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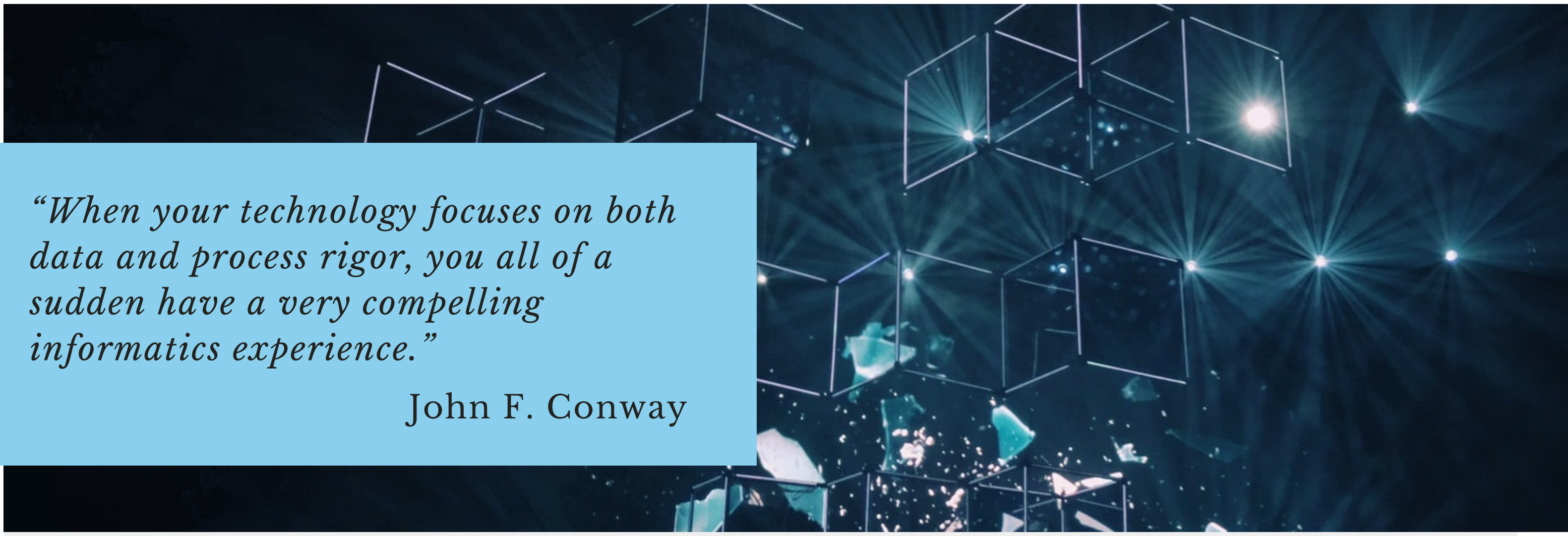
COMPOSABLE ARCHITECTURE ENABLES DIGITAL TRANSFORMATION FOR DATA-DRIVEN ORGANIZATIONS

By
20/15 Visioneers, Leaders in Science and Technology

A Research, Development, Clinical, and Manufacturing Industry Perspective



"When your technology focuses on both data and process rigor, you all of a sudden have a very compelling informatics experience."

John F. Conway

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EXECUTIVE SUMMARY

Selecting next-generation scientific software solutions built with composable architecture is a critical step in ensuring a successful digitalization "journey," a state-of-the-art no-code/low-code user experience, and remarkable IT and business efficiency gains. Experience teaches us that the Total Cost of Ownership (TCO) for most enterprise-oriented IT projects is usually much higher than first estimated or shared. When an organization embarks on an informatics journey, it is easy to overlook the many mismatches in data and process preparedness, the persistent influence of entrenched yet obsolete technologies, and the challenge of an unprepared or inflexible culture. Maximizing Return on Investment (ROI) requires mastering the change management elements inherent in most major enterprise IT projects, a factor that must be honestly assessed in any preparatory due diligence.

Despite the challenges, there are large ROIs to be had through the proper execution of digital strategies. FAIRification of data and processes - generating model-quality data that is Findable, Accessible, Interoperable, and Reusable - can deliver an efficiency most R&D organizations have never experienced. In addition, organizations need to apply the FAIR principles to their scientific business processes as well. The processes produce the data and are a key factor in science and manufacturing reproducibility.

Several contributing factors can derail efforts to execute a comprehensive digital strategy. The largest is a dysfunctional corporate culture with associated counterproductive management incentives, leading to insurmountable resistance to change and often exploiting inefficiency to achieve job security. Treating data and process as long-term assets have been a missing element in many corporations for quite some time, and even after a year-long pandemic, some companies have still been unable to make the transition. Doing so requires strong leadership with sufficient C-suite top-cover. Clinging to legacy technology and architecture is another impediment. The age of monolithic architecture has come and gone for most if not all scientific enterprise IT solutions. A real-world example is a monolithic LIMS environment that is inflexible and takes serious money to customize. It's now a legacy tool that costs an organization too much money to maintain and keep limping along. It's now several versions behind in upgrades and is actually a liability to the organization for multiple reasons! Today's data-driven technologies need flexibility and scalability that you don't get in legacy monolithic approaches, aka legacy LIMS tools. Fig 1

"A real-world example is a monolithic LIMS environment that is inflexible and takes serious money to customize. It's now a legacy tool that costs an organization too much money to maintain and keep limping along. It's now several versions behind in upgrades and is actually a liability to the organization for multiple reasons!"

Figure 1: Pancha Rathas monolith rock-cut temple, late 7th century

As we have pointed out in several of our whitepapers and blog articles, the IT and informatics environments of R&D are changing rapidly, driven by externalization options like Cloud Lab and Cloud Computing as well as complex hybrid processes (on-prem/externalized CXO) in biologics, cell, and gene therapies. Scientific software and process development take significant time, careful planning, and flexibility. There is a big difference between a point solution and an enterprise-wide solution that can be depended upon for volume, accuracy, safety, and knowledge.

Fortunately, composable architecture and infrastructure frameworks are here for data and process-driven organizations. Reusable building blocks or "Primitives," data fabric, and process orchestration are now available, and are all designed for agility and scalability. The result is a No Code/Low Code unified platform-ecosystem that allows the provider to focus on enhancements leaving the consumer to focus on integrations, configurations, and process applicability. Fig 2

Across the Life Science/Material Science/Agri Science continuum, the high-level workflows that must be covered in organizations today are Request, Sample, Test, Experiment, Analysis, and Reporting. The data and processes must be FAIR (Findable, Accessible, Interoperable, and Reusable). The interfaces must be intuitive and productive. Lastly, sustainability of the Platform Ecosystem is imperative, which is the primary virtue of a composable architecture and infrastructure. Having to repave your information highway every couple of years would not be a viable solution! This is why the inflexible monolithic landscape is becoming extinct.

A composable solution drives higher IT (including DevOps) and end-user efficiencies. It replaces the long tail of costs associated with many monolithic platforms by managing and reducing complexity and cost, delivering higher ROIs (Return on Investments) and lower TCOs (Total Cost of Ownership). This is a critical time as some companies are struggling with their digitization and digitalization strategies and execution. Every CXO should care about this. If your infrastructure technology is inferior, your quality of life will suffer as you will repeatedly get to market later, most likely behind your competitors.

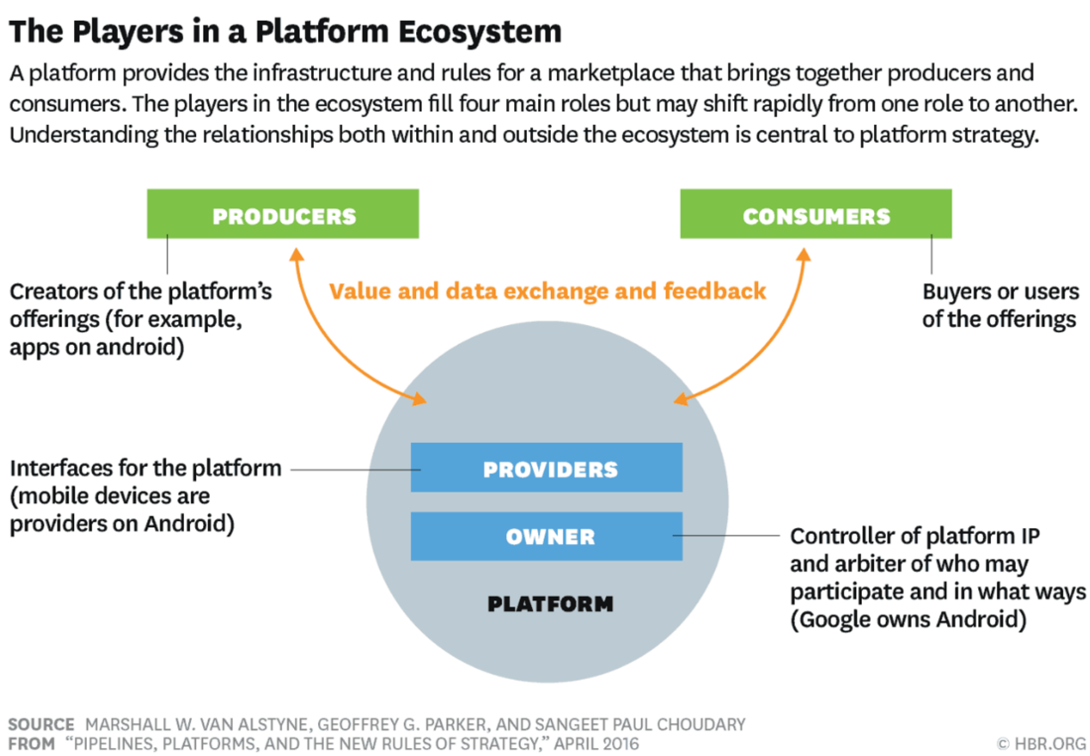

Figure 2: Platform Ecosystem Model

1. WHAT IS A COMPOSABLE ARCHITECTURE?

Composable Architecture is now the term given to something that many in the industry have been evangelizing for at least the past five years. It is a microservice, unified platform-ecosystem that is written to scale and is flexible to handle the minor to major required changes as business processes morph and evolve. It requires strong and open APIs, intuitiveness, and the independence of the professional partner-vendor to provide continual professional service.

The outcome will drive better business practices. Based on the needs of Biopharma, Diagnostic, Agriculture, and other major data-driven businesses, these five basic principles can be identified:

1. More and faster innovation.
2. Plug and play with microservices and app building.
3. FAIR data and process environment drive better decision-making through advanced data driven knowledge and intelligence.
4. Platform Ecosystem, No Code/Low Code approach reduces vendor-partner dependency and drives a best-case hybrid approach.
5. Sustainability with a clean exit.

Composable Architectures leverage both compute power (cloud) and proper software. The execution and operation of the software will have independent compute, data storage, and what is called fabric resources. (Fabric computing or unified computing involves constructing a computing fabric consisting of interconnected nodes that look like a "weave" or a "fabric" when viewed/envisaged collectively from a distance.[1]) Fig 3

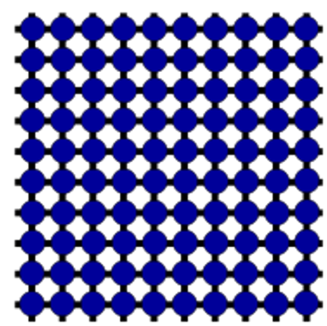

Figure 3: Computing Fabric Nodes

This, along with a unified API, allows for the computing, storage, and fabric resources to be independently changed—combined, separated, and composed—based on evolving application requirements.[2]

With a next-generation tech stack, your software infrastructure becomes self-managing. This means you are not dedicating a system administrator or two to oversee this implementation and constantly monitor it and maintain it.

The result is an environment that is much more manageable from an IT services and infrastructure perspective.

With a single line of code, an IT professional or developer can precisely get the right number of resources configured exactly as needed to match the application. An architecture using less than these three layers of technology provides some composable features, but it is not a fully composable architecture. Only a fully composable architecture allows users to execute both traditional and cloud-style agile operations from a single infrastructure. Fig. 4

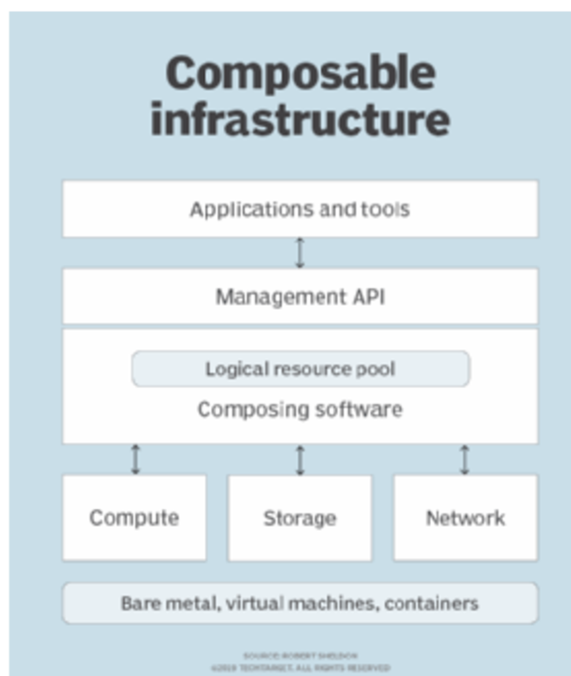

Figure 4: Composable infrastructure/architecture

1.1 DYNAMICALLY MANAGE AND PROVISION RESOURCES

With a composable infrastructure, organizations can instantly and dynamically provision hardware and software using a unified API. This allows resources to change based on either a specific application or the ebb and flow of system workload.

1.2 CLOUD/OS AGNOSTIC

With composability, critical IT infrastructure can run without being limited to a single computing technology or concept. It can run on virtual machines through bare-metal deployment, containers, and cloud-native applications.

1.3 LEAPFROG ANTIQUATED APPROACHES

Because composable infrastructure uses intelligent software, your operation will be smarter as well. From the outset, a composable system can automatically discover the resources available to it. If, for example, some hardware asset is not attached or configured correctly, the system automatically detects these issues and offers suggestions on how to resolve the problem.

1.4 SCALABILITY

Because composable infrastructure is readily scaled, its use can be increased over time at the rate that works best for your organization.[3]

2. WHY SHOULD YOU CARE?

There are few more vexing challenges than inheriting a poorly performing and entrenched legacy enterprise IT environment! The cost, politics, and persuasion needed for change can often be a career killer and not just a contributor to poor R&D outcomes. The European Commission and Price Waterhouse Cooper published the Cost of not having FAIR research data in 2019, showing that this shortcoming alone is costs the European Union ~ €26 billion a year. We suspect this figure may be low as our own analysis shows the cost per researcher being kept busy “wrangling data” forty percent of their time is higher. Pursuing a Digital and Insilco Model-First strategies become unattainable, along with the ability to fully leverage “Big” data. So, it would help if you cared because the cost, poor performance, inefficient processes are not only eroding your capabilities but will not allow the bright people you have hired to perform at a high level.

3. HISTORY OF SCIENTIFIC COMPUTING/SOFTWARE AND WHY IT MATTERS

The history of scientific computing can be traced back to its primitive roots in early civilizations - the history of scientific software dates to the early 20th century. Until recently, most applications were fundamentally limited by computing power, but that is no longer the case. Instead, reliance on outmoded legacy architectures is the main impediment to progress.

Advances in cloud computing, deep learning, Artificial Intelligence (AI), and Machine Learning (ML), as well as tech stacks (microservices and unified platform ecosystems with a composable architecture), have changed the game. Efficient adoption is the only thing getting in the way.

20/15 Visioneers believe that technology has reached a point where we can drive digitalization, New Molecular Entity (NME), and therapy or treatment discovery, and manufacturing life cycles to a much higher state of efficiency. But like public policy, change in many data-driven organizations seems to come slowly. Adoption can proceed much more quickly with the proper scientific data and process strategy, proper change management, and selection of the proper solution stack. Whether assisting researchers in their approaches, organization, and data science or driving Insilico/Model first approaches to science, scientific computing and software will always be a major part of scientific discovery and future decision making. Humans simply will not be able to manage the amount and diversity of data that they are exposed to.

Figure 5: History of Computing (1200 C.E.-Present)

4. BIOPHARMA ENVIRONMENT CONSTRAINTS

In drug discovery or therapeutics R&D, research typically proceeds in a dynamic state (with pockets of stability) then progresses to a more static state as a new product moves closer to manufacturing. Fig. 6. Other differences that impose exogenous constraints are the need for GXP and validation, which is on the Development, Clinical, and Manufacturing side of the house.

The opportunity to reduce a company's IT footprint is substantial and pressing. There are platforms available that can replace multiple legacy and antiquated tools and do it with speed, flexibility, and risk reduction. Based on everything we discussed earlier, composable approaches will help drive these efficiency gains by reducing costs associated with poorer IT.

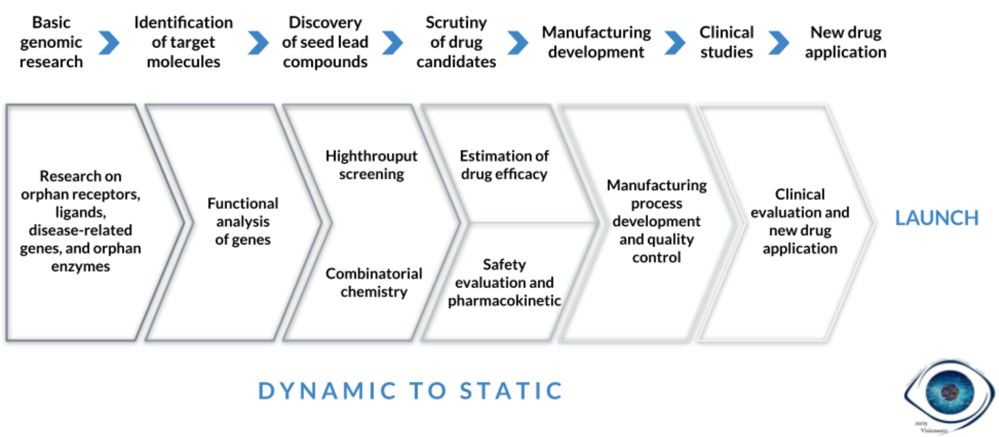

Figure 6: Drug/Therapy Discovery Processes Progression

5. USE CASES AND HOW THEY ARE GUIDING NEXT-GENERATION DEVELOPMENT AND KNOWHOW

5.1 DATA AND PROCESS ENVIRONMENTS

Scientific research and development have many challenges, and unfortunately, FAIR data is only one of those. In fact, FAIR processes are also a problem! The days of large expensive relational “discovery databases” that took a small army to maintain and keep up to date are old-school and antiquated. We followed with data marts, then data lakes, and now knowledge graphs. The composable architectures and infrastructures could be sitting on top of all of this. Key R&D processes that you should be concerned with are:

1. Request management.
2. Sample management.
3. Test management.
4. Experiment management.
5. Analysis management.
6. Reporting management.
7. Capture of the scientific method.
8. Storage of pertinent information of many various data types, transactions, reference data, and master data in a FAIR way.
9. Proper archival.
10. Validation, compliance assurance.
11. Ability to capture the continuum and represent it when needed from an information and knowledge perspective.

Key opportunities to save significant time and money are related to the inordinate effort involved in integration, validation, and knowledge/tech transfer (scale-up). Deploying an enterprise solution that can span the R&D continuum (whether Ag Science, Therapeutics or Material Science), even if separated instances, supports a more efficient lifecycle concept. The goal is to capture all the data and processes an organization encounters from inception to manufacturing (Applied Digitalization). In Life Sciences, the repurposing of all this knowledge and intelligence has the potential to drive massive efficiency gains. The goal is lofty, but major success can come even at 70% compliance. When drugs and therapies or cleaner fuels/materials come to market faster, sustainable food production is raised, the impacted industries will notice, and smart players will adopt these new technologies and processes to compete.

5.2 INTEGRATIONS, A LARGE EXPENSE FOR ORGANIZATIONS

Integration includes instruments, applications, data, services, and workflow. Many large data-driven organizations seem to have accumulated at least one of everything and are reluctant to let go of legacy assets. Some of this may make sense depending on the domain of study and how cohesive or strategic an organization has been. One important factor in helping reduce integration costs is taking a more enterprise approach, avoiding point-to-point integrations.

5.3 VALIDATION AND COMPLIANCE

Another high cost for companies is validation and compliance where Good Laboratory Practices (GLP) or Good Manufacturing Practices (GMP) are required. These costs can be 4% to 10% of an enterprise's annual budget, especially if not done properly.

Validation, unfortunately, is one of the three costs that sap an IT organization; doing it smarter will save significant time and money for a GXP organization.

Imagine reducing the time and cost of GXP validation thanks to a more agile building-block approach. This enables more reuse and can isolate processes so that every minor change does not require a major re-documentation effort.

"Validation, unfortunately, is one of the three costs that sap an IT organization; doing it smarter will save significant time and money for a GXP organization."

5.4 KNOWLEDGE AND TECH TRANSFER

Knowledge and tech transfer can be another costly exercise in most companies. Having the benefits of a composable architecture that has implemented contextualized and detailed processes allows for digital solutions that include electronic batch records.

It is 2021, and unfortunately, many people are still constrained with paper and spreadsheet processes. One of the biggest headaches is the inability to transfer technology and acknowledge from one group to another. We are not saying you will prevent all of these headaches because it's science, but what we are saying is that you can dramatically reduce these and actually have the information and data to solve the difficult situations faster.

Tech and Knowledge transfer is another important need throughout the continuum. It can become a serious obstacle during scaleup if the data and processes are not well captured and contextualized. We have personally experienced this in the research to development and development to manufacturing transfers, with the latter being very costly in a pressure cooker environment. What is fundamentally missing is the data and process rigor to drive reproducibility. Many legacy environments are not easily configurable or even usable and many companies revert to inadequate tools and even paper. Biologics, gene and cell therapy organizations are finding that it is next to impossible to operate in this mode. This includes the CDMOs that are the externalized partners as well.

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6. L7 INFORMATICS L7|ESP™

The composable architecture described above, and the flexibility and preparedness it delivers, provide a blueprint for L7 Informatics' L7|ESP (Enterprise Science Platform™). L7|ESP is a unified platform ecosystem that is continually adds functionality and capabilities; with a rate of innovation that sets the standard in the field.

Figure 7: L7's ESP Unified Platform

The current Biopharma/Healthcare, Agricultural Science, Material Science verticals are not that simple for to existing environments, vendor partners, and externalization and collaboration, all of which carry a vast amount of legacy IT. L7 integrates with existing systems and environments, allowing for a plug-and-play approach to evolving hybrid solutions while staying positioned to consolidate and simplify the overall IT footprint. Each step reduces unnecessary complexity, driving digitalization strategy in a coherent and manageable manner. This approach results in FAIR data and processes, opening the door to an Entity Life Cycle management approach that can drive innovation. A city planning analogy would be Boston versus Chicago. Have you ever been lost in Boston for hours trying to figure out how you will find your way back? (Thank the Gods for GPS)

L7's ESP allows a well-written and architected tool to handle the complexities in major data-driven organizations. Whether it is gene editing data and processes, cell therapy, small molecule or large molecule development and manufacturing, agricultural sciences, or oil and gas, the L7|ESP framework can handle the workflows due to its flexibility, scalability, and reuse delivered by a composable architecture. Complex biologics development, quality and manufacturing groups, including CDMOs, quickly see the value in this approach. Their business processes can become very variant due to new modalities and customer-specific precision medicine therapies. L7|ESP, with its single data fabric, has all the apps to design, develop, and execute integrated manufacturing and QC processes. Fig 8. Out-of-the box L7|ESP apps to support advanced therapies include Builders, MES/EBR, LIMS, Environmental Monitoring, Inventory Management, Location Management, Stability, etc.

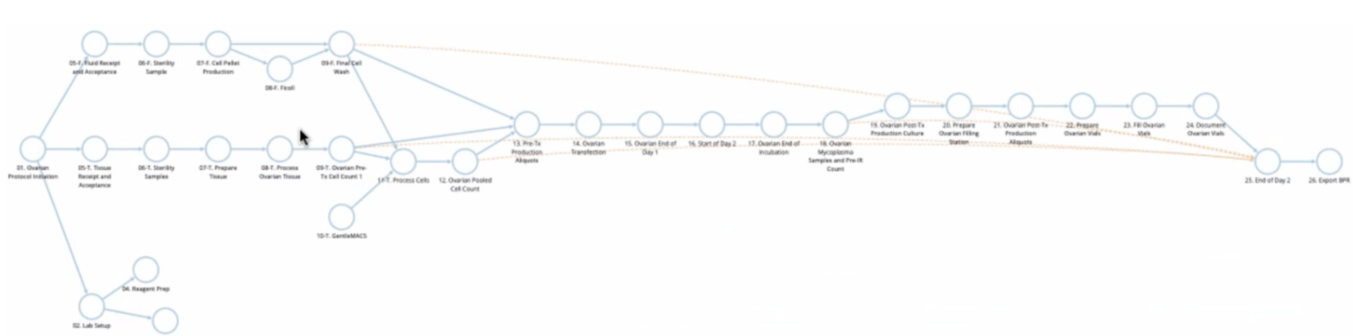

Figure 8: Integrated manufacturing and QC workflow for advanced therapies

It does not take a year to configure the system; rather, it can be fully operational in 3-4 months. This ultimately means lifesaving or altering products will get to market faster. Complexity in processes can be a precarious thing. Only significant change management can address the complexity of the problem due to poor processes, curation, and/or bureaucracy. If the complexity is due to science and technology processes alone, L7 can reduce and manage it through its composable L7|ESP platform. The implementation details will depend on each environment's current and type complexity and L7|ESP's role initially or in the months and years ahead.

6.1 THE POWER OF REUSABLE BUILDING BLOCKS OR PRIMITIVES

What makes L7|ESP stand out as a unique Next-Generation platform are its reusable, FAIR-compliant building blocks. Scientific business processes are not only well defined but exist as a primitive or building block. Need to combine processes? No problem! Want to do this with data models? You can do it!

With the L7 approach, instruments, applications, and services connectors are also part of the primitive framework. There is a growing element of COTS (Commercial Off the Shelf), but the ability to create new connectors becomes routine.

7. SUMMARY

Science and technology are evolving at an unprecedented pace. Great care is called for when gathering requirements and making choices for scientific informatics and software needs. Digital strategies and the pursuit of FAIR data and processes will undoubtedly be part of any successful implementation. Because of the level of effort and cost when selecting and implementing scientific software platforms, it can take years before newer and better technologies and approaches like Composable Infrastructures can be adopted to drive a Unified Platform Ecosystem. These UPEs drive innovative and efficient FAIR data and process environments that dramatically reduce the TCOs and increase the ROIs for new deployments across the data-driven continuum in Life Sciences and Material Sciences. These are just two important verticals that can use UPEs to achieve of FAIR data and process environments and the massive reduction of “Data Wrangling.” The goal is more and more efficient scientific business processes, leading to a better quality of life for scientists and researchers and the consumers they are working for. Until now, there are very few enterprises Scientific IT platforms that can span the continuum of Life and Material Science organizations (Discovery to Product). The flexibility, scalability, and ability to impose rigor on complex processes will drive reproducibility, compliance, and FAIR data and processes. This will ultimately deliver reproducibility in science, better availability and use of Model-Quality Data, and smoother or even seamless knowledge and tech transfer. L7 has built one of the best scientific unified platforms on the market and has raised the bar for enterprise scientific software with its No Code/Low Code capabilities and its efficiency gaining Composable Architecture!

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