

# Revolutionizing Pharmaceutical Operations

Discover how API-driven architectures are reshaping the pharmaceutical industry by enabling scalable, secure, and regulatory-compliant connectivity across the entire enterprise.

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# About Me

Professional Experience: 9+ years leading enterprise integration initiatives

Current Role: Principal Integration Engineer

Industry Expertise: Life Sciences, Pharmaceutical Manufacturing, and Supply Chain Optimization



# mRNA Vaccine Development Revolution



## Virus Identification and Genetic Sequencing

Scientists identify the virus and decode its RNA sequence to find target proteins.

ATTAAAGGTTTATACCTTCCCAGGTAACAAACCAACCAACT...



## mRNA Design

Scientists design synthetic mRNA that instructs human cells to produce the selected viral protein safely.



## Clinical Trials

Human trials are conducted in phases to confirm safety, dosage, and effectiveness.



## Rapid Manufacturing

Once proven safe and effective, the vaccine is mass produced and regulatory agencies like the FDA approve its use.



## Supply Chain and Distribution

Specialized supply chains are set up, including cold storage and transportation, to ensure vaccines are delivered safely to global populations.

# Digital Transformation Journey



## The Problem

Outdated legacy systems, isolated data silos, manual workflows, and compliance challenges created significant bottlenecks.



## API Integration

We implemented secure, standardized data exchange protocols to enable seamless connectivity across all systems.



## Acceleration

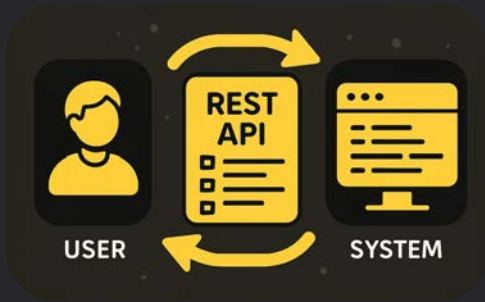
With connected systems, processes accelerated significantly, making information accessible faster across 110+ platforms—reducing delays and enhancing delivery times.



## Continuous Improvement

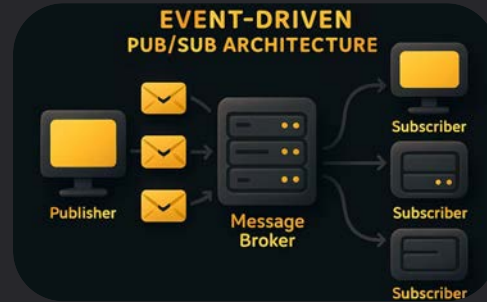
Leveraging real-time data analytics, we continuously streamline operations, enabling rapid adaptation and sustained flexibility.

# Key API Patterns in Practice



## REST APIs

Provide simple and standardized access to user and organization data through secure API endpoints.



## Pub/Sub

Enable real-time, event-driven data sharing for immediate responsiveness across systems.



## ETL

Facilitate batch processing and data synchronization between manufacturing systems efficiently.



## Hybrid (API + File)

Combine APIs with file transfers to support vendors who have limited integration capabilities.

# The Integration Layer is the Enabler



## Unified Data Connectivity

Seamlessly integrates diverse data sources across research, manufacturing, and supply chain, ensuring consistent and reliable data flow for complex ecosystem.



## Accelerated Collaboration

Facilitates real-time collaboration between global teams, partners, and regulatory bodies, improving responsiveness and alignment throughout the development lifecycle.



## Regulatory Agility

Supports dynamic compliance management and traceability with automated audit trails and reporting to meet stringent pharmaceutical regulations.



## Innovative Workflow Automation

Enables integration of AI-driven diagnostics, predictive analytics, and smart manufacturing processes to boost productivity and innovation velocity.



# Manufacturing Transformation

## Legacy Manufacturing Process

- Disconnected systems with manual handoffs
- Manual data entry between systems caused delays and increased risk of human error
- Quality control processes lacked auditability and traceability
- Limited scalability to meet growing demand and support distributed operations

## Digital Manufacturing Excellence

- Fully connected systems across manufacturing units, eliminating manual and paper-based workflows
- Automated synchronization of process orders and material staging
- Event-driven workflows that reduce lead times and enable faster decision-making
- Built-in compliance features including traceability, audit logging, and validation-ready processes



# Clinical Trial Acceleration

Connected digital systems and event-driven workflows cut delays, speed decisions, and ensure compliance for faster clinical trials.



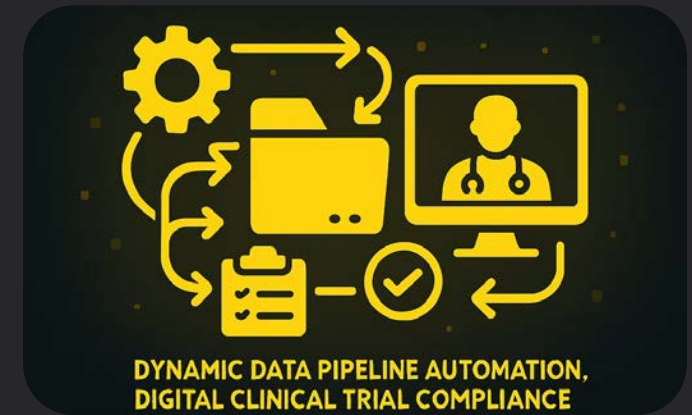
## Integrated Systems Cut Delays

- Automatic data transfer from CROs to internal systems
- Real-time updates from labs and sites
- Timelines shortened by 30–40%



## Event-Driven System Speeds Decisions

- Pub/Sub APIs send instant safety and efficacy alerts
- Problems found within hours, not days
- Supports fast escalation and protocol updates



## Dynamic Data Pipelines Cut Revalidation Time

- Automatic protocol updates across clinical systems, removing delays and risks
- Cycle time reduced from 14 days to under 4 days
- Always maintains GxP compliance



# Work Hour Savings



## Manual Data Entry Eliminated

Saved over 90,000 hours each year by stopping repeated paperwork, and cut errors by 78%.



## Automated Workflows

24 smart automations save 35 minutes on each protocol with built-in quality checks.



## Strategic Reallocation

More than 90,000 work hours freed up yearly to let scientists focus on new ideas.



## Enhanced Productivity

Researchers now spend 42% more time on vital scientific work and patient studies.

# Infrastructure Scaling Approaches



## Cloud-Native Architecture

- Deployed on AWS EC2 using Molecule clusters to support GxP and enterprise workloads
- Automatically scaled across 3 availability zones for high availability and zero downtime
- Enabled patching, updates, and deployments without business disruption



## Modular Architecture with Reusable Components

- Utilized pre-existing libraries, templates, and extensions
- Developed microservice-style reusable APIs
- Accelerated deployment time by 5x through pre-approved integration patterns



## Security Foundation

- Maintained isolated environments for GxP, non-GxP, and SOX-regulated workflows
- Validated integration pipelines to comply with 21 CFR Part 11
- Ensured secure token-based authentication using OAuth2, Okta, and WAF firewalls

# Key Takeaways

## Speed & Efficiency

API-driven architecture enables 60% faster time-to-market and reduces clinical trial cycles by 38%, accelerating decision-making with real-time data alerts.

## Quality & Safety

Automated validations boost accuracy to 99.1%, cut compliance incidents by 94%, and maintain strict GxP adherence with secure, validated integration pipelines.

## Patient-Centric Innovation

AI-powered biomarker identification supports personalized treatments, while smart automation reallocates over 90,000 work hours annually to focus on scientific breakthroughs.

## Next Steps

Build your scalable, secure infrastructure using modular, cloud-native designs to drive future pharmaceutical innovation and transform drug development.



Thank you