COLLABORATIVE SYSTEMS INTEGRATION

WHITE PAPER · PROCESS CONTROL ARCHITECTURE

Open Process Automation for Pharmaceuticals and Life Sciences

Where open, standards-based control fits a modular, short-lifecycle industry: standardized modular integration and Module Type Package for mainstream batch and skid-based plants, and the O-PAS Standard for API, chemical-synthesis, and large continuous operations

Prepared by Collaborative Systems Integration (CSI)

For pharmaceutical and life sciences leadership, automation and controls engineering, and procurement

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A note on sourcing and certainty

This paper is written to be useful to people who will make or influence a capital decision, so it distinguishes clearly between what is established, what is vendor claim, and what is still emerging. Figures drawn from third-party analyses are attributed to their source in the text and collected in the References section. Quantitative comparisons of Open Process Automation against traditional systems come predominantly from continuous-process industries such as oil, gas, and chemicals. Pharmaceuticals is not among them. This paper therefore treats those figures as directional context, not pharma-specific evidence, and is explicit about where the pharmaceutical case rests on different economics, above all the cost of validation. Where a figure has not been demonstrated in a GMP-regulated setting, this paper says so. This paper is also explicit about scope, because pharmaceutical manufacturing is not one thing and open automation applies to its segments differently. For the mainstream of the industry, batch and skid-based production assembled from OEM unit operations and orchestrated by a plant supervisory system, the most relevant open idea is standardized modular integration, above all Module Type Package. Full Open Process Automation, replacing the base control system with a multi-vendor O-PAS architecture, fits best the minority of pharmaceutical production that behaves like continuous chemical processing: active-pharmaceutical-ingredient and chemical-synthesis plants, and large continuous operations. This paper tries to say clearly which idea applies where, rather than claiming a single answer for the whole industry. Open Process Automation and the O-PAS standard are evolving, and standard versions and certification programs continue to advance beyond the dates cited here; readers making procurement decisions should confirm current standard versions, certified products, and pricing directly with The Open Group and with suppliers.

Contents

1. Executive Summary

Pharmaceutical and life sciences facilities run some of the most tightly regulated control systems in any industry: process control on utilities and continuous operations, batch and recipe-driven trains with electronic batch records, packaging and serialization lines on their own PLCs, and historians and laboratory systems that hold data under 21 CFR Part 11. But the sector's automation economics differ sharply from the continuous-process industries where open control first took hold, and any honest case for openness in pharma has to start there. A pharmaceutical plant is increasingly a short-lived asset. When a product goes off patent, loses revenue, or is overtaken by a better medicine, the facility is commonly mothballed and its equipment sold for a fraction of its cost; targeted medicines are shrinking batch sizes and plant footprints; and plants are now designed with a short productive life in mind. The dominant response to control-system obsolescence is therefore not to nurse an ageing system for decades, but to build new and scrap the old when a facility is repurposed, or to perform routine, vendor-supported version upgrades that suppliers have made comparatively straightforward to document and validate. Most modern plants are assembled from OEM unit operations with the PLC built in, orchestrated by a plant supervisory system, most commonly Emerson DeltaV or Inductive Automation Ignition.

Open Process Automation™ (OPA) is a different way to build the control system. Rather than buying a closed platform from one vendor, the operator buys to an open standard, the O-PAS™ Standard, published by The Open Group®'s Open Process Automation Forum. O-PAS defines standard interfaces so that controllers, input and output modules, applications, and software from different suppliers can interoperate on a common connectivity backbone, and so that control applications can be moved from one conforming platform to another. The stated goals of the standard are to stimulate innovation, lower system lifecycle cost, and give end users more freedom to manage obsolescence.

The central argument of this paper is more carefully bounded than for other sectors. Open Process Automation was created to solve problems, obsolescence of proprietary hardware, vendor lock-in, and the difficulty of adding modern software to a closed system, that bite hardest on long-lived continuous plants. In pharmaceuticals those problems concentrate in the segment that most resembles such plants: active-pharmaceutical-ingredient (API) and chemical-synthesis facilities and large continuous operations, where a full O-PAS architecture is a genuine and attractive option. For the batch and skid-based mainstream of the industry, where the plant itself is short-lived and built from OEM modules directed by a supervisory system, the open idea that pays off is not replacing the base control system but standardizing how modules integrate, which is the domain of Module Type Package (MTP) and plug-and-produce orchestration. The honest qualifiers, addressed throughout, are that OPA has not yet been proven at scale in a GMP environment, and that its strongest pharmaceutical fit is a specific segment rather than the industry as a whole.

What the evidence shows so far

- **Cost.** A cost analysis presented by Collaborative Systems Integration at the 2024 ARC Industry Forum, based on a modeled continuous-process plant with roughly 14,000 I/O, found approximately 52% lower capital cost for system hardware and software using an O-PAS system versus a traditional DCS, narrowing to about 10% total project savings once system-integration cost was included. A separate 25-year cost-of-ownership study calculated by Wood found roughly 47% savings, rising to an estimated 60% to 70% once the cost of downtime for control-system maintenance was included. These figures come from a modeled continuous-process plant, not from pharma, and they exclude validation, the largest cost lever in this industry; treat them as directional context and re-derive the case on your own numbers.
- **Interoperability and portability.** O-PAS is built on widely adopted open standards, notably OPC UA for connectivity, IEC 61131 and IEC 61499 for control logic, and the ISA/IEC 62443 series for cybersecurity. This lets a manufacturer mix conforming products from multiple suppliers and avoid re-engineering the whole system when one component reaches end of life.

- **Cybersecurity.** O-PAS mandates conformance to the ISA/IEC 62443 cybersecurity series, and in August 2024 the Open Process Automation Forum named ISASecure as the exclusive verification provider for those requirements. Security is specified into the architecture rather than added afterward.
- **Maturity.** OPA has been proven in the field, but not in pharma. The flagship deployment is ExxonMobil's OPA Lighthouse at its Baton Rouge petrochemical plant, which cut over at the end of 2024 and has since run a live production unit, reportedly without major interruption. There is no public, at-scale deployment in a GMP-regulated pharmaceutical facility yet, so a manufacturer adopting now is a genuine early adopter and must work the validation and regulatory-acceptance questions deliberately. The most natural near-term pharmaceutical entry point is an API or chemical-synthesis plant, which behaves like the continuous-process facilities where OPA is already proven.

This paper explains what OPA is, characterizes how it differs from PLC and DCS approaches, compares the three on the dimensions that matter to a manufacturer, maps concrete pharmaceutical and life sciences use cases, and lays out a pragmatic, low-risk path to evaluate the architecture without betting a line on it.

Further reading from CSI

This paper is a sector-focused summary. For the underlying architecture in depth, see Trevor Cusworth's book *Open Process Automation: Architecture, Execution & Transformation*. For where the standard, the suppliers, the integrators, and the economics actually stand this year, see CSI's flagship report, *State of Open Process Automation 2026* (a 40-page assessment published May 2026). To model the economics for a specific facility, CSI provides an OPA lifecycle-cost (ROI) calculator at csi-automation.com/opa-roi-calculator, and CSI Academy offers OPA training for engineering and operations staff at csi-automation.com/academy. All are listed in the References.

2. The State of Automation in Pharmaceuticals and Life Sciences

To understand why an open architecture is attractive here, it helps to be specific about how pharmaceutical and life sciences control is built today and where it strains.

2.1 How a modern pharmaceutical plant is actually built

A typical pharmaceutical facility does not run one monolithic control system, and to hit aggressive time-to-market targets it increasingly does not try to. Wherever possible, manufacturers buy OEM unit operations, chromatography and filtration skids, bioreactors, single-use assemblies, fill-finish and packaging lines, with the automation built in, each arriving as a self-contained unit with its own embedded PLC and local controls. A plant supervisory system sits over the top, directing those units, holding the recipes, and presenting a common operator environment; in practice this is most often Emerson DeltaV or Inductive Automation Ignition. Around it run the layers that carry the regulated record: the batch and electronic-batch-record layer, frequently built to ISA-88, a manufacturing execution system, and the historian and laboratory systems that hold data under 21 CFR Part 11.

This model works, and it is chosen deliberately: buying pre-automated modules and integrating them under one supervisory system is faster and lower-risk than engineering a bespoke, plant-wide control system from scratch. Its weakness is not day-to-day function; it is integration. Every OEM module expresses its automation in its own way, so bringing each one under the supervisory layer, its tags, its screens, its alarms, its sequences, is custom engineering repeated skid by skid and project by project. And lock-in does not disappear, it moves: to the supervisory platform the plant standardizes on, and to each embedded PLC brand a module happens to ship with.

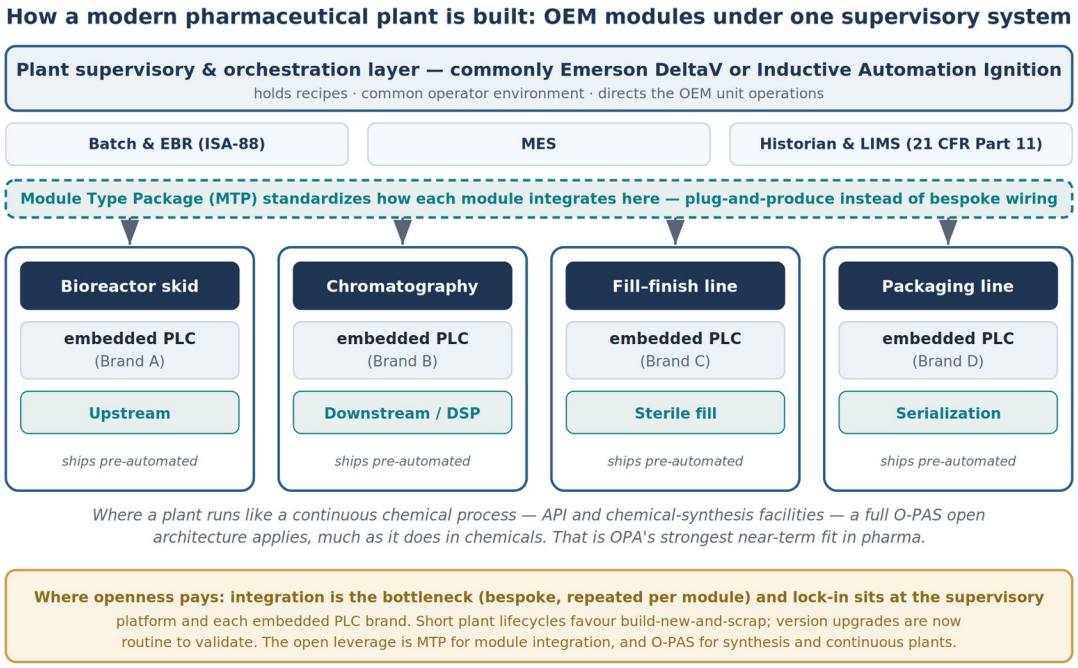

Figure 1. *A modern pharmaceutical plant is assembled from OEM unit operations with the PLC built in, directed by a plant supervisory system (commonly DeltaV or Ignition) and wrapped by the batch/EBR, MES, and historian layers that hold Part 11 data. The automation bottleneck is integrating each module by hand. Module Type Package standardizes that integration; full O-PAS applies where a plant runs like a continuous chemical process.*

2.2 Obsolescence, handled by building new rather than freezing

Two decades ago the picture was different: a validated DCS was frequently frozen in place for as long as possible because any change risked revalidation, and plants ran systems well past end of support. That dynamic still exists in corners of the industry, but it no longer describes the mainstream, and two things changed it. First, product and plant lifecycles shortened. A facility's productive life now often falls short of patent expiry, because a competitor introduces a superior medicine, so plants are designed, and depreciated, with a short life in mind; when a product winds down, the plant is commonly mothballed and its equipment sold for a fraction of its cost rather than modernized in place. Second, the vendors made staying current genuinely manageable. Where a plant does keep a control platform for years, upgrading it is now a routine, well-documented, well-validated activity, some operators move their DeltaV version forward on roughly a biannual cycle, rather than the high-risk revalidation event it once was. *(Practice varies widely by company, product, and plant type; manufacturers should assess their own installed base, product pipeline, and upgrade practices rather than rely on a sector generalization.)*

So the obsolescence question in pharma usually resolves in one of two ways, and neither is the decades-long nursing of a dead system. Either the facility is rebuilt for a new product with new equipment and the old control system is simply discarded, or a specific ageing platform is converted to a current one, most often to consolidate on the plant's supervisory standard. Wholesale DCS-to-DCS conversions are comparatively rare in branded, small-molecule and biologics pharma. They are far more common, and the case for an open O-PAS architecture is far stronger, in API and chemical-synthesis plants, which behave like traditional chemical facilities and carry the same long-lived-asset economics that make obsolescence and lock-in expensive.

2.3 Vendor lock-in and proprietary protocols

Lock-in in a modern pharmaceutical plant is real, but it sits in different places than the old single-DCS picture implies. It concentrates in the supervisory platform the plant standardizes on, whose proprietary engineering tools, drivers, and licensing the manufacturer commits to, and across the assortment of embedded PLC brands that arrive inside OEM skids, each with its own tools, spares, and conventions. Because bringing each module under the supervisory layer is bespoke work, that integration effort is itself a form of lock-in: it is expensive to redo, so the plant stays with the platform it first integrated against. Where the asset is short-lived this matters less, the plant is scrapped before the commitment compounds. Where it is long-lived, in API, synthesis, and continuous operations, single-supplier dependence on a decades-long production asset is exactly the leverage an open architecture is meant to recover.

2.4 Cybersecurity as a first-order requirement

The threat model for a pharmaceutical plant centers on two things a chemical plant worries about less: data integrity and patient safety. Control systems and historians generate the electronic records that prove a batch was made correctly, and those records fall under 21 CFR Part 11, which requires audit trails, access control, and assurance that data cannot be silently altered. Older control systems were designed for isolated networks and often predate both modern security and modern data-integrity expectations, yet they are increasingly connected to MES, historians, and enterprise systems. Retrofitting segmentation, authentication, tamper-evident audit trails, and monitoring onto architectures never designed for them is difficult and expensive. Manufacturers need security and record integrity engineered into the control system, not bolted on after validation.

2.5 Workforce and knowledge risk

The workforce that built and maintains these systems is retiring, and operators compete for a shrinking pool of controls and advanced-process-control talent. Proprietary platforms compound the problem: each vendor has its own tools, languages, and conventions, so skills are not readily transferable and training is vendor-specific. When the one engineer who understands the legacy configuration leaves, the operator inherits a system it can run but struggles to change safely.

2.6 Batch, data, and quality systems live in separate silos

Several of the most important layers in a pharmaceutical plant sit outside the base control system as separate, proprietary systems with their own engineering environments: the batch and recipe layer with its electronic batch records, the manufacturing execution system, and the historian and laboratory systems that hold Part 11 data. Each is a separate vendor relationship, a separate lifecycle, a separate validation, and a separate integration to maintain. The recipes and applications that define how product is made are usually proprietary and re-integrated, and re-validated, at every migration. An architecture that provides standard, documented interfaces lets these layers connect consistently and lets batch and control applications, and their validated state, move forward rather than being rebuilt each cycle.

2.7 Regulatory pressure is rising

Pharmaceutical manufacturing is among the most heavily regulated activities in industry, and the regulation reaches directly into the control system. Production runs under FDA current Good Manufacturing Practice (21 CFR Parts 210 and 211), and any computerized system that creates or manages GMP records falls under 21 CFR Part 11, with its requirements for audit trails, electronic signatures, and data integrity. The automation itself must be validated, historically through computer system validation guided by ISPE's GAMP 5, now shifting toward the FDA's more risk-based Computer Software Assurance approach. Manufacturers with international operations also work to EU Annex 11. None of this goes away under OPA; the question is whether an open, well-documented, standards-based architecture makes the validated state easier to establish and maintain than a closed one.

There is also a modernization pull, not just a compliance push. The FDA has actively encouraged process analytical technology and continuous manufacturing, now framed by ICH Q13, both of which reward flexible control platforms that can take in new analyzers and advanced control without a proprietary rebuild. A standards-based architecture that documents its interfaces and can evidence ISA/IEC 62443 conformance fits the direction the agency is pushing rather than fighting it. *(Regulatory requirements and guidance evolve, and some items summarized here, including the status of the Computer Software Assurance guidance, are recent; manufacturers should confirm current expectations with the FDA and their quality and regulatory functions.)*

2.8 The economics are driven by validation and time to market

A pharmaceutical plant's economics are not primarily about turnaround windows, and they are no longer mainly about nursing an ageing control system. They are about time to market for a high-value product, the speed of technology transfer, and the cost of validating change, set against a plant that may have a deliberately short life. That combination pushes manufacturers toward building new and scrapping the old, and toward buying pre-automated modules that shorten project schedules, rather than toward deep, long-horizon control-system investments. It also reshapes where openness pays. For the short-lived, modular mainstream, the return is faster, cheaper, repeatable module integration, the MTP argument, and portable configuration that lets a validated solution move across identical lines and sites with less rework, which is the real pain of technology transfer today. For long-lived API, synthesis, and continuous plants, the classic lifecycle-cost and obsolescence-avoidance case for a full open architecture applies much as it does in chemicals. Downtime still matters, and on a high-margin product it matters a great deal. *(These effects are structural rather than measured: the published cost studies come from continuous-process industries and do not include pharmaceutical validation. Manufacturers should model their own validation, transfer, and downtime costs rather than rely on a sector generalization.)*

3. What Is Open Process Automation?

Open Process Automation is an approach to building process control systems from interoperable, standards-based components rather than from a single vendor's closed platform. The technical expression of the approach is the O-PAS Standard.

3.1 Origins and governance

The initiative grew out of work led by ExxonMobil beginning around 2016, driven by frustration with proprietary DCS platforms that were expensive to sustain and slow to accept new technology. ExxonMobil engaged Lockheed Martin as a systems integrator for an early prototype and convened end users and suppliers to define a common standard. That standards work moved to The Open Group, a vendor-neutral standards body, which established the Open Process Automation Forum (OPAF) to develop and maintain the O-PAS Standard. As of 2024, OPAF reported more than 120 member organizations spanning end users, suppliers, system integrators, and academia.

O-PAS (the Open Process Automation Standard) is deliberately described as a "standard of standards." Rather than inventing new technology where good standards already exist, it composes established ones, OPC UA, IEC 61131, IEC 61499, ISA/IEC 62443, and DMTF Redfish among them, into a coherent reference architecture for open, interoperable, secure process control.

3.2 The core architectural ideas

A few concepts carry most of the weight. They are worth understanding because they are exactly what differentiates OPA from a conventional PLC or DCS.

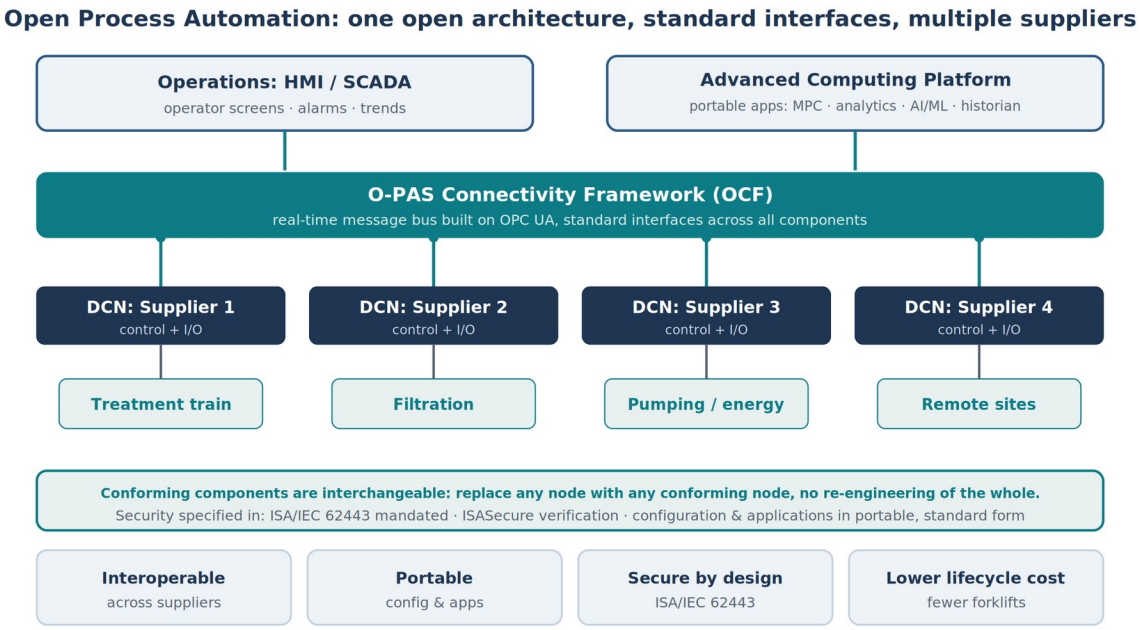

Figure 2. *In an OPA system, conforming components from multiple suppliers connect through the OPC UA-based O-PAS Connectivity Framework. Distributed Control Nodes, applications, and supervision all share standard interfaces, so any conforming component can be replaced without re-engineering the whole.*

Distributed Control Node (DCN)

The DCN is the standard building block of control. It is a compact, comparatively low-cost compute element that performs control, connects to I/O, and speaks the standard interfaces. Instead of a large proprietary controller cabinet, control is distributed across many small conforming nodes, which can, in principle, be sourced from different suppliers because they conform to the same standard.

O-PAS Connectivity Framework (OCF)

The OCF is the standardized connectivity backbone, a real-time message bus that carries data among all the components of the system. It is built on OPC UA, the widely adopted industrial interoperability standard. Because every conforming component connects through the OCF using standard interfaces, a controller from one supplier and an application from another can exchange data without custom integration for each pairing.

Advanced Computing Platform and applications

O-PAS anticipates that meaningful computation, data acquisition, filtering, monitoring, diagnostics, advanced control, and analytics, runs on standard computing platforms and can be deployed as portable applications rather than being locked inside proprietary controllers. This is what makes it practical to add modern software, including model-based control and machine learning, to the control system over its life.

Physical platform and system management

The standard also specifies the physical platform and system-management interfaces, including the use of DMTF Redfish for hardware management, so that conforming devices can be managed in a consistent, vendor-neutral way.

3.3 The three properties that matter: interoperability, portability, and configuration portability

OPA's value is best understood through three related but distinct properties. Procurement and engineering teams should be precise about them, because vendors sometimes use them loosely.

1. **Interoperability.** Components from different suppliers can exchange data and work together through standard interfaces. This is what breaks the requirement that controllers, I/O, and applications all come from one vendor.
2. **Configuration portability.** The configuration of the system, its setup and parameters, can be expressed in a standard form so it is not trapped in one supplier's proprietary engineering tool. O-PAS Version 2 introduced configuration portability, and Version 2.1 extended it.
3. **Application portability.** A control application written to the standard can be moved from one conforming platform to another without being rewritten. This is the most powerful property for long-term obsolescence management, and it is the focus of the forum's work toward Version 3.0.

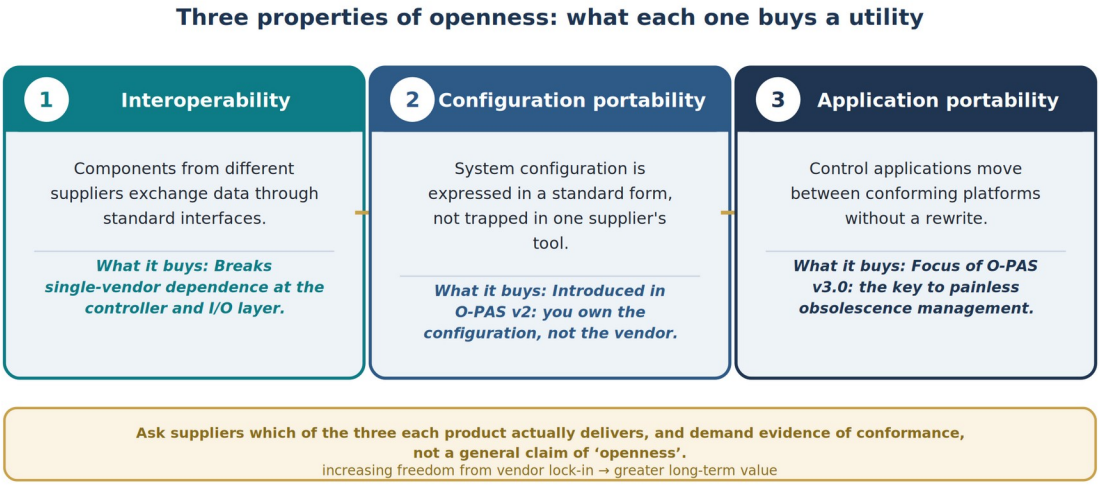

Figure 3. *Interoperability, configuration portability, and application portability are distinct properties. A product can deliver one without the others, so an operator should ask specifically which it provides and require evidence of conformance.*

Why the distinction matters for an operator

Interoperability lets you buy the best component today. Portability lets you replace a component in fifteen years without re-engineering the control logic that runs your plant. A supplier can be interoperable at the connectivity layer while still making your applications hard to move. When evaluating products, ask specifically which of the three properties a product delivers, and demand evidence of conformance rather than a marketing claim.

3.4 Standard structure and versions

The O-PAS Standard is published in parts, each addressing a layer of the architecture. In Version 2.1 the standard comprises the following parts:

Part	Title / scope
Part 1	Technical Architecture Overview (informative)
Part 2	Security
Part 3	Profiles (informative)
Part 4	O-PAS Connectivity Framework (OCF)
Part 5	System Management
Part 6.1–6.6	Information and Exchange Models: overview and interfaces, basic configuration, alarms and events, function blocks, IEC 61499, and IEC 61131
Part 7	Physical Platform

The standard has advanced through successive versions, broadening what "open" delivers at each step:

- **Version 1 (2019)** established interoperability.
- **Version 2 (January 2020)** added configuration portability.
- **Version 2.1 (preliminary standard, 2021)** progressed the information model and extended configuration portability.
- **Version 3.0 (in development)** targets application portability and system orchestration.

Verify current status

Standard versions, part numbering, and certification programs continue to evolve past the dates above and beyond this author's knowledge horizon. Confirm the current published version, conformance program, and list of certified products directly with The Open Group before making procurement commitments.

3.5 Conformance and cybersecurity certification

An open standard is only as good as the ability to verify that a product actually conforms to it. Two mechanisms matter. First, The Open Group operates a conformance program for O-PAS so that products can be certified against the standard rather than merely claiming compatibility. Second, on cybersecurity specifically, O-PAS mandates conformance to the ISA/IEC 62443 series in Part 2, and in August 2024 OPAF selected ISASecure as the exclusive verification provider for those cybersecurity requirements, leveraging ISASecure's network of accredited certification bodies. For an operator, this means security conformance can be evidenced by third-party certification rather than taken on faith.

A complementary standard: Module Type Package (MTP)

O-PAS is not the only open standard reshaping process automation. Module Type Package (MTP), published as VDI/VDE/NAMUR 2658 and progressing toward the international standard IEC 63280, standardizes how a modular process unit, a skid or Process Equipment Assembly, describes its own automation, its services, operator screens, and alarms, so it can be integrated into a plant's orchestration layer in a plug-and-produce manner rather than through bespoke engineering. Like O-PAS, MTP is built on OPC UA. The two are complementary: O-PAS opens the base control system, while MTP opens the integration of modular equipment on top of it. For pharma, where modular and flexible manufacturing is a strategic direction, they point the same way, toward interoperable, portable, standards-based automation.

4. How Traditional Architectures Work, and Where They Strain

OPA is best judged against the systems it would replace or complement. This section characterizes the two dominant traditional approaches fairly, including their genuine strengths, before the structured comparison that follows.

4.1 The Distributed Control System (DCS)

A DCS is an integrated, vendor-supplied platform designed to control a continuous process as a coordinated whole. It bundles controllers, I/O, engineering tools, operator interface, alarming, and historian into one tightly engineered product line. In pharmaceuticals and life sciences, the DCS is the backbone of process control, coordinating hundreds or thousands of loops per unit and operated from a central control room.

The strengths are real. A DCS offers a mature, coherent operator environment, strong alarm and batch handling, high reliability, and a single vendor accountable for the whole system. For a large, continuous, safety-relevant process, that integration is valuable. The cost of that integration is closure: the pieces are proprietary and are designed to work together and, by extension, not to be mixed with anyone else's. Lifecycle costs accumulate through the vendor's support contracts, migration cycles, and the practical impossibility of competitive sourcing for controllers and I/O.

4.2 Programmable Logic Controllers (PLCs) and SCADA

Alongside the DCS, pharmaceutical plants use PLCs extensively on package units, compressors, and skids, often paired with SCADA or tied back into the DCS. PLCs are rugged, fast, widely understood, and comparatively inexpensive, and there is a deep labor pool of engineers and integrators who work with the major brands. They are excellent at what they do, but they add another set of proprietary controllers, tools, and interfaces to the estate.

This approach is flexible and cost-effective, but its limitations show up at the system level. The PLC brand is still proprietary at the controller and I/O layer, so lock-in persists even if it feels lighter than a DCS. Integration between PLCs, SCADA, the DCS, and any advanced applications is custom work that must be re-created and re-validated at each upgrade. Cybersecurity is uneven, because it depends on how each layer and each integration was implemented. And portability of the control logic is essentially absent: logic written for one brand does not move to another without a rewrite.

> **The common thread**
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> Both traditional approaches are proprietary at the layer that matters most for long-term freedom: the controller and I/O, and the engineering tools that configure them. That is the specific point of closure OPA is designed to open. The question is not whether DCS and PLC and SCADA systems work, they plainly do, but whether the operator should keep accepting single-vendor dependence on a production asset with a multi-decade life.

5. OPA versus PLC versus DCS: A Structured Comparison

The table below summarizes the comparison across the dimensions that most affect a pharmaceutical manufacturer over a system's life. The discussion after it adds nuance, because a summary table necessarily simplifies, and the weight of each dimension differs between a short-lived batch plant and a long-lived synthesis or continuous unit.

Dimension	Traditional DCS	PLC + SCADA	Open Process Automation
Sourcing model	Single vendor, fully integrated platform	Proprietary PLC brand plus separate SCADA; some multi-vendor mixing	Multi-vendor by design; buy conforming components to one open standard
Interoperability	Within the vendor's ecosystem; limited outside it	Via protocols and custom integration; brand-locked at controller and I/O	Standard interfaces (OPC UA-based OCF) across suppliers
Application portability	Very low; logic tied to platform	Very low; logic tied to PLC brand	A core goal of the standard (advancing toward v3.0)
Obsolescence management	Vendor-driven migration cycles	Component swaps, but brand-locked	Replace conforming parts without re-engineering the whole
Cybersecurity	Vendor-dependent; often retrofit	Uneven; implementation-dependent	ISA/IEC 62443 mandated; ISASecure verification
Advanced apps (MPC, analytics, AI/ML)	Add-on modules, often proprietary	Custom integration required	Portable apps on standard compute platforms
Capital cost profile	Highest for integrated platform	Lower entry cost	Lower hardware/software cost; integration cost still developing
Maturity in pharma & life sciences	High; the sector backbone	High; batch and packaging lines	Proven in other sectors; not yet at scale in GMP pharma

5.1 Interoperability

The decisive difference is at the controller and I/O layer. In both traditional models, that layer is proprietary, which is what sustains lock-in. OPA standardizes the interfaces there, and connects everything through the OPC UA-based OCF, so conforming products from different suppliers interoperate without one-off integration. For an operator, the practical payoff is competitive sourcing and the ability to introduce a better component without replacing the surrounding system.

5.2 Portability and obsolescence

This is where OPA's long-term value concentrates in the sectors it was built for. In pharma it matters most for long-lived plants and for technology transfer, rather than as an industry-wide obsolescence cure. Under the traditional model, obsolescence in a long-lived plant forces a migration that is effectively a re-implementation and resets vendor lock-in for the next cycle. Under OPA, configuration and, increasingly, applications are expressed in standard forms, so a node that reaches end of life can be replaced by any conforming node and the control logic moves with far less rework. For an API, synthesis, or continuous plant on a 25-year asset life, this is the difference between incremental component refreshes and several disruptive forklift migrations. For a short-lived batch plant that will be scrapped with its product, the more valuable face of portability is different: a validated configuration that moves across identical lines and sites, which is the technology-transfer problem, not multi-decade obsolescence avoidance.

5.3 Cybersecurity

Traditional systems vary widely in security posture because it depends on when and how they were built and integrated. OPA specifies security into the architecture by mandating ISA/IEC 62443 conformance and providing third-party verification through ISASecure. This does not make an OPA system automatically secure, security still depends on correct deployment and operations, but it raises the floor and makes conformance verifiable, which matters for a critical-infrastructure operator answerable to regulators.

5.4 Scalability across units and the enterprise

Because control is distributed across small conforming nodes rather than concentrated in large proprietary controllers, OPA scales granularly. An operator can standardize on the same interfaces from a major process unit down to a single package skid, and across multiple plants in a manufacturing network, while still choosing fit-for-purpose hardware at each point. A single standard across many units and sites reduces spares, training, and integration overhead and makes fleet-wide advanced control and analytics far easier to deploy.

5.5 Cost

The most cited cost evidence comes from a Coalition for Open Process Automation analysis presented by Don Bartusiak, president of Collaborative Systems Integration, at the 2024 ARC Industry Forum. Modeling a continuous-process plant with roughly 14,000 I/O against traditional DCS installations, the analysis found approximately **52% lower capital cost for system hardware and software** with an O-PAS system, narrowing to about **10% total project savings** once system-integration cost was included. On a 25-year cost-of-ownership basis, Wood calculated roughly **47% savings**, and when the cost of plant downtime for control-system maintenance was included, customer-calculated savings reached an estimated **60% to 70%**. Analysts expect the integration-cost gap to shrink as application reuse and portability mature.

> **Read these numbers carefully**
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> These figures come from continuous-process industries (oil, gas, chemicals), not from pharmaceutical manufacturing, and they exclude the single largest cost lever in pharma: validation. Treat them as directional context, not a pharma number. They indicate that open architecture lowers hardware and lifecycle cost, but a pharmaceutical business case has to be built on the plant's own I/O count, its validation and technology-transfer burden, and its product economics, and should treat the single-digit near-term project savings, not the headline capital figure, as the conservative planning number.

6. Applying OPA to Pharmaceuticals and Life Sciences

The abstract advantages become concrete when mapped to the situations manufacturers actually face, but they do not apply evenly across the industry. The strongest and most immediate fit is modular integration through MTP for the batch and skid-based mainstream, and a full O-PAS architecture for API, synthesis, and continuous plants that behave like traditional chemical facilities. The use cases below are set out with that scoping in mind, and none of them requires the operator to convert everything at once.

6.1 Where a full open architecture fits best: API and chemical-synthesis plants

The clearest home for a full O-PAS architecture in pharma is the part of the industry that behaves least like the rest of it: active-pharmaceutical-ingredient and chemical-synthesis plants, and large continuous operations. These facilities run continuous or long-campaign chemistry, carry long asset lives, and face the same obsolescence, lock-in, and lifecycle-cost pressures as the chemical plants where OPA is already proven. For them the case is essentially the chemicals case: specify an O-PAS-conforming system at the next major control-system investment, gain multi-vendor sourcing and portable configuration, and buy out of the next proprietary migration. The economics and the maturity caveats from the chemicals sector carry across most directly here, which is why an API or synthesis unit is the most natural first OPA project for a pharmaceutical manufacturer. For the batch and skid-based mainstream, the more relevant open lever is modular integration, covered in section 6.5.

6.2 Technology transfer across identical lines and sites

Moving a validated process from development to production, from one line to an identical one, or from an internal site to a contract manufacturer is one of the most expensive and slowest activities in pharma, in large part because each target runs different proprietary automation that has to be re-engineered and re-validated. A common, standards-based architecture with portable configuration and applications is aimed directly at this problem: the same validated control solution deployed on conforming hardware across lines and sites, with far less rework each time. For a manufacturer with a network of plants or a contract-manufacturing strategy, this is the single most compelling use case for OPA.

6.3 Adding advanced control and optimization

The FDA has spent two decades encouraging process analytical technology and continuous manufacturing, now framed by ICH Q13, because real-time measurement and control improve quality and yield. Both depend on a control platform that can take in new analyzers and run advanced, model-based control without a proprietary integration rebuilt at every system change. OPA's model of portable applications running on standard compute platforms makes it materially easier to add PAT and advanced control, and to carry those applications, and their validated state, forward as the hardware is refreshed rather than rebuilding them each time.

6.4 Enterprise-wide architecture and data integrity

A manufacturer running several sites benefits from a single architectural standard across all of them: common interfaces, common security and data-integrity controls, transferable validation and staff skills, and consolidated spares. Because every conforming component connects through documented standard interfaces, data flows to historians and MES in a consistent, auditable way, which supports the 21 CFR Part 11 record integrity that a closed, bespoke integration makes harder to guarantee. OPA provides that standardization without forcing every site onto identical hardware.

6.5 Modular manufacturing and Module Type Package (MTP)

For most pharmaceutical plants, this, not a wholesale control-system replacement, is the primary open-automation opportunity. Pharma is moving toward modular and flexible production: single-use skids, ballroom facilities, cell and

gene therapy suites, and continuous-manufacturing trains assembled from standardized units, most of them bought as OEM unit operations with the automation built in. The bottleneck in that model is integrating each module into the plant's supervisory and orchestration layer, which today is custom engineering repeated for every skid and every project. Module Type Package (MTP), the VDI/VDE/NAMUR 2658 standard now progressing toward IEC 63280, addresses exactly this: a module ships with an MTP description of its services, screens, and alarms, and a Process Orchestration Layer, in practice the plant's DeltaV, Ignition, or equivalent supervisory system, consumes it in a plug-and-produce fashion instead of by hand.

MTP and OPA are natural partners. An open, standards-based control system provides the orchestration layer and the common connectivity that MTP modules plug into, both built on OPC UA, so a manufacturer can standardize the base architecture with O-PAS and the modular integration with MTP. In a validated environment the payoff compounds: a module qualified once, with a standardized automation interface, is far easier to integrate and re-qualify across lines and sites than one wired in by hand. MTP is more mature in specialty chemicals than in pharma today, so it carries the same early-adopter caveat as the rest of this paper, but it is a concrete, standards-based route to the flexible manufacturing pharma is pursuing.

A realistic note on adoption

This is the most important caveat in the paper. OPA has been proven in the field in oil, gas, and chemicals, most visibly ExxonMobil's Lighthouse at its Baton Rouge petrochemical plant, but there is no public, at-scale deployment in a GMP-regulated pharmaceutical facility yet. A manufacturer adopting OPA now is a genuine early adopter, and the validation and regulatory-acceptance questions have to be worked through deliberately rather than assumed away. That argues strongly for the phased, pilot-first approach described in the next section: prove it first where the GMP stakes are lowest.

7. A Practical Migration Path

Operators cannot and should not replace working control systems wholesale, and OPA does not require them to. The sound approach is incremental, evidence-driven, and designed so that each step delivers value on its own while building toward the target architecture.

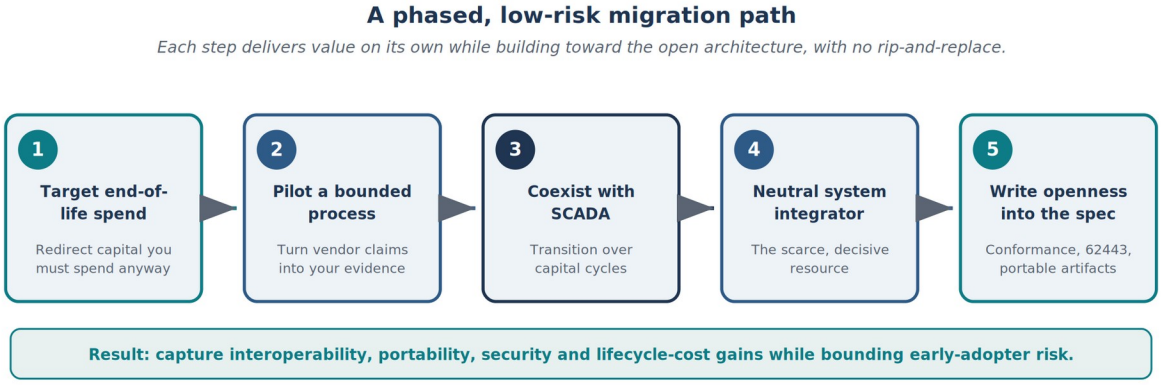

Figure 4. *A phased path lets an operator adopt OPA where obsolescence is already forcing spend, prove it on a bounded pilot, and expand through coexistence, rather than a single high-risk replacement.*

7.1 Start where you are already spending: new modular builds and synthesis modernizations

In continuous industries the natural entry point is an asset already scheduled for control-system replacement. In pharma the equivalent is slightly different, and there are two. The first is any new modular or skid-based build, where specifying MTP-conforming module interfaces and an open orchestration layer costs little extra at design time and removes bespoke integration on every future skid. The second is a modernization of an API, synthesis, or continuous unit, where an O-PAS-conforming replacement can be evaluated against the proprietary successor on lifecycle cost and obsolescence exposure. In both cases the capital is being spent anyway; the choice is whether to spend it on an open architecture or a closed one, because the alternative is not "do nothing," it is "buy proprietary again."

7.2 Pilot on a bounded, non-critical process

Choose a contained utility or non-GMP system, or a low-criticality line, where failure modes are well understood and the consequences of problems are manageable. Use the pilot to validate conformance claims from suppliers, exercise the OPC UA-based connectivity in the manufacturer's real network, test the security posture, and, crucially, work out the validation approach with the quality organization on something low-stakes. The pilot's purpose is to convert vendor claims, and validation assumptions, into your own evidence.

7.3 Coexist, do not rip and replace

OPA components can interoperate with existing SCADA and, through standard connectivity, with parts of the legacy system, so the transition can be gradual. New and refreshed assets move to the open architecture while the rest of the plant continues to run, and the two coexist through the SCADA layer during a transition that can span multiple turnaround cycles.

7.4 Use an experienced, vendor-neutral system integrator

The value of an open architecture is realized in integration, and today integration expertise is the scarcer resource, which is exactly why near-term project savings are smaller than the headline hardware savings. A system integrator with genuine OPA experience and a vendor-neutral stance, rather than an integrator effectively tied to one platform, is central to a good outcome. This is the specific gap Collaborative Systems Integration exists to fill. Operators that

want to build capability in-house can also train engineering and operations staff directly through CSI Academy (csi-automation.com/academy), which shortens the learning curve and reduces dependence on any single integrator over the asset's life.

7.5 Write openness into the specification

The architecture only stays open if procurement keeps it open. Specifications and contracts should require demonstrated O-PAS conformance and ISA/IEC 62443 verification, should call out interoperability, configuration portability, and application portability explicitly rather than accepting a general claim of "openness," and should require that configuration and application artifacts be delivered in the standard, portable forms so the operator, not the supplier, controls them over the asset's life.

8. Cost and Value Over the Asset Life

Some pharmaceutical plants carry a control system, and its validated state, for two or three decades; many now do not, because the plant itself is retired sooner when its product winds down. Either way, the right frame for an open-architecture decision is lifecycle cost and the cost of change across the asset's life, not just installed cost, and it is the frame in which OPA's argument is strongest, above all for the long-lived API, synthesis, and continuous plants where the asset persists long enough for the case to compound.

8.1 Capital versus lifecycle

The evidence comes from continuous-process industries rather than pharma, and separates two effects. The capital-cost advantage of open hardware and software is large in the modeled cases, on the order of 52% for system hardware and software in the CSI-presented analysis. The near-term total-project advantage is much smaller, roughly 10%, because system-integration cost currently offsets much of the hardware saving. The lifecycle advantage is where the case compounds: a 25-year ownership analysis by Wood found roughly 47% savings, and 60% to 70% when downtime cost was included. For pharma this lifecycle case is strongest in the long-lived API, synthesis, and continuous plants, where the asset persists long enough for forced migrations to recur. For short-lived batch plants the lever is not multi-decade ownership but the cost and speed of validated change and technology transfer, which these studies do not measure.

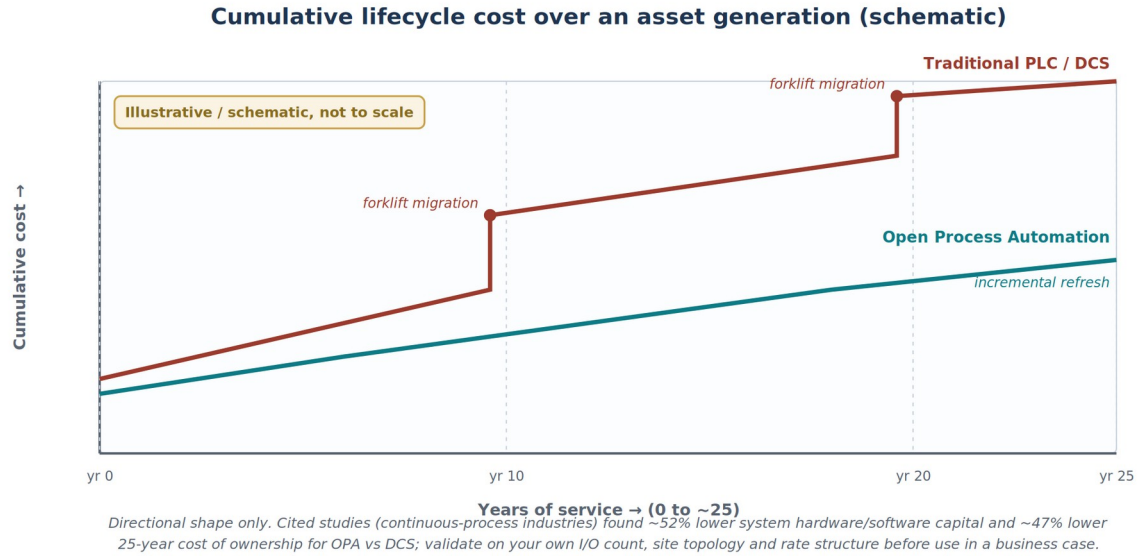

Figure 5. *Schematic of cumulative lifecycle cost. Traditional systems step up at each forced forklift migration; an open architecture is refreshed incrementally. Shape is illustrative only; the cited savings come from continuous-process studies and should be re-derived on an operator's own numbers.*

CSI's flagship report, *State of Open Process Automation 2026*, frames a 60% to 70% lifecycle-cost reduction over 25 years as the headline economic case for open architecture, alongside an assessment of where the standard, suppliers, integrators, and project-execution discipline stand this year. As an assessment authored from inside the standard by former Open Process Automation Forum leadership, it is a well-informed industry view rather than a fully independent audit, and its economics come from the same continuous-process context as this sector. It is a useful next read for an operator building its own business case.

8.2 The value that does not show up as a line item

Several of OPA's benefits are real but harder to price, and an operator's business case should name them even where it cannot precisely quantify them: avoided cost and disruption of future forklift migrations; competitive sourcing

leverage on controllers, I/O, and applications instead of sole-source dependence; verifiable cybersecurity conformance in a regulated critical-infrastructure setting; the ability to add and carry forward margin-capturing advanced process control without a proprietary integration each time; and reduced spares and training overhead from standardizing across units and sites.

To turn these effects into facility-specific numbers, CSI publishes an OPA lifecycle-cost (ROI) calculator (csi-automation.com/opa-roi-calculator) that lets an operator model hardware, integration, and 25-year ownership cost against its own I/O count and unit configuration, which is the right way to convert the directional figures above into a defensible business case.

The conservative planning posture

Build the near-term business case on the modest single-digit project savings, not the headline capital figure, and treat obsolescence avoidance and sourcing leverage as the strategic returns that accrue over the asset's life. If integration costs fall as the ecosystem matures, as analysts expect, the near-term case improves; if they do not, the operator has still bought out of the next forced, locked-in migration. Every figure in this section originates in continuous-process studies and should be re-derived on the operator's own numbers.

9. Risks, Limitations, and Honest Caveats

A credible case names its own weaknesses. The following are the real limitations a pharmaceutical manufacturer should weigh, stated plainly.

- **Its pharmaceutical fit is segment-specific.** A full O-PAS architecture fits API, chemical-synthesis, and continuous plants well, because they behave like the chemical facilities where OPA is proven. For the short-lived, batch and skid-based mainstream, the relevant open idea is modular integration through MTP, not wholesale control-system replacement. Applying the continuous-plant OPA case indiscriminately across all of pharma overstates it, and this paper deliberately does not.
- **No pharma field references yet.** OPA has been proven in oil, gas, and chemicals, but there is no public, at-scale deployment in a GMP-regulated pharmaceutical plant. A manufacturer adopting now is a genuine early adopter with no directly comparable pharma reference to point to.
- **Near-term integration cost.** System-integration cost currently offsets much of the hardware saving, which is why near-term project savings are single-digit rather than the headline capital figure. This should improve with ecosystem maturity, but that is an expectation, not a guarantee.
- **The skills to do it well are scarce.** Realizing an open architecture depends on integration expertise that is still concentrated in a small number of practitioners. Choosing the integrator carefully is not optional.
- **The standard is still evolving.** Key properties, most notably full application portability, are maturing through successive versions. Operators should track the current version and certified-product list rather than assume a fixed state.
- **Openness must be actively maintained.** An open standard does not by itself prevent lock-in; an operator that does not write conformance and portability into its specifications and contracts can end up dependent on a single supplier's implementation despite the open label.
- **Validation and procurement models lag.** Computer system validation and supplier-qualification practices are built around single-vendor systems. A multi-vendor, standards-based architecture must be worked through with the quality organization, and the validation strategy agreed before the architecture is fixed.

None of these is a reason not to evaluate OPA. They are reasons to evaluate it the way section 7 describes: incrementally, with pilots, with conformance written into contracts, and with an experienced vendor-neutral integrator, so the operator captures the upside while bounding the risk.

10. Recommendations

1. **Treat the next forced control-system replacement as a decision point, not a formality.** When a platform reaches end of life, evaluate an O-PAS-conforming replacement alongside the proprietary successor, and compare them on lifecycle cost and obsolescence exposure, not just installed price.
2. **Run a bounded pilot.** Prove conformance, connectivity, security, and integration on a contained, non-critical process before committing to a broader program, and convert supplier claims into your own evidence.
3. **Standardize interfaces across units and sites.** Adopt common O-PAS-based interfaces for new and revamped units and package systems to cut spares, training, and integration overhead over time.
4. **Write openness and security into every specification.** Require demonstrated O-PAS conformance, ISA/IEC 62443 verification, and delivery of configuration and application artifacts in portable, standard forms, and name interoperability, configuration portability, and application portability explicitly.
5. **Engage a vendor-neutral integrator early.** Integration expertise is the scarce resource and the largest single determinant of outcome; involve it before the architecture is fixed.
6. **Build the business case on your own numbers.** Re-derive cost figures from your I/O counts, unit configuration, and downtime valuations, use the conservative near-term project savings for planning, and carry obsolescence avoidance and sourcing leverage as strategic returns.

11. Conclusion

Pharmaceutical manufacturing does not fit the mould of the continuous-process industries where open control was born, and an honest case has to respect the difference. Its plants are increasingly short-lived assets, built from OEM modules under a supervisory system, retired when the product does, and kept current through routine, validated upgrades rather than frozen in place by revalidation. The obsolescence-and-lock-in story that drives OPA in refining and chemicals is muted here for the batch and skid-based mainstream, and sharp only in the segment that runs like a chemical plant. Open Process Automation was created in the process industries to make control systems interoperable across suppliers, to make configurations and applications portable, to specify cybersecurity into the architecture, and to lower lifecycle cost by ending the reliance on one vendor's proprietary hardware, and those aims translate into pharma unevenly, which is the point.

So the open opportunity in pharma has two faces. For most plants it is modular integration: standardizing how OEM skids plug into the supervisory and orchestration layer through Module Type Package, which attacks the real bottleneck, bespoke integration repeated skid by skid, and makes validated modules easier to reuse across lines and sites. For API, chemical-synthesis, and large continuous plants it is the full O-PAS architecture, where the lifecycle-cost, portability, and cybersecurity case carries across from chemicals much as written. The honest qualifier is larger here than in any other sector: OPA has not been proven at scale in a GMP environment, its strongest fit is a specific segment, near-term integration costs still offset much of the hardware saving, and the validation path has to be built deliberately. The useful question for a manufacturer is therefore not whether to convert the whole industry to open control, but where openness actually pays, at the module boundary for most plants and at the base control system for the synthesis-like few, and to spend the next automation dollar accordingly.

Appendix A. Frequently Asked Questions

The questions below are the ones pharmaceutical and life sciences leaders and engineers most often raise when they first evaluate Open Process Automation. The answers are deliberately direct, including where the honest answer is a qualification.

Does any of this apply to my plant if it is batch and built from OEM skids?

Yes, but through a different door than the continuous-process case. For a batch, skid-based plant, the open payoff is not replacing your DeltaV or Ignition supervisory system with a multi-vendor O-PAS stack; it is standardizing how each OEM module integrates into that supervisory layer, through Module Type Package (MTP), so integration stops being bespoke engineering repeated on every project and validated modules become easier to reuse across lines and sites. A full O-PAS architecture is aimed at API, chemical-synthesis, and continuous plants, which behave like traditional chemical facilities. If you run one of those, the continuous-process case in this paper applies to you fairly directly. If you run a batch, modular plant, focus on MTP and an open orchestration layer; that is where the return is.

Is OPA actually proven, or is it still a science project?

The standard is real and published, conformant products exist, and it has been proven in the field: ExxonMobil's Lighthouse has run a live unit at its Baton Rouge petrochemical plant since the end of 2024. What does not yet exist is a public, at-scale deployment in a GMP-regulated pharmaceutical facility. So in pharma it is proven as an architecture but unproven in your regulatory context, which is exactly why the paper recommends starting where the GMP stakes are lowest and building the validation case deliberately.

Who supports the system at 3 a.m. when something fails?

The same kind of party that supports it today: a system integrator and the component suppliers, under a support contract. The difference is that support is no longer locked to a single proprietary vendor. With an open architecture the operator can hold a vendor-neutral integrator accountable for the whole system and can change that relationship over time without replacing the control system. Support should be specified and contracted explicitly, exactly as it is for a DCS or PLC today.

What happens if one of the component suppliers goes out of business or exits the market?

This is precisely the risk OPA is designed to reduce. Because components conform to a common standard, a node or application from a departed supplier can be replaced by a conforming product from another supplier without re-engineering the surrounding system. Under the traditional model, the same event forces a far more disruptive and expensive migration.

How is O-PAS different from a vendor telling me their system is already 'open'?

Almost every vendor uses the word 'open,' usually to mean their system speaks a common protocol at the edges while remaining proprietary at the controller and I/O layer. O-PAS is a specific, published standard with a conformance program, covering interoperability, configuration portability, and application portability. The practical test is to ask which of those three properties a product actually delivers and to require evidence of conformance rather than a marketing claim (see Appendix C for specification language).

Do we have to replace everything at once?

No. OPA components interoperate with existing SCADA and, through standard connectivity, with parts of the legacy system, so the transition can be gradual and can span multiple capital cycles. The recommended entry point is an asset already scheduled for replacement, or a bounded pilot, not a plant-wide rip-and-replace.

What does this mean for validation and data integrity?

OPA does not remove the need to validate; it changes where the effort goes. Because interfaces are standard and documented and configuration is held in a portable form, the system is easier to describe, test, and re-qualify than a closed, bespoke integration, and that documentation supports 21 CFR Part 11 data integrity. On security, O-PAS

mandates ISA/IEC 62443 conformance with third-party verification through ISASecure. The validation strategy still has to be agreed with your quality organization up front; the architecture is designed to make that strategy easier to execute, not to bypass it.

We are a smaller or specialty manufacturer. Is this only for large sites?

No. Because control is distributed across small, comparatively low-cost conforming nodes, the architecture scales from a single batch skid or packaging line up to a multi-site network, and does not depend on the scale of a large manufacturer. For any manufacturer, and especially for a contract manufacturer or a company transferring processes between sites, standardizing interfaces is one of the strongest sources of value.

What is the catch? Where is OPA genuinely weaker today?

Two honest weaknesses, and in pharma a third. First, near-term integration cost currently offsets much of the hardware saving, so early-project savings are modest even though lifecycle savings are large. Second, there is no at-scale pharmaceutical deployment yet, so you would be an early adopter with no directly comparable GMP reference. Third, validation and regulatory acceptance of an open, multi-vendor control system in a GMP environment have to be established deliberately with your quality organization. All three are manageable, and they are the reason for a measured, pilot-first rollout.

Appendix B. Glossary of Terms and Acronyms

Brief, working definitions of the terms used in this paper. They are intended for orientation, not as formal standard definitions.

Term	Definition
ACP	Advanced Computing Platform. Standard computing hardware in an OPA system on which applications (control, analytics, historian) run, rather than being locked inside a proprietary controller.
APC	Advanced Process Control. Model-based control (often MPC) layered on the base control system to optimize yield and quality; used in continuous pharmaceutical processes and continuous manufacturing.
DCS / PCS	Distributed (or Process) Control System. An integrated, single-vendor platform that controls a process as a coordinated whole; the backbone of pharmaceutical unit control.
DCN	Distributed Control Node. The standard building block of control in an OPA system: a compact, low-cost compute element that performs control, connects to I/O, and speaks the standard interfaces.
ISA-88 (S88)	The international standard for batch control, defining recipes, procedures, and equipment models; the backbone of batch and specialty production, including pharmaceutical batch manufacturing.
MTP (Module Type Package)	A vendor-neutral standard (VDI/VDE/NAMUR 2658, progressing toward IEC 63280) for integrating modular process equipment. A module, or Process Equipment Assembly (PEA), ships an MTP description of its automation that a Process Orchestration Layer (POL) consumes plug-and-produce; built on OPC UA and complementary to O-PAS.
PEA (Process Equipment Assembly)	A modular process unit or skid, often an OEM unit operation with its automation built in, described by an MTP so it can be integrated into the orchestration layer without bespoke engineering.
POL (Process Orchestration Layer)	The plant-level layer that directs modular units and consumes their MTP descriptions plug-and-produce. In practice it is the plant's supervisory system, commonly Emerson DeltaV or Inductive Automation Ignition.
Supervisory system	The plant-level control and operator layer that directs OEM unit operations, holds recipes, and presents a common operator environment; in modern pharma most often Emerson DeltaV or Inductive Automation Ignition.
HMI	Human-Machine Interface. The operator's screens and controls.
I/O	Input/Output. The signals and modules that connect a controller to field sensors and actuators.
IEC 61131 / 61499	International standards for control programming. O-PAS supports both; 61499 targets distributed, event-driven control.
ISA/IEC 62443	The international series of standards for the cybersecurity of industrial automation and control systems. Conformance is mandated by O-PAS.
ISASecure	The third-party certification scheme for ISA/IEC 62443; named by OPAF as the exclusive verifier of O-PAS cybersecurity requirements.
MPC	Model Predictive Control. An advanced control technique that optimizes a process against a model; used for energy and efficiency gains.
O-PAS	The Open Process Automation Standard, published by The Open Group. The technical definition of an open, interoperable, secure process control architecture.
OCF	O-PAS Connectivity Framework. The standardized, OPC UA-based connectivity backbone through which all conforming components communicate.

Term	Definition
OPA	Open Process Automation. The overall approach of building control systems from interoperable, standards-based components.
OPAF / The Open Group	The Open Process Automation Forum, part of The Open Group, the vendor-neutral body that develops and maintains the O-PAS Standard.
OPC UA	OPC Unified Architecture. The widely adopted industrial interoperability standard on which the OCF is built.
OT	Operational Technology. The hardware and software that monitors and controls physical processes, as distinct from enterprise IT.
PLC	Programmable Logic Controller. A rugged, widely used industrial controller; in pharma, common on packaging, serialization, and skid systems.
cGMP	Current Good Manufacturing Practice (US FDA, 21 CFR Parts 210 and 211). The regulatory foundation for pharmaceutical manufacturing quality.
GAMP 5	ISPE's good-practice guide for computer system validation; the de facto framework for validating automation in GMP environments, now aligning with risk-based Computer Software Assurance.
SCADA	Supervisory Control and Data Acquisition. The software layer providing operator screens, alarming, historian, and telemetry across a distributed system.
21 CFR Part 11	US FDA rule governing electronic records and electronic signatures; central to pharmaceutical data integrity, requiring audit trails and access control.
TCO	Total Cost of Ownership. The full lifecycle cost of a system, including capital, maintenance, migrations, and downtime, not just installed price.
Validation (CSV / CSA)	Documented evidence that a computerized system does what it should. FDA's Computer Software Assurance guidance introduces a more risk-based approach than traditional computer system validation.

Appendix C. Procurement Specification Language

An open architecture stays open only if procurement keeps it open. The clauses below are drafting starting points an operator can adapt into a specification, request for proposal, or contract to ensure that an 'open' procurement is genuinely open, portable, secure, and free of hidden lock-in. They are written to be edited: bracketed items are placeholders, and the Owner should tailor them, with procurement and legal counsel, to the project and jurisdiction.

> **Not legal advice**
> These are illustrative drafting aids, not legal or contractual language for use as-is. Have qualified procurement and legal professionals adapt and review them, and confirm the current O-PAS version and conformance program with The Open Group before citing specific requirements.

1. **Standards conformance.** The control system shall conform to the current published version of the O-PAS Standard. The Supplier shall state the O-PAS version and parts to which each component conforms and shall provide evidence of conformance through The Open Group's conformance program where such certification is available.
2. **Interoperability.** All controllers, distributed control nodes, input/output, applications, and supervisory components shall interoperate through the O-PAS Connectivity Framework using OPC UA. No proprietary protocol shall be required for interoperation among components of the system.
3. **Configuration portability.** System configuration shall be delivered in the standard, portable form defined by the O-PAS information and exchange models, such that the Owner can read, modify, and migrate the configuration without dependence on any single Supplier's proprietary engineering tool.
4. **Application portability.** Control applications shall be portable to any conforming platform. The Supplier shall deliver application definitions in the standard form and shall place no technical or contractual encumbrance on their migration to another conforming Supplier's platform.
5. **Cybersecurity and data integrity.** Components shall conform to the applicable ISA/IEC 62443 requirements and, where available, shall carry ISASecure certification. The Supplier shall provide certification evidence and shall support the Owner's computer system validation, 21 CFR Part 11 data-integrity, and GMP documentation obligations, including access control and tamper-evident audit trails.
6. **Multi-vendor sourcing.** The architecture shall allow the Owner to procure conforming replacement or additional components from any qualified Supplier over the system's life, without re-engineering the surrounding system, and the Supplier shall not condition warranty or support on sole-source procurement.
7. **Documentation and ownership.** The Owner shall own, and shall receive complete documentation for, all configuration and application artifacts. Interfaces shall be documented to the standard so that the Owner is not dependent on the Supplier for routine configuration changes.
8. **Obsolescence and lifecycle.** The Supplier shall support component-level replacement across a [25]-year design life and shall not condition continued operation, patching, or expansion on migration to a proprietary successor platform.
9. **Conformance evidence and acceptance.** Acceptance shall be contingent on demonstrated conformance to the standards, security, and portability requirements above, verified during factory and site acceptance testing, and shall not rest on Supplier assertion alone.

About Collaborative Systems Integration

Collaborative Systems Integration (CSI) is a vendor-neutral systems integrator focused on Open Process Automation and the migration of legacy DCS and PLC control systems to open, standards-based architectures. CSI's leadership includes practitioners who helped shape the Open Process Automation movement and who have delivered large control-system programs in industries where downtime is measured in millions of dollars. CSI's role is to help end users evaluate, specify, and implement open architectures on their own terms, capturing the interoperability, portability, cybersecurity, and lifecycle-cost advantages of the O-PAS Standard while managing the practical risks of early adoption.

CSI also publishes on the subject. Trevor Cusworth, CSI's VP of Sales and Marketing, is the author of *Open Process Automation: Architecture, Execution & Transformation*, a practitioner's treatment of open control architecture, and CSI produces the flagship *State of Open Process Automation* report, whose 2026 edition assesses the standard, suppliers, integrators, economics, and project-execution practices in a single 40-page industry review.

To learn more or to discuss an obsolescence or migration decision, contact Collaborative Systems Integration. Related resources: the OPA lifecycle-cost (ROI) calculator (csi-automation.com/opa-roi-calculator), CSI Academy training (csi-automation.com/academy), the OPA Community (OPAcommunity.com), and CSI's OPA materials at csi-automation.com.

References and Further Reading

The sources below informed the factual claims in this paper. Figures attributed to a specific organization in the text should be verified against the primary source before use in a formal business case. Standard versions and certification programs continue to evolve; confirm current status with The Open Group.

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