce pressures, improving product utilization, and enhancing speed to market,

Brand-powered value propositions

In time to come, life Sciences supply chains will move from traditional cost centers to brand influencers. By integrating data security, ensuring transparent privacy policies, and providing traceability of products with ESG goals, businesses can gain a competitive edge and win the hearts and minds of consumers.

Hyper-personaized Offerings

Digital Platfrom Ecosystems

Faster-operating Model

Brand-powered Value Propositions

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New technology paradigm for a new life sciences world

Technology continues to exist as a strategic imperative for supply chain organizations. According to a recent Gartner report published in April'2022 by Sarah Hippold, 61% of respondents say technology is a source of competitive advantage. Many also identify several emerging technologies as critical investment areas, with 20% investing in robotics.

As a pioneer in Life Sciences cloud technology, **Oracle Health Sciences Clinical One and Safety One** are most trusted globally by professionals in both large and emerging companies engaged in clinical research and pharmacovigilance. With over 20 years of experience, Oracle Health Sciences is committed to supporting clinical development, delivering innovation to accelerate advancements, and empowering the Life Sciences industry to improve patient outcomes. Let's check out what Oracle's evolving life sciences solutions are:

Clinical Research

Increase efficiency and cut expenses across the clinical trial life cycle

Pharmaco vigilance

Establish clinical trial compliance through post-marketing surveillance

Business Operations

Improve insight and efficiency by consolidating clinical trial management

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Conclusion

Many life sciences organizations that will start the supply chain transformation journey first will gain a competitive advantage in the future, while those who concentrate on making incremental improvements may risk losing a competitive advantage.

About Trinamix

Trinamix is a global solution provider specializing in Oracle Applications with a focus on Oracle SCM, ERP, EPM, CX & IOT/Blockchain-based applications. Trinamix offerings include Advisory, Roadmap, Implementation, Business Process Transformation, Value Assessment, Change Management, Optimization, and Managed Services.

We provide industry-specific PaaS-based solutions complementing Oracle Cloud Applications for Industrial Manufacturing, High Tech, Healthcare, Distribution, Telecom, CPG/Retail, and F&B industries.

We offer a gamut of resilient planning products complementing Oracle to enhance the digital thread of our customers. Trinamix is headquartered in the US with local offices in Canada, the UK, Australia, Japan, & India.

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Inspirational success stories of our customers

Life Science companies need to update their customer-centric strategies to meet changing consumer expectations as customers are moving to new online channels, experimenting with emerging cloud solutions, and engaging with effective community partnerships. Let's check out how Trinamix has helped customers overcome their technology shortcomings and laid down the smooth path to success:

- **Glaukos** selected Trinamix and GoSaaS for end-to-end Oracle ERP-PLM-SCM-HCM Cloud implementation. We helped this medical technology and pharmaceutical giant in their vertical and horizontal expansion by setting harmonized business processes. We leverage 3PL relationships, outside US distribution across business units. By eliminating paper trails and offline communication, we improved process efficiencies with the implementation of Oracle features. **Read more**

- **A leading American biotechnology company** that designs and manufactures technology used for scientific research sought out the expertise of Trinamix for Oracle ERP, PDH, and SCM Cloud implementation. Through this, they wanted to achieve scalability through the global rollout of the product and have a single platform that will support its end-to-end processes. **Read more**

- A North American Biotechnology company collaborated with Trinamix for Oracle Supply Planning Cloud and Trinamix Allocation Workbench implementation. Trinamix Allocation Workbench is a PaaS-based solution delivered on APEX to support Shelf Life across and lot-based allocation. These features are compliant with the Life Sciences/Biotechnology industry regulations. **Read more**

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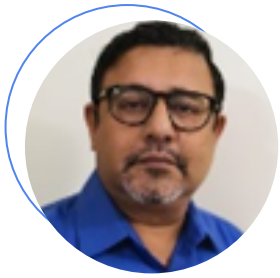

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