



MANUSPACE

Unlocking Trusted Data Sharing
in Pharmaceutical Contract Manufacturing



Pharmaceutical & Manufacturing

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With the contribution of:



Challenge & Context

In today's hyper-competitive pharmaceutical and biotechnology sectors, the ability to innovate while maintaining stringent compliance and operational efficiency is not just a goal — it's a business imperative. The challenges are far-reaching and have immediate and long-term business consequences. For instance, the current manual methods of data sharing are not just technologically outdated; they represent a direct cost to the business. The labor and time invested in these manual processes could be more strategically allocated to areas like research and development or market expansion, which are core to business growth.

Moreover, the involvement of multiple external partners, such as Contract Manufacturing Organizations (CMOs), adds layers of complexity to the already challenging issue of data security. In an industry where regulatory compliance is non-negotiable, any lapse in data security isn't just an operational hiccup; it's a business risk that can result in severe financial penalties and damage to brand reputation.

The absence of real-time data further compounds these challenges. Operational inefficiencies that arise from delays in data sharing can result in lost market opportunities and increased operational costs, directly affecting the bottom line. Additionally, the industry is plagued by disparate and outdated legacy systems that create data silos, hindering effective decision-making—a critical aspect for any business aiming for agility and responsiveness.

As pharmaceutical companies increasingly rely on outsourcing to CMOs for cost benefits and operational flexibility, the need for a robust, secure, and efficient data-sharing infrastructure has escalated from being a logistical requirement to a business-critical issue. This need extends beyond the realm of manufacturing to include other operational facets like maintenance contracts, location data sharing, and even regulatory submissions, all of which have a direct impact on business performance and competitiveness.

Now, envision an operational ecosystem where data is not a bottleneck but a catalyst for business growth and innovation. Imagine a scenario where pharmaceutical companies and CMOs are integrated through a seamless, secure, and real-time data-sharing network. This is not a futuristic aspiration but

an achievable reality with today's technology. Smart data models, blockchain solutions, and advanced analytics are not just technological advancements; they are strategic business enablers.

Initiatives like Manuspace and i4Trust serve as more than just technological solutions; they are strategic business assets that offer a framework for secure and efficient data exchange. By adopting these initiatives, companies can focus on their core competencies, such as innovating and delivering value to shareholders and customers alike. In summary, the challenges in data sharing and compliance are not mere operational hurdles; they are business challenges that, when addressed strategically, can be turned into opportunities for growth, efficiency, and competitive advantage.

Solution

The MANUSPACE experiment is a pioneering initiative designed to tackle the complex challenges of data sharing, compliance, and operational efficiency in the pharmaceutical and biotechnology industries. The project's central aim is to establish a digital trust ecosystem that facilitates the secure and efficient sharing of data across organizational boundaries. This is not just a technological aspiration but a business necessity, as reducing the time from batch manufacture at the contract organization to batch disposition at the brand owner is a key performance metric in manufacturing.

One of the standout features of MANUSPACE is its nuanced approach to data flows and data sovereignty. The experiment employs smart data models and analytics to enable real-time decision-making, a critical component for maintaining a competitive edge in a rapidly evolving industry.

Data sovereignty is maintained by ensuring that each piece of data remains under the control and governance of the organization that generated it. In simpler terms, this means that data is stored, processed, and managed according to the originating company's policies and practices, irrespective of where the data is accessed or shared. This organizational approach to data sovereignty ensures that each participating company retains full control and authority over its own data, aligning with internal data protection and security

protocols. This is especially crucial in sectors like pharmaceuticals, where data integrity and compliance are non-negotiable.

Leading the experiment is ServBlock, a Wicklow-based company specializing in supply chain compliance. As the data space administrator, ServBlock ensures that data sharing across all parties is seamless, secure, and compliant with each organization's data sovereignty policies. They set the governance and security standards for the entire operation.

The consortium for MANUSPACE comprises a diverse range of expertise:

- [NEXA EAM](#): Based in Cork, NEXA serves as both a Data Provider and Data Consumer, contributing its extensive experience in Enterprise Asset Management.
- Ingeniero Solutions: Operating out of Dublin, Ingeniero focuses on acquiring live and historical batch performance data, acting as a Data Consumer.
- Unison Process Solutions: Located in Limerick, Unison provides essential data related to the manufacturing process.
- PlantQuest: Based in Waterford, PlantQuest specializes in location intelligence and will act as another Data Provider.

MNX Online, as an implementation partner, added additional technical expertise required for the seamless integration and functioning of this intricate data-sharing ecosystem.

The role of Trust Anchor is expertly managed by iSHARE, a cross-domain trust framework that ensures all data sharing is secure, authorized, and in compliance with standardized protocols.

Further enriching the initiative is Irish Manufacturing Research (IMR). As a leading research institution, IMR provides invaluable insights into the challenges and opportunities in the manufacturing sector, ensuring that the MANUSPACE experiment remains cutting-edge yet practically applicable.

In summary, MANUSPACE is more than a technological project; it's a comprehensive business solution spearheaded by ServBlock. It aims to address real-world challenges through a collaborative, data-driven approach, setting new benchmarks for efficiency, compliance, and competitiveness in the manufacturing sector, all while respecting the principles of data sovereignty within organizational boundaries.

How it works

Technical Description:

The MANUSPACE experiment is an advanced digital ecosystem engineered to enable secure, efficient, and compliant data sharing among key players in the pharmaceutical and biotechnology industries. Utilizing a blend of IoT devices, context brokers, and identity management systems, the architecture ensures a seamless flow of data while maintaining data sovereignty within the confines of organizational policies and guidelines.

Use of FIWARE and iSHARE:

- FIWARE: The Orion Context Broker is a central component, acting as a hub for collecting, managing, and disseminating data to various stakeholders. Additionally, an Authorization Registry provided by FIWARE's Keyrock is employed for user authentication and authorization, ensuring secure access to specific data types.
- iSHARE: Serving as the Trust Anchor, iSHARE Satellite validates and certifies all participants in the dataspace. It establishes a list of trusted parties by verifying keys, certificate authorities, and other credentials, thereby ensuring secure and authorized data sharing according to standardized protocols.

More specifically:

1. Data Providers (UNI, NEXA, PQ): Generate data and send it to their Orion Context Brokers via IoT devices/agents and connectors.
2. Orion Context Broker: Acts as the central broker for data collection and management. The key component for and FIWARE-enabled solution.
3. Fiware Authorization Registry Keyrock: Manages user authentication and authorization.
4. iSHARE Trust Anchor: Validates and certifies all participants, ensuring a trusted environment.
5. Data Consumers (ING): Access and utilize data via their Orion Context Broker, post-authentication and authorization.

Description of Dataspace:

The MANUSPACE dataspace is a secure digital platform where entities in the pharmaceutical and biotechnology sectors can share and access data. To join the dataspace, parties must register with the iSHARE Trust Anchor, agree to terms of use, and pass a verification process. Once approved, they can participate in data sharing and consumption within the dataspace.

Major Lessons Learnt:

1. **Trust is Paramount:** The role of a trust anchor like iSHARE is vital for data security and integrity.
2. **FIWARE's Versatility:** Both the Orion Context Broker and Keyrock have proven to be adaptable, accommodating a range of data types and user needs.
3. **Data Sovereignty:** Ensuring data sovereignty within organizational guidelines was a complex but necessary undertaking for compliance and trust.
4. **Interoperability:** The adoption of standardized protocols, such as NGSI-LD, is crucial for seamless, low-overhead, data exchange among diverse participants.
5. **User Authentication:** Strong authentication and authorization mechanisms are essential for maintaining data security in a multi-stakeholder environment.

Benefits & Impact

The MANUSPACE experiment is more than just a technological advancement; it's a strategic business solution designed to address the multifaceted challenges of data sharing, compliance, and operational efficiency in the pharmaceutical and biotechnology sectors. Here's a more detailed look at its projected benefits and impact:

Current and Future Users:

- At present, each consortium member has 2 active users, making a total of 10 users who are directly benefiting from the platform.
- As the platform gains traction and proves its value in secure, efficient data sharing, we expect the user base to grow exponentially, potentially reaching hundreds of users across multiple organizations.

Customers and Potential Clients:

- Each consortium member serves as an initial customer, testing and benefiting from the platform's capabilities.
- Given the industry-wide challenges of data management and compliance, the potential for new clients is substantial. We foresee attracting at least 20-30 new clients in the next two years.

Financial Projections:

- Investments in the MANUSPACE platform are expected to yield a high ROI. Specifically, we project a 20% increase in operational efficiency due to streamlined data sharing and decision-making processes. This figure is based on initial tests that showed marked improvements in data accessibility and utilization.
- Additionally, we anticipate a 15% reduction in compliance-related costs. This is because the platform's real-time auditing capabilities will significantly reduce the man-hours and resources typically required for compliance checks.

Target Group Impact:

- Contract Manufacturing Organizations (CMOs) are the primary beneficiaries. The ability to monitor processes in real-time is a game-changer for compliance and operational efficiency, reducing both risks and costs.

Importance to Companies:

- For companies striving to stay competitive, MANUSPACE is indispensable. It not only enhances operational efficiency but also minimizes legal and compliance risks, thereby safeguarding brand reputation.

Sustainability Alignment:

- The project is in line with sustainability objectives by enabling more efficient resource utilization. Data-driven insights can lead to better energy management, waste reduction, and overall more sustainable operational practices.

Revenue Growth:

- We expect a 30% increase in sales/revenue for involved SMEs, substantiated by:
 1. Reduced Time-to-Market: Faster, more informed decision-making will expedite product development and launches, thereby increasing revenue streams.
 2. Compliance Savings: The platform's real-time auditing capabilities will drastically cut down on the financial and time resources traditionally allocated for compliance, allowing for re-investment in growth-driving activities.
 3. New Client Acquisition: The unique capabilities of MANUSPACE will serve as a strong selling point, attracting new clients who are looking for secure, efficient data management solutions.
 4. Data Monetization: The secure data-sharing environment also opens up opportunities for data monetization, adding an entirely new revenue stream for companies.

In summary, MANUSPACE is set to redefine industry standards for data management, compliance, and operational efficiency. Its far-reaching impact promises significant operational improvements, cost reductions, and revenue growth, all while aligning with sustainability objectives.

Added value through i4Trust

Our experience with i4Trust has been nothing short of transformative. The platform has provided us with a plethora of opportunities for growth, networking, and business development. The support and coaching activities have been invaluable, offering insights into best practices, compliance, and operational efficiency that we would not have gained otherwise.

Value-Adds Created in the Project:

1. Secure Data Sharing: i4Trust's robust security protocols have enabled us to share data securely across organizational boundaries, thereby reducing risks and enhancing compliance.

2. **Data Sovereignty:** i4Trust allows companies to maintain control over their data, respecting company boundaries. This is crucial for organizations that need to adhere to strict data governance and privacy regulations.
3. **Interoperability:** The platform's use of standardized protocols and data models ensures that data can be easily shared and understood across different systems and organizations, breaking down silos and enhancing collaboration.
4. **Scalability:** i4Trust is designed to grow with your business. Whether you're adding more data sources, integrating with other platforms, or expanding your user base, i4Trust can handle it, making it a future-proof solution.
5. **Networking:** Being part of the i4Trust community has opened doors to partnerships and collaborations that we had not considered before, expanding our business horizons.

Why i4Trust is the Right Technology:

i4Trust is not just a one-off solution but a scalable, adaptable technology that can be applied to a multitude of projects and solutions in the future. Its architecture is designed for flexibility, allowing for easy integration with existing systems and scalability to meet future demands. The platform's focus on security, data sovereignty, and interoperability makes it an ideal choice for any organization looking to optimize its data management practices.

Moreover, the i4Trust community itself is a treasure trove of innovation and expertise. The networking opportunities it offers can lead to collaborations that result in groundbreaking solutions for a wide range of challenges.

In summary, i4Trust has added immense value to our MANUSPACE project, not just in terms of the technology it offers but also the broader ecosystem of support, expertise, and opportunities it provides. We see it as the go-to technology for our current and future data management and operational efficiency needs.

Next steps

As we wrap up the initial phase of the MANUSPACE project, our focus shifts to scaling and refining the solutions we've developed. The immediate next steps include:

1. **Data Analysis:** A comprehensive review of the data collected to assess the impact of the project on operational efficiency and compliance.

2. User Feedback: Gathering feedback from consortium members to understand the user experience and identify areas for improvement.
3. Technology Update: Based on the feedback and data analysis, we plan to roll out updates to the i4Trust platform components used in the project.
4. Sustainability Assessment: Conduct a sustainability audit to ensure that the project aligns with long-term environmental and social goals.
5. Expansion Plans: We are in talks to extend the project to include more data providers and consumers, thereby increasing the scope and impact of the MANUSPACE experiment.

A follow-up project is in the planning stages, aimed at addressing some of the more complex challenges that were identified during the initial phase. This will be designed to integrate seamlessly with the existing MANUSPACE framework, ensuring continuity and scalability.

All these steps are in line with our sustainability plan, focusing not just on technological solutions but also on creating a sustainable, long-lasting impact. We aim to make data sharing in the pharmaceutical and biotechnology sectors not just more efficient but also more responsible and sustainable.

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Categories

User(s):

1. Data Providers
 - Contract Manufacturing Organizations (CMOs)
 - Enterprise Asset Management Companies
 - Location Intelligence Companies
2. Data Consumers
 - Pharmaceutical Sponsors
 - Regulatory Auditors
 - Supply Chain Managers
3. Data Administrators
 - Compliance Specialists
 - Data Space Managers
4. Research Institutions
 - Manufacturing Research Centers
 - Data Science Institutes
5. Technology Partners
 - IoT Device Manufacturers
 - Data Security Firms

6. Regulatory Bodies

- Industry Regulators
- Compliance Auditors

7. Implementation Partners

- Software Development Companies
- Data Integration Specialists

Key words:

Data Sharing, Pharmaceutical Manufacturing, Biotechnology, contract manufacturing Compliance, Operational Efficiency, Digital Trust Ecosystem, Smart Data Models, Real-time Decision-making, Supply Chain, Data Space Administrator, Data Provider, Data Consumer, Trust Anchor, Analytics, Quality and ESG Credentials, NGSI-LD Standard, Linked Data, Regulatory Audits, IoT Devices, MQTT, Data Sovereignty

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Founding Partners



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