

REGDATALAB · SOFTWARE RESEARCH

RegDataLab Software Research Guide

2026-10-04 edition

A public-source market guide to MES, QMS, and LIMS for pharmaceutical and biotech manufacturers, CDMOs, and GMP QC labs.

33 products (MES 9, QMS 10, LIMS 8, adjacent 6). 1,182 sourced claims. Dataset as of 2026-10-04.

NEUTRALITY STATEMENT

Public-source research, not a ranking and not a recommendation to buy, reject, or shortlist. Important claims carry their source. Where a vendor publishes no list price, the guide says quote-only and invents no price. Welf Ludwig, who runs RegDataLab, works at MasterControl; the two MasterControl profiles (Manufacturing Excellence and Quality Excellence) say so and, like every other profile, draw on public pages only, with no internal MasterControl sales material.

Online edition with full profiles, evidence sets, and sources notes: <https://www.regdatalab.com/software>

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How this was researched

Sources and inclusion rules

The research covers MES, QMS, and LIMS products that a pharmaceutical or biotech manufacturer, CDMO, or GMP QC lab would shortlist, plus six adjacent products filed separately so they are not mistaken for core systems: an electronic lab notebook, a frontline operations platform, two serialization products, a scientific data management system, and a biopharma R&D informatics platform. MasterControl Manufacturing Excellence and Quality Excellence are in scope on the same basis. Every product has a profile with a source on each important claim, an evidence set with one claim per row (source URL, source type, passage, confidence, caveats), and a sources note listing each source and what it supports. Every dossier passes an independent review before publication; a dossier that has not passed stays out.

Source types are vendor statement, customer account, regulator record, procurement, press, and our analysis. A vendor sentence stays a vendor sentence, and procurement amounts are buyer records, not list prices. Logos, sponsor lines, and analyst quadrants that were not read do not count as proof of deployment or capability. A missing document is a research gap, not a product defect. Quote-only is a reported result: where a vendor publishes no list price, the dossier says quote-only and gives no seat price, site price, or typical deal size. A public floor price appears only when the vendor page, or a marketplace page the profile cites, states the number, and the profile's caveat stays with it. Regulator and procurement searches carry their date. A register that could not be queried is reported as such, never as a zero.

COMPARISON

Comparison table by category

The map places every profiled product in its category and sets out vendor, deployment, pricing stance, and regulatory posture side by side. Each cell restates its dossier. Pricing is the profile's stance, not a new quote. Regulatory entries are vendor claims, not FDA or EMA certificates.

Welf Ludwig, who runs RegDataLab, works at MasterControl; the two MasterControl profiles (Manufacturing Excellence and Quality Excellence) say so and, like every other profile, draw on public pages only, with no internal MasterControl sales material.

Manufacturing execution systems (MES) • 9

PRODUCT	VENDOR	CATEGORY	DEPLOYMENT NOTE	PRICING STANCE	REGULATORY POSTURE
DeltaV MES	Emerson	MES	2025 core MES data sheets describe a server install, not SaaS. New features from v7 are on subscription. Perpetual is not described as cancelled.	Quote-only. No public dollar list price.	Life-sciences FAQ: GAMP 5-aligned documentation in support of 21 CFR Part 11. Profile: not a certification. Syncade is lineage, not a second MES.
Opcenter Execution Pharma	Siemens	MES	Not a single deployment model in the dossier. Cloud appears as a project architecture, a partner migration offer, and a stated goal for a future eBR Apps Suite.	Quote-only. Contact for sales and pricing. Discrete marketplace dollars are a different product.	ERES booklet for V2405: Siemens says it evaluated that version against 21 CFR Part 11 (1997) and EU GMP Annex 11 (2011). Vendor evaluation, not a certificate.
FactoryTalk PharmaSuite	Rockwell Automation	MES	Release 12.00: cloud, on-premises, or hybrid; Kubernetes and Linux containers.	Quote-only. Catalog pages had no dollar amount.	12.00 press: cybersecurity to support compliance and data integrity in regulated life sciences. A Part 11 / Annex 11 assessment package is a buyer question in the profile, not a documented certificate.
SAP Digital Manufacturing	SAP	MES	Cloud on SAP Business Technology Platform. Retrieved product-page text does not state private cloud, on-premise, or a customer-managed option.	Quote-only. US pricing page body had the heading and no amount.	Part 11, Annex 11, and GAMP were not on the pages opened. Regulated-environment help PDFs were not retrieved (a gap, not a finding that the controls are absent). Cross-industry cloud MOM, not a pharma-only suite.
POMSnet Aquila	POMS Corporation	MES	On-premises and SaaS / private cloud.	Quote-only. "Transparent, simple pricing" with no currency amount.	Product page names a quality module that automates 21 CFR Part 11 electronic signatures and records. Vendor claim. Not Honeywell POMS.
Tempo	Apprentice	MES	Cloud-native. An on-prem Tempo option was not documented.	Quote-only. Pricing URL redirected home. \$5,000 is a pilot liability cap, not a license fee.	Vendor sentence: full IQ/OQ for cGXP and 21 CFR Part 11. Not an FDA certification. Not documented as plant-wide.
Performix	Honeywell	MES	2026 product page does not state on-premise, private cloud, or SaaS.	Quote-only.	Part 11, Annex 11, and GAMP were not documented on the pages opened.

Manufacturing execution systems (MES) (continued)

PRODUCT	VENDOR	CATEGORY	DEPLOYMENT NOTE	PRICING STANCE	REGULATORY POSTURE
Manufacturing Excellence (Mx)	MasterControl	MES	Cloud / SaaS on the pages opened. Not a three-model matrix.	Quote-only. Named-user metric, no published price. Employment disclosed.	A vendor resource page says Mx is a platform for manufacturers facing EU GMP Annex 11 and UK MHRA guidelines. Not an FDA certificate. Not the eQMS product.
Aizon Execute	Aizon	MES	LLM-directed pages: not on-premise; single-tenant AWS.	No list price on aizon.ai. AWS Marketplace: \$50,000 per site per 12 months, with the profile's caveats.	Vendor GMP, ALCOA+, and Part 11 support claims. Not an FDA certification. Not documented as plant-wide.

Electronic quality management systems (QMS) · 10

PRODUCT	VENDOR	CATEGORY	DEPLOYMENT NOTE	PRICING STANCE	REGULATORY POSTURE
Vault Quality	Veeva Systems	QMS	Multi-tenant cloud SaaS on Veeva Vault. No on-prem SKU documented for QMS or QualityDocs.	Quote-only.	Cloud suite for GxP quality processes. Vendor positioning, not an FDA certificate.
Reliance	Octave (formerly ETQ)	QMS	Cloud-native SaaS on AWS, per the Reliance FAQ.	Quote-only. Subscription by users, modules, or sites, with no price table.	Enterprise eQMS. ETQ name kept as history. Not recorded here as an FDA certificate.
Qualio	Qualio	QMS	Online hosted platform. Browser and internet required.	Quote-only. Named plans without a currency amount.	Not an FDA-cleared product on the records found. Vendor help article: a Part 11 assessment is in the validation pack, and 21 CFR 11.100(c) remains the customer's certification duty.
TrackWise Digital	Honeywell	QMS	SaaS on Salesforce. Classic TrackWise is the separate on-prem name.	Quote-only.	Buyer press describes GMP and GCP reporting. Vendor product, not an FDA certificate.
Quality Excellence (Qx)	MasterControl	QMS	Cloud / SaaS. Named-user licenses.	Quote-only. Employment disclosed.	Vendor pages claim help with 21 CFR Part 11, EU Annex 11, ISO, and GAMP-oriented validation. Profile: not a regulator certification.
Greenlight Guru QMS	Greenlight Guru	QMS	Cloud, browser. FAQ says the customer cannot install it on their own server.	Public floor: eQMS packages start at \$12,000 per year. Not a per-user price and not a full list. EDC starts at \$9,000 per year and is a separate subscription.	Med-device eQMS. Pricing page: aligned to ISO 13485, FDA QMSR, ISO 14971, and IEC 62304. Part 11 workflow is a vendor claim. Not a pharma MES.
Dot Compliance eQMS	Dot Compliance	QMS	Cloud, native on Salesforce. On-prem not documented.	Quote-only. TED 814489-2025 ceiling of 4,800,000.00 DKK is an estimate, not a list price.	Vendor: technical controls that support 21 CFR Part 11 and EU Annex 11. Not a certification.

Electronic quality management systems (QMS) (continued)

PRODUCT	VENDOR	CATEGORY	DEPLOYMENT NOTE	PRICING STANCE	REGULATORY POSTURE
ComplianceQuest QMS	ComplianceQuest	QMS	100% SaaS on Salesforce.	Quote-only on the vendor site. AppExchange lowest plan USD 30 per user per month is not the vendor list price.	Vendor Part 11 page (forced authentication, audit trail). Not an FDA certificate.
SmartSolve eQMS	IQVIA	QMS	Microsoft Azure on current pages.	Quote-only.	Vendor Part 11 / Annex 11 / ISO wording. Profile: not an FDA product clearance.
Ennov QMS	Ennov	QMS	100% web-based. Cloud and on-premises are both named; the commercial difference is not documented.	Quote-only.	Electronic signatures claimed under 21 CFR. Vendor claim.

Laboratory information management systems (LIMS) • 8

PRODUCT	VENDOR	CATEGORY	DEPLOYMENT NOTE	PRICING STANCE	REGULATORY POSTURE
LabWare LIMS	LabWare	LIMS	Four deployment options named. The blurbs that rendered were cloud-hosted by LabWare. SaaS described as monthly; hosted and "your cloud" as annual.	Quote-only for a current unit price. 2009 version 6.0 at \$4,750 per concurrent user is historical.	LIMS page: pharma and biopharma labs use it for traceability against ISO 17025, FDA 21 CFR Part 11, EU Annex 11, and CLIA. Vendor claim that those controls are built into how the system operates.
STARLIMS	STARLIMS	LIMS	On-premises, cloud hosting, and cloud subscription. Cloud uses AWS private cloud managed by STARLIMS.	Quote-only.	LIMS for pharmaceutical, biotech, and QC labs. Part 11 language that was opened is attached to SDMS, not to a LIMS certificate. Abbott Informatics is the historical name.
LabVantage LIMS	LabVantage	LIMS	On-premises and SaaS. SaaS infrastructure described as managed by LabVantage and Amazon Web Services.	Quote-only.	Pharma page: pre-validation in compliance with GAMP 5, and compliance wording for 21 CFR Part 11 and EU Annex 11. Vendor statement only. Not an MES or QMS.
SampleManager LIMS	Thermo Fisher Scientific	LIMS	Cloud managed by Thermo Fisher on AWS, with an annual hosting fee calculated from the number of licenses and no rate printed. Other options are in the implementation page.	Quote-only. Catalog INF-11000: "Price (USD) - Request A Quote."	FAQ: designed to support ALCOA++ and configurable for GMP, ISO 17025, and 21 CFR Part 11. Vendor claim. LES, SDMS, and ELN functions stay labeled as such.
Matrix Gemini LIMS	Autoscribe Informatics	LIMS	Local server, remote site, or cloud. Instem FAQ also says on-premises, cloud, or hybrid.	Quote-only.	Blog describes electronic signatures built into the LIMS, including 21 CFR Part 11 behavior. Annex 11 was not documented in the inspected sources.
SLIMS	Agilent	LIMS	On premise, cloud hosted by Agilent, or cloud hosted by the customer.	Quote-only.	Vendor: technical controls for labs that must follow 21 CFR Part 11, EU Annex 11, and GAMP 5. Not a certificate. Same product is also described as ELN and LES.

Laboratory information management systems (LIMS) (continued)

PRODUCT	VENDOR	CATEGORY	DEPLOYMENT NOTE	PRICING STANCE	REGULATORY POSTURE
Sapio GMP LIMS	Sapio Sciences	LIMS	General Sapio LIMS page lists cloud or on-premise. Not stated as a GMP-only architecture.	Quote-only. "Annual Value" ranges on a QC page are not license prices.	GMP-oriented LIMS for QC, environmental monitoring, stability, and a 2024 EBR add-on. Platform, ELN, Jarvis, and ELaiN are not this row.
BIOVIA ONE Lab LIMS	Dassault Systèmes	LIMS	Parent page: cloud and on-premise, same code stream. LIMS Essentials is a cloud package.	Quote-only. £576 per user per year on G-Cloud 14 is a different service title and is not this LIMS price.	Parent page: built for FDA 21 CFR Part 11, Annex 11, and EPA, with audit trails and electronic signatures. Vendor claim about the suite.

Adjacent products • 6

Outside the MES, QMS, and LIMS shortlists. Listed so the names are filed correctly.

PRODUCT	VENDOR	CATEGORY	DEPLOYMENT NOTE	PRICING STANCE	REGULATORY POSTURE
Benchling Notebook	Benchling	Adjacent ELN	Cloud. An on-prem Notebook SKU was not documented.	No public commercial list price. Academic plan is free for a defined subset and is not the enterprise price.	Vendor Part 11 claim on the Notebook page. Not a certification. Not a QC LIMS.
Tulip	Tulip	Adjacent frontline operations	Cloud, with a support article offering AWS GovCloud and an on-prem connector host on higher tiers.	Essentials \$100 and Professional \$250 per interface per month, billed annually, 10 interface minimum. Enterprise and Regulated Industries: no dollar amount.	Part 11 e-signatures are not on the \$100 Essentials line. They are on Regulated Industries and as an Enterprise add-on. Not treated as a plant-wide GMP MES.
TraceLink serialization	TraceLink	Adjacent SNM / SOM	Cloud versus on-premises not documented beyond marketing ("centralized" platform / hub).	Quote-only.	Serialization and track-and-trace. Not an MES, LIMS, or QMS. No validation-pack day count was published on the pages opened.
NuGenesis SDMS	Waters	Adjacent SDMS	Marketing page does not say cloud or SaaS. Releases overview reads as on-prem technology. A full deployment matrix is not in the pricing section.	Quote-only for SDMS. Opened SAM notices had no SDMS unit price.	SDMS for instrument and document data. Not a LIMS. NuGenesis LMS is a different name.
IDBS Polar	IDBS (Danaher)	Adjacent R&D informatics	Cloud-based, per the GxP article. On-premise Polar was not documented.	Quote-only. No Polar license price. The 2016 CPI notice is E-WorkBook support, framework GBP 250,000–800,000, not paid and not Polar.	GxP or non-GxP configuration is a customer choice on the product page. Part 11 wording is a feature claim. Not a separate GMP LIMS or plant MES.
PAS-X Track & Trace	Körber	Adjacent serialization	V3: on-premise, customer cloud, or Körber-managed SaaS.	Quote-only.	Packaging page names GS1 and 21 CFR Part 11 coding requirements. Not PAS-X MES.

Comparison date: dossiers as of 2026-10-04.

Emerson DeltaV MES

VENDOR	Emerson
CATEGORY	MES
PRICING STANCE	Quote-only. (Pricing class: quote-only.)
INDEPENDENT REVIEW	Passed 2026-10-03
ONLINE PROFILE	https://www.regdatalab.com/software/emerson-deltav-mes

Profile summary

The product page places DeltaV MES in the Life Sciences Software Suite on the DeltaV Automation Platform. It names Workspaces, Quality Review Manager, a dual workflow engine (legacy WF and WFX in one instance), material management, equipment management, and integration with process control, ERP, LIMS, and CMMS. (DeltaV MES, vendor page, retrieved 2026-10-03.)

Top claims with sources (5 of 46)

Each claim is followed by its caveat (if the evidence row has one), then topic · source type · confidence · dates · source title, then the source URL. The online profile has the full evidence set.

- Emerson's current DeltaV MES page positions the product as a life-sciences manufacturing execution system for equipment management and faster batch-record generation.

Caveat: Vendor product page. No publication date on the page.

identity · vendor statement · high confidence · retrieved 3 Oct 2026 · DeltaV Manufacturing Execution System
<https://www.emerson.com/en/automation-systems/operations-business-management/deltav-mes>
- The life-sciences platform describes DeltaV MES as workflow management, electronic batch records, and quality review, distinct from DeltaV DCS batch execution, RTS scheduling, and PKM.

Caveat: Vendor FAQ. Portfolio marketing, not a specification.

identity · vendor statement · high confidence · retrieved 3 Oct 2026 · DeltaV | Life Sciences Automation Platform
<https://www.emerson.com/en/automation-systems/automation-systems-for-life-sciences>
- The subscription sheet tells buyers to contact a local Emerson representative for an enterprise subscription and does not print a price.

Caveat: Quote-only. Not a list price.

pricing · vendor statement · high confidence · published 2025-02 · retrieved 3 Oct 2026 · DeltaV MES Subscription service data sheet
<https://www.emerson.com/is/content/emerson/en/systems-and-software/deltav-manufacturing-execution-system-mes/product-data-sheets/documents/deltav-mes-subscription.pdf>
- No public dollar list price and no procurement award amount for DeltaV MES or Syncade were found; one contract was not available to scale, and a search miss is not proof of no buyers.

Caveat: Quote-only conclusion. The vendor's 'up to 40%' claim is not a price.

pricing · our analysis · high confidence · retrieved 3 Oct 2026 · Pricing conclusion across vendor sheet and procurement searches
<https://www.emerson.com/is/content/emerson/en/systems-and-software/deltav-manufacturing-execution-system-mes/product-data-sheets/documents/deltav-mes-subscription.pdf>
- The life-sciences platform says documentation is GAMP 5-aligned and that capabilities are developed in support of 21 CFR Part 11 and EU Annex 11, including ALCOA+.

Caveat: Vendor support claim. Not an FDA or EMA certification of the product.

regulatory · vendor statement · high confidence · retrieved 3 Oct 2026 · DeltaV | Life Sciences Automation Platform
<https://www.emerson.com/en/automation-systems/automation-systems-for-life-sciences>

Siemens Opcenter Execution Pharma

VENDOR	Siemens
CATEGORY	MES
PRICING STANCE	Quote-only. (Pricing class: quote-only.)
INDEPENDENT REVIEW	Passed 2026-10-02
ONLINE PROFILE	https://www.regdatalab.com/software/siemens-opcenter-pharma

Profile summary

Opcenter Execution Pharma is Siemens's MES for paperless pharmaceutical production and electronic batch records. The product page describes master-batch-record-driven manufacturing, resource guidance, control of human and automated steps, a single store of batch documents, and review by exception. (Siemens product page, retrieved 2026-10-02.)

Top claims with sources (5 of 30)

Each claim is followed by its caveat (if the evidence row has one), then topic · source type · confidence · dates · source title, then the source URL. The online profile has the full evidence set.

- 1.** Opcenter Execution Pharma is a manufacturing execution system offering paperless manufacturing and electronic batch recording of pharmaceuticals.

Caveat: Vendor positioning.

identity · vendor statement · high confidence · retrieved 2 Oct 2026 · Opcenter Execution Pharma product page
<https://www.siemens.com/en-us/products/opcenter/execution/pharma/>
- 2.** The Execution family page lists Discrete, Process, Electronics, Medical Device and Diagnostics, Pharma, and Semiconductor as separate Opcenter Execution MES products.

Caveat: Sibling products are out of scope for this dossier except as boundaries.

identity · vendor statement · high confidence · retrieved 2 Oct 2026 · Opcenter Execution family page
<https://www.siemens.com/en-us/products/opcenter/execution/>
- 3.** AWS Marketplace publishes a starting price of 88,000 US dollars for 12 months for 20 users of Opcenter Execution Discrete. That listing is not Opcenter Execution Pharma.

Caveat: Sibling product. Do not use as a Pharma price. Page was seen via search snippet of the public listing, not a signed-in quote.

pricing · vendor statement · high confidence · retrieved 2 Oct 2026 · AWS Marketplace: Opcenter Execution Discrete
<https://aws.amazon.com/marketplace/pp/prodview-x6ma4vhfksbds>
- 4.** TED, SAM.gov exact search, Contracts Finder, and Find a Tender returned no notice for Opcenter Execution Pharma or for SIMATIC IT eBR. None of those results names a buyer or a price.

Caveat: Keyword and exact-phrasе searches. A buyer could have described the purchase without the product name.

pricing · procurement · high confidence · retrieved 2 Oct 2026 · TED, SAM.gov, Contracts Finder, and Find a Tender searches
<https://api.ted.europa.eu/v3/notices/search>
- 5.** The product page says batch manufacturing is fully compliant with FDA and GMP regulations, and it tells the reader to contact Siemens for sales and pricing.

Caveat: Vendor compliance claim, not an agency certificate. No price figure on the page.

regulatory · vendor statement · high confidence · retrieved 2 Oct 2026 · Opcenter Execution Pharma product page
<https://www.siemens.com/en-us/products/opcenter/execution/pharma/>

Rockwell FactoryTalk PharmaSuite

VENDOR	Rockwell Automation
CATEGORY	MES
PRICING STANCE	Quote-only. (Pricing class: quote-only.)
INDEPENDENT REVIEW	Passed 2026-10-02
ONLINE PROFILE	https://www.regdatalab.com/software/rockwell-pharmasuite

Profile summary

The life-sciences product page calls PharmaSuite the leading MES purpose-built for pharmaceutical and biopharmaceutical manufacturing, integrating from enterprise systems to the shop floor. (Life sciences MES page, retrieved 2026-10-02.) The overview page adds role-based optimization, an intelligent upgrade engine, value-based applications for batch and discrete processing, and help adhering to regulatory compliance guidelines. That compliance line is a vendor claim, not a certification, GAMP category, or agency finding. (PharmaSuite overview.)

Top claims with sources (5 of 28)

Each claim is followed by its caveat (if the evidence row has one), then topic · source type · confidence · dates · source title, then the source URL. The online profile has the full evidence set.

- 1.** The live life-sciences page presents FactoryTalk PharmaSuite as Rockwell's MES purpose-built for pharmaceutical and biopharmaceutical manufacturing, and it links the 12.00 press release.

Caveat: 'Leading' is vendor wording.

identity · vendor statement · high confidence · retrieved 2 Oct 2026 · MES Solutions for Life Sciences | FactoryTalk PharmaSuite
<https://www.rockwellautomation.com/en-us/products/software/factorytalk/operationsuite/mes/life-sciences.html>
- 2.** Rockwell announced FactoryTalk PharmaSuite 12.00 on 13 May 2025 as the latest release of its MES for regulated pharmaceutical and biopharmaceutical manufacturing.

Caveat: Vendor press release. Also carried on PR Newswire; the Rockwell page was the one read in full.

identity · press · high confidence · published 2025-05-13 · retrieved 2 Oct 2026 · Rockwell Automation Launches PharmaSuite 12.00
<https://www.rockwellautomation.com/en-us/company/news/press-releases/FactoryTalk-PharmaSuite-12-00.html>
- 3.** No public list price for FactoryTalk PharmaSuite was found in the pages opened on 2026-10-02.

Caveat: Does not prove Rockwell never quotes a price in a private proposal or behind the agreement selector.

pricing · our analysis · high confidence · retrieved 2 Oct 2026 · Local pricing conclusion
<https://commerce.rockwellautomation.com/rockwell/en/USD/p/9519-FTPSSB/bundleBrand>
- 4.** USAspending public award search returned zero awards whose keyword was PharmaSuite or FactoryTalk PharmaSuite, for contracts and for IDVs.

Caveat: Keyword search of award records back to the API's 2007-10-01 floor. A description that never uses the product name would not appear.

pricing · procurement · high confidence · retrieved 2 Oct 2026 · USAspending spending_by_award keyword search
https://api.usaspending.gov/api/v2/search/spending_by_award/
- 5.** PharmaSuite 12.00 is described as deployable in the cloud, on-premises, or hybrid, running in Kubernetes using Linux containers, with a setup tool named MICKA, containerized components, centralized monitoring, and a new upgrade engine.

Caveat: Vendor feature list. No cloud vendor, GAMP category, or validation protocol named.

architecture · press · high confidence · published 2025-05-13 · retrieved 2 Oct 2026 · Rockwell Automation Launches PharmaSuite 12.00
<https://www.rockwellautomation.com/en-us/company/news/press-releases/FactoryTalk-PharmaSuite-12-00.html>

SAP Digital Manufacturing

VENDOR	SAP
CATEGORY	MES (cross-industry cloud MOM, not pharma-only)
PRICING STANCE	Quote-only. (Pricing class: quote-only.)
INDEPENDENT REVIEW	Passed 2026-10-02
ONLINE PROFILE	https://www.regdatalab.com/software/sap-digital-manufacturing

Profile summary

SAP's product page calls SAP Digital Manufacturing a manufacturing operations management (MOM) platform for agile operations. It connects the shop floor with the top floor, deploys on SAP Business Technology Platform, and coordinates execution with planning and logistics. There is no life-sciences edition. (SAP Digital Manufacturing product page, retrieved 2026-10-02.)

Top claims with sources (6 of 23)

Each claim is followed by its caveat (if the evidence row has one), then topic · source type · confidence · dates · source title, then the source URL. The online profile has the full evidence set.

- SAP's product page calls SAP Digital Manufacturing a manufacturing operations management (MOM) platform, not a pharma-only suite.

Caveat: Vendor positioning.

identity · vendor statement · high confidence · retrieved 2 Oct 2026 · SAP Digital Manufacturing product page
<https://www.sap.com/products/scm/digital-manufacturing.html>
- Gambit says SAP renamed Digital Manufacturing Cloud to Digital Manufacturing in 2023, and that it is SaaS on BTP.

Caveat: Integrator wiki, not an SAP press release. No publication date on the page.

identity · press · medium confidence · retrieved 2 Oct 2026 · Gambit wiki, What is SAP DM?
<https://www.gambit-group.com/ch/en/wiki/sap-dm/>
- The live U.S. and Australia pricing pages for SAP Digital Manufacturing show a Request a quote link and no amount or pricing metric.

pricing · vendor statement · high confidence · retrieved 5 Oct 2026 · SAP Digital Manufacturing pricing (Australia)
<https://www.sap.com/australia/products/scm/digital-manufacturing/pricing.html>
- USAspending spending_by_award for keyword SAP Digital Manufacturing, contract types A-D, 2018-10-01 through 2026-10-02, returned no awards.

Caveat: Keyword search miss is not proof no agency bought SAP software under another description.

pricing · procurement · medium confidence · retrieved 2 Oct 2026 · USAspending spending_by_award
https://api.usaspending.gov/api/v2/search/spending_by_award/
- FDA site searches for the product name did not return a page about SAP Digital Manufacturing.

Caveat: Search miss is not proof the string never appears in an FDA PDF that was not indexed. No clearance record was found.

regulatory · regulator record · medium confidence · retrieved 2 Oct 2026 · FDA digital stockpile page (example of a non-matching hit)
<https://www.fda.gov/emergency-preparedness-and-response/innovative-technologies/digital-stockpile-and-manufacturing-response-network>
- An EMA site search for SAP Digital Manufacturing did not return a page about the product.

Caveat: Search miss is not a full-archive review.

regulatory · regulator record · medium confidence · retrieved 2 Oct 2026 · EMA digitalisation event (example of a non-matching hit)
<https://www.ema.europa.eu/en/events/digitalisation-artificial-intelligence-pharmaceutical-manufacturing-quality-innovation-group-qig-follow-roundtable-meeting>

POMSnet Aquila

VENDOR	POMS Corporation
CATEGORY	MES
PRICING STANCE	Quote-only. (Pricing class: quote-only.)
INDEPENDENT REVIEW	Passed 2026-10-02
ONLINE PROFILE	https://www.regdatalab.com/software/pomsnet-aquila

Profile summary

The product page describes a web MES on Microsoft .NET and HTML5 covering recipe and specification management, materials, equipment, production orders, recipe execution, eBR, and device history, deployed on premises or as SaaS in a single install. (POMSnet Aquila product page, retrieved 2026-10-02.)

Top claims with sources (5 of 29)

Each claim is followed by its caveat (if the evidence row has one), then topic · source type · confidence · dates · source title, then the source URL. The online profile has the full evidence set.

- 1.** POMSnet Aquila is a web-based life-sciences MES on Microsoft .NET and HTML5, covering recipes, materials, equipment, orders, execution, electronic batch records, and device history.

Caveat: Vendor product page.

identity · vendor statement · high confidence · retrieved 2 Oct 2026 · POMSnet Aquila Manufacturing Execution System
<https://www.poms.com/pomsnet/>
- 2.** POMSnet Falcon is a separate POMS page for an electronic batch record dashboard and GMP data warehouse, with its own percentage claims, and is not the Aquila MES.

Caveat: Marketing percentages on this page are not Aquila results. License overlap with Aquila is not stated.

identity · vendor statement · high confidence · retrieved 2 Oct 2026 · POMSnet Falcon
<https://www.poms.com/pomsnet-falcon/>
- 3.** EU TED exact full-text searches on 2026-10-02 for POMSnet and POMSnet Aquila each returned totalNoticeCount 0. Related-name similarity queries for POMS Corporation, Honeywell POMS, and POMS net also returned 0. No notice in those queries names the product, a buyer, or a price.

Caveat: The tilde operator is similarity, not a contains match, so the 1431 count is not a product hit. A zero on TED is not proof no public buyer exists outside this index.

pricing · procurement · high confidence · retrieved 2 Oct 2026 · TED notice search API, scope ALL
<https://api.ted.europa.eu/v3/notices/search>
- 4.** UK Contracts Finder portal searches on 2026-10-02 for POMSnet, POMSnet Aquila, POMS Corporation, POMS net, and Honeywell POMS each returned the results page text We've found 0 notices. No notice names the product, a buyer, or a price.

Caveat: A zero on this index is not proof no public buyer exists outside it.

pricing · procurement · high confidence · retrieved 2 Oct 2026 · Contracts Finder search form, awarded included
<https://www.contractsfinder.service.gov.uk/Search/Results>
- 5.** SaaS is offered with partner Validated Cloud, on a monthly to annual subscription, and the page lists Part 11, Annex 11, HIPAA, GAMP5, MHRA, ISO 13485, ISO 9001:2015, and ISO 27001:2013 as host requirements met.

Caveat: Vendor statement about a partner. No certificate numbers. Not a price.

architecture · vendor statement · medium confidence · retrieved 2 Oct 2026 · POMSnet Aquila product page
<https://www.poms.com/pomsnet/>

Apprentice Tempo

VENDOR	Apprentice
CATEGORY	MES, cloud batch execution, not documented as plant-wide
PRICING STANCE	Quote-only. \$5,000 in the terms is a pilot liability cap, not a license fee. (Pricing class: quote-only.)
INDEPENDENT REVIEW	Passed 2026-10-03
ONLINE PROFILE	https://www.regdatalab.com/software/apprentice-tempo

Profile summary

The Navigator page “What is Tempo MES?” calls Tempo a fully cloud-native MES “designed exclusively for pharma” that plans, executes, and releases an end-to-end batch, with no-code integrations for equipment and systems. It covers preclinical benchtop through commercial manufacturing, and operators use AR, AI, and voice on wearable, mobile, and desktop devices. (Tempo MES overview, updated 25 Oct 2023.)

Top claims with sources (3 of 50)

Each claim is followed by its caveat (if the evidence row has one), then topic · source type · confidence · dates · source title, then the source URL. The online profile has the full evidence set.

- Public Navigator docs define Tempo MES as a fully cloud-native manufacturing execution system to plan, execute, and release an end-to-end batch, with no-code integrations for equipment and system automation, from preclinical benchtop to large-scale commercial, using AR, AI, and voice on wearable, mobile, and desktop devices, and described as designed exclusively for pharma.

Caveat: Public excerpt. The page says the full knowledge base requires login. HTML chrome said published 21 Oct 2022 and updated 25 Oct 2023; markdown frontmatter lists both published and updated as 2023-10-25.

identity · vendor statement · high confidence · published 2023-10-25 · retrieved 3 Oct 2026 · Manufacturing Execution System (MES) Overview

<https://navigator.apprentice.io/docs/about-tempo-mes>
- The Tempo Manufacturing Cloud overview, updated 9 Jan 2025, describes one platform connecting teams and sites and lists packages CMN, MES, LES, Augmented Work Instructions, and Tandem, with a matrix that gives Batches, Parameter Groups, and Scheduling to MES only, Samples and Plates to LES only, and Remote Collaboration to all four.

Caveat: The public markdown still contains editorial notes marked Internal, including 'Link to CMN page once its created,' although a CMN article now exists. Scheduling is a checkmark, not a description of finite-capacity plant scheduling.

identity · vendor statement · high confidence · published 2025-01-09 · retrieved 3 Oct 2026 · Tempo Manufacturing Cloud

<https://navigator.apprentice.io/docs/tempo-manufacturing-cloud-overview>
- That overview names newer packages Digital, Core, or Pro and points readers to apprentice.io/pricing for the feature breakdown. The live /pricing URL on this date returned an HTML refresh redirect to the homepage and showed no package table and no dollar amount.

Caveat: Package names are documented. What each includes, and any price, was not on the live pricing URL.

pricing · our analysis · high confidence · retrieved 3 Oct 2026 · apprentice.io/pricing (redirect)

<https://www.apprentice.io/pricing>

Honeywell Performix

VENDOR	Honeywell
CATEGORY	MES
PRICING STANCE	Quote-only. (Pricing class: quote-only.)
INDEPENDENT REVIEW	Passed 2026-10-02
ONLINE PROFILE	https://www.regdatalab.com/software/honeywell-performix

Profile summary

The live Performix page calls the product a flexible, modular, no-code manufacturing execution system for life sciences. It integrates with existing ERP systems, needs no programming knowledge to deploy, and aims to eliminate paper, cut cycle time, and improve quality and supply-chain traceability. It lists four modules: xMES Digital Batch, xMES Digital Procedures, xMES Weigh & Dispense, and xMES Digital Logbooks. It names no version, price, deployment model, or customer. (Honeywell Performix page, retrieved 2026-10-02.)

Top claims with sources (5 of 31)

Each claim is followed by its caveat (if the evidence row has one), then topic · source type · confidence · dates · source title, then the source URL. The online profile has the full evidence set.

- 1.** The live Performix page describes a flexible, modular, no-code life-sciences MES that is designed to integrate with existing ERP systems, does not require programming knowledge, and is aimed at eliminating paper, reducing cycle time, and improving quality and supply-chain traceability.

Caveat: No version, price, or customer.

identity · vendor statement · high confidence · retrieved 2 Oct 2026 · Performix
https://process.honeywell.com/us/en/industries/life-sciences/pharmaceuticals_biotechnology/performix
- 2.** Performix Inc. was headquartered in Houston with additional offices in India. The press says it served some of the world's leading pharmaceutical and biotech companies and that senior leadership was expected to join Honeywell. No customer is named.

Caveat: Unnamed customers. Not a deployment list.

identity · press · high confidence · published 2021-09-27 · retrieved 2 Oct 2026 · Honeywell acquisition of Performix Inc.
<https://www.honeywell.com/us/en/press/2021/09/honeywell-bolsters-digital-automation-capabilities-in-life-sciences-through-acquisition-of-performix-inc>
- 3.** The acquisition press says terms were not disclosed and that the deal did not change Honeywell's financial outlook.

Caveat: This is the company transaction, not a software list price. No dollar amount is stated.

pricing · press · high confidence · published 2021-09-27 · retrieved 2 Oct 2026 · Honeywell acquisition of Performix Inc.
<https://www.honeywell.com/us/en/press/2021/09/honeywell-bolsters-digital-automation-capabilities-in-life-sciences-through-acquisition-of-performix-inc>
- 4.** No public list price for Performix software was on the pages opened.

pricing · our analysis · high confidence · retrieved 2 Oct 2026 · Performix
https://process.honeywell.com/us/en/industries/life-sciences/pharmaceuticals_biotechnology/performix
- 5.** The 2026 Performix page does not state a deployment model, database, tenant model, version, Part 11 sentence, Annex 11 sentence, or customer name.

architecture · our analysis · high confidence · retrieved 2 Oct 2026 · Performix
https://process.honeywell.com/us/en/industries/life-sciences/pharmaceuticals_biotechnology/performix

MasterControl Manufacturing Excellence

VENDOR	MasterControl
CATEGORY	MES / electronic production records, not the eQMS
PRICING STANCE	Quote-only. Employment disclosed. (Pricing class: quote-only.)
INDEPENDENT REVIEW	Passed 2026-10-03
ONLINE PROFILE	https://www.regdatalab.com/software/mastercontrol-manufacturing-excellence

Welf Ludwig, who runs RegDataLab, works at MasterControl; the two MasterControl profiles (Manufacturing Excellence and Quality Excellence) say so and, like every other profile, draw on public pages only, with no internal MasterControl sales material.

Profile summary

The manufacturing hub describes Mx as a digital manufacturing platform for paperless production records (EBR and eDHR), MES-style execution, electronic logbooks, and asset management, aimed at regulated manufacturing: GMP work instructions, operator guidance, batch and device production, and review by exception. (Manufacturing hub, retrieved 2026-10-03.)

Top claims with sources (5 of 45)

Each claim is followed by its caveat (if the evidence row has one), then topic · source type · confidence · dates · source title, then the source URL. The online profile has the full evidence set.

- 1.** MasterControl Manufacturing Excellence (Mx) is marketed as a digital manufacturing platform covering production records (EBR/eDHR), MES, electronic logbooks, and asset management.

Caveat: Vendor positioning. Logbooks and asset management are also described on separate product pages.

identity · vendor statement · high confidence · retrieved 3 Oct 2026 · Manufacturing

<https://www.mastercontrol.com/manufacturing/>
- 2.** Made with Mx calls Mx an MES and places digital logbooks, production controls, asset management, and KPI data inside the Mx suite story.

Caveat: Marketing page. Connecting quality and assets is not the same as those products being Mx.

identity · vendor statement · high confidence · retrieved 3 Oct 2026 · Made with Mx

<https://www.mastercontrol.com/madewithmx/>
- 3.** Pricing FAQ says MasterControl SaaS offerings are cloud-based and that Quality Excellence and Manufacturing Excellence use a named-user license model.

Caveat: No dollar amount, user-band, or site metric. The same page's 1,200+ customer claim is company-level, not an Mx census.

pricing · vendor statement · high confidence · retrieved 3 Oct 2026 · Pricing

<https://www.mastercontrol.com/pricing/>
- 4.** The pricing page says to contact representatives for pricing and publishes no list price.

Caveat: Quote-only. A second sales number on that page is +1-888-874-9270; the site footer still shows +1-866-747-8767.

pricing · vendor statement · high confidence · retrieved 3 Oct 2026 · Pricing

<https://www.mastercontrol.com/pricing/>
- 5.** The EBR page says FDA cGMP requires batch-record accountability and claims that adopting an EBR system such as Mx must comply with 21 CFR Parts 210-211, including audit trail, reporting, electronic signature, and security.

Caveat: Vendor claim, not an FDA certification. The same page also says Part 11 in 1997 is when FDA 'began to accept' EBR systems like Mx. The page attributes signature and audit-trail controls to Parts 210-211.

regulatory · vendor statement · high confidence · retrieved 3 Oct 2026 · Electronic Batch Records (EBR) Software

<https://www.mastercontrol.com/manufacturing/batch-records/>

Aizon Execute

VENDOR	Aizon
CATEGORY	MES set as an intelligent batch record, not documented as plant-wide
PRICING STANCE	No list price on aizon.ai. AWS Marketplace states \$50,000 per site per 12 months, with the profile's caveats. (Pricing class: marketplace.)
INDEPENDENT REVIEW	Passed 2026-10-02
ONLINE PROFILE	https://www.regdatalab.com/software/aizon-execute

Profile summary

The product page titles Execute an Intelligent Batch Record (iBR) and an electronic batch record for pharmaceutical manufacturing, promising customers can “go digital” “in only 6 weeks,” with “Full integration, conversion and GxP validation in just 6 weeks” (Aizon, product page, retrieved 2026-10-02).

Top claims with sources (4 of 34)

Each claim is followed by its caveat (if the evidence row has one), then topic · source type · confidence · dates · source title, then the source URL. The online profile has the full evidence set.

1. Aizon's product page titles Aizon Execute an Intelligent Batch Record (iBR) and an electronic batch record, and says go-live positioning is 'in only 6 weeks,' including a claim of full integration, conversion, and GxP validation in just 6 weeks.

Caveat: The same vendor's FAQ says a typical Execute project is 6 to 12 weeks, and the LLM-directed pages say kick-off to production including GxP validation takes less than 6 months. This page does not say Execute is not an MES.

identity · vendor statement · high confidence · retrieved 2 Oct 2026 · Aizon Execute - Intelligent Batch Record (iBR)
<https://www.aizon.ai/execute>

2. Aizon's FAQ says Execute is not a traditional MES. It says Execute covers the electronic batch record block and does not cover inventory management, quality management, or equipment logs.

Caveat: Execute 3.0 release notes later describe a materials list and ERP integration, which narrows, but does not formally retract, the 'not inventory management' sentence. The FAQ page has no publication date.

identity · vendor statement · high confidence · retrieved 2 Oct 2026 · FAQs
<https://www.aizon.ai/faqs>

3. AWS Marketplace lists Aizon Execute at \$50,000 per 12 months for one site subscription that the listing says allows unlimited users at that site. aizon.ai does not publish a list price.

Caveat: This does not price additional sites, GxP validation services, Aizon Consulting Services, Unify, Predict, Agentic Studio, or custom integration. A generic SaaS paragraph on the same page says buyers 'will pay recurring monthly usage fees,' which sits unresolved next to the annual dimension. Vendor refund policy on the listing: "No refund allowed." 0 ratings and 0 reviews. Support contact shown: sales@aizon.ai.

pricing · vendor statement · high confidence · retrieved 2 Oct 2026 · Aizon Execute | AWS Marketplace
<https://aws.amazon.com/marketplace/pp/prodview-lwhcpm6isb3zk>

4. A separate AWS Marketplace listing for Aizon Predict shows \$100 per 12 months for an application-subscription unit that the page does not define. That number is not an Execute price.

Caveat: Sibling product. The \$100 unit is undefined on the page and should not be quoted as Predict's commercial price or compared with the Execute \$50,000 site dimension. Predict product page says 'modest and low-risk investment' with no number: <https://www.aizon.ai/predict>.

pricing · vendor statement · medium confidence · retrieved 2 Oct 2026 · Aizon Predict | AWS Marketplace
<https://aws.amazon.com/marketplace/pp/prodview-nzxk7ee3bsnwa>

Veeva Vault Quality

VENDOR	Veeva Systems
CATEGORY	QMS
PRICING STANCE	Quote-only. (Pricing class: quote-only.)
INDEPENDENT REVIEW	Passed 2026-10-02
ONLINE PROFILE	https://www.regdatalab.com/software/veeva-vault-quality

Profile summary

Veeva Quality Cloud is the quality suite on Veeva's life-sciences Vault platform, sold alongside Veeva's Development, Commercial, and Data clouds. Its buyers are biopharma companies, contract manufacturers, generics makers, and medtech firms; Veeva says “More than 600” of them “standardize and optimize quality management with Veeva Quality applications” (Veeva Quality Cloud, vendor page).

Top claims with sources (5 of 36)

Each claim is followed by its caveat (if the evidence row has one), then topic · source type · confidence · dates · source title, then the source URL. The online profile has the full evidence set.

- 1.** Veeva Quality Cloud unifies content management, training, QMS, and QC lab (LIMS) applications for life-sciences quality.

Caveat: Vendor positioning page.

identity · vendor statement · high confidence · retrieved 2 Oct 2026 · Veeva Quality Cloud
<https://www.veeva.com/products/quality-cloud/>
- 2.** On 26 May 2016 Veeva unveiled Vault QMS as a cloud application unifying quality processes including external partners, available late June 2016, alongside QualityDocs.

Caveat: Vendor IR press.

identity · press · high confidence · published 2016-05-26 · retrieved 2 Oct 2026 · New Veeva Vault QMS Brings Next-Generation Quality Management to Life Sciences
<https://ir.veeva.com/news/news-details/2016/New-Veeva-Vault-QMS-Brings-Next-Generation-Quality-Management-to-Life-Sciences/default.aspx>
- 3.** Veeva does not publish Quality Cloud list prices on the product pages inspected; commercial motion is contact-sales / quote.

Caveat: Quality Basics 'no implementation or maintenance costs' is an offer claim, not a full public price list.

pricing · our analysis · high confidence · retrieved 2 Oct 2026 · Veeva Quality Cloud
<https://www.veeva.com/products/quality-cloud/>
- 4.** USAspending spending_by_award searches for keyword Veeva and recipient text Veeva Systems returned no awards under the filters used on 2026-10-02.

Caveat: Could miss resellers or alternate legal names.

pricing · procurement · medium confidence · retrieved 2 Oct 2026 · USAspending spending_by_award API
https://api.usaspending.gov/api/v2/search/spending_by_award/
- 5.** No FDA clearance/approval or EMA product authorization of Vault Quality software itself was found in fda.gov / ema.europa.eu searches on 2026-10-02.

Caveat: Search miss is not proof of never-mentioned-in-inspection.

regulatory · our analysis · medium confidence · retrieved 2 Oct 2026 · FDA QMSR landing (example non-hit context)
<https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-management-system-regulation-qmsr>

Octave Reliance (formerly ETQ Reliance)

VENDOR	Octave
CATEGORY	QMS
PRICING STANCE	Quote-only. (Pricing class: quote-only.)
INDEPENDENT REVIEW	Passed 2026-10-03
ONLINE PROFILE	https://www.regdatalab.com/software/octave-reliance

Profile summary

Octave Reliance is the configurable enterprise eQMS long sold as ETQ Reliance, now owned by Octave Intelligence plc after Hexagon's May 2026 spin-off. Its buyers are multi-site manufacturers in medical devices, life sciences, pharmaceuticals, automotive, aerospace, food and beverage, electronics, and heavy industry; most published cases are device, electronics, and industrial companies rather than pharma plants (Octave Reliance product page; eQMS page).

Top claims with sources (5 of 39)

Each claim is followed by its caveat (if the evidence row has one), then topic · source type · confidence · dates · source title, then the source URL. The online profile has the full evidence set.

- Octave Reliance is the rebranded version of ETQ Reliance; the live product page states Formerly ETQ Reliance and that core functionality remains consistent after Octave's independent spin-off branding.

Caveat: Vendor product page. Branding claim, not a technical migration guide.

identity · vendor statement · high confidence · retrieved 3 Oct 2026 · Octave Reliance | Octave
<https://www.octave.com/products/asset-performance-management/reliance>
- Octave's product-naming page states ETQ Reliance is now Octave Reliance (page last updated April 8, 2026) and lists multiple former ETQ Reliance module names under the Operate pillar.

Caveat: Naming map also covers many non-Reliance Octave products.

identity · vendor statement · high confidence · published 2026-04-08 · retrieved 3 Oct 2026 · Octave Product Name Changes
<https://www.octave.com/legal/product-naming>
- No public list price was found on the inspected Octave Reliance product pages; buyers are directed to contact sales or request a demo.

Caveat: A price could exist behind a form or on an unopened page.

pricing · our analysis · high confidence · retrieved 3 Oct 2026 · Octave Reliance | Octave
<https://www.octave.com/products/asset-performance-management/reliance>
- FAA delivery order DTFAAC12D00005CALL0010 obligated USD 247,750 to ETQ, LLC for purchase of 100 ETQ Reliance licenses plus maintenance and 24/7 tech support, firm fixed price, not competed, one offer, signed 2014-08-25.

Caveat: One historical award is not a list price. AJI context is FAA training/safety, not pharma manufacturing.

pricing · procurement · high confidence · published 2014-08-25 · retrieved 3 Oct 2026 · USAspending award DTFAAC12D00005CALL0010
https://www.usaspending.gov/award/CONT_AWD_DTFAAC12D00005CALL0010_6920_DTFAAC12D00005_6920
- No FDA warning letter or Form 483 naming ETQ Reliance, ETQ (as this QMS), or Octave Reliance as the inspected software was found in the fda.gov / openFDA searches run; Reliance Life Sciences Private Limited warning letter was excluded as a different entity.

Caveat: Negative search is not proof facilities do not use the software.

regulatory · our analysis · high confidence · published 2026-08-18 · retrieved 3 Oct 2026 · FDA warning letter — Reliance Life Sciences Private Limited (excluded)
<https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/reliance-life-sciences-private-limited-730801-08182026>

Qualio

VENDOR	Qualio
CATEGORY	QMS
PRICING STANCE	Quote-only. (Pricing class: quote-only.)
INDEPENDENT REVIEW	Passed 2026-10-02
ONLINE PROFILE	https://www.regdatalab.com/software/qualio

Profile summary

Qualio is a cloud-only, multi-tenant eQMS for medical device, SaMD, GxP software, pharma, and biotech companies, now sold as an “Agentic Compliance Platform” that layers AI gap analysis and regulatory monitoring on document control, training, supplier quality, and quality events. Its plans run from teams preparing a first regulatory submission to multi-site operations, and Qualio reports “700+ highly regulated customers” (Qualio homepage; Pricing).

Top claims with sources (5 of 33)

Each claim is followed by its caveat (if the evidence row has one), then topic · source type · confidence · dates · source title, then the source URL. The online profile has the full evidence set.

- 1.** The current homepage calls Qualio an agentic compliance platform for life sciences that unites quality management, product lifecycle, and compliance intelligence.

Caveat: Vendor positioning. Marketing percentages on the same page are separate claims.

identity · vendor statement · high confidence · retrieved 2 Oct 2026 · Qualio homepage
<https://www.qualio.com/>
- 2.** Both generations of terms say the platform is a quality-management tool and not a substitute for legal standards.

Caveat: Contract limitation. Does not describe which modules exist.

identity · vendor statement · high confidence · published 2024-08-13 · retrieved 2 Oct 2026 · Qualio Terms of Service, effective 13 August 2024
<https://www.qualio.com/docs/terms>
- 3.** The pricing page has no dollar amount. It offers Foundation (5 edit users), Growth (10 edit users), and Scale (custom pricing), and says an implementation fee applies to all plans.

Caveat: Quote-only. Not a list price.

pricing · vendor statement · high confidence · retrieved 2 Oct 2026 · Qualio pricing
<https://www.qualio.com/pricing>
- 4.** Qualio sells an annual subscription. Basic users are unlimited at no extra cost on the published plans, additional edit users can be added, and cloud storage is included.

Caveat: 'Both plans' in the FAQ refers to the two plans with published user counts, not a priced Scale tier.

pricing · vendor statement · high confidence · retrieved 2 Oct 2026 · Qualio pricing FAQ
<https://www.qualio.com/pricing>
- 5.** FDA's 3 June 2025 warning letter to Insightra Medical says that firm's CAPAs are generated in Qualio, which FDA calls an electronic record system used to manage quality documents.

Caveat: Evidence of one customer's use. The violations are charged to Insightra, not to Qualio. Not an FDA clearance of the software.

regulatory · regulator record · high confidence · published 2025-06-03 · retrieved 2 Oct 2026 · FDA warning letter CMS 706921, Insightra Medical Inc.
<https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/insightra-medical-inc-706921-06032025>

Honeywell TrackWise Digital

VENDOR	Honeywell
CATEGORY	QMS
PRICING STANCE	Quote-only. (Pricing class: quote-only.)
INDEPENDENT REVIEW	Passed 2026-10-02
ONLINE PROFILE	https://www.regdatalab.com/software/honeywell-trackwise

Profile summary

TrackWise Digital is the cloud successor to TrackWise, the on-premise QMS that Sparta Systems sold to large pharma and medical-device makers, and Honeywell has owned the line since February 2021. Its buyers are pharma and device quality organizations; Honeywell says 84% of top pharma companies and 66% of top med device companies use TrackWise (Quality Management Solutions, vendor page).

Top claims with sources (5 of 28)

Each claim is followed by its caveat (if the evidence row has one), then topic · source type · confidence · dates · source title, then the source URL. The online profile has the full evidence set.

- 1.** TrackWise Digital is marketed as a cloud-based QMS with integrated modules, AI-augmented capabilities, and SaaS delivery built on the Salesforce platform.

Caveat: Vendor product page.

identity · vendor statement · high confidence · retrieved 2 Oct 2026 · TrackWise Digital Quality Management Software
<https://www.spartasystems.com/trackwise/>
- 2.** The TrackWise Quality Suite page distinguishes TrackWise Digital (cloud QMS) from TrackWise / TrackWise QMS as on-premise QMS software.

Caveat: Both remain publicly marketed on the same hub.

identity · vendor statement · high confidence · retrieved 2 Oct 2026 · TrackWise Quality Suite
<https://www.spartasystems.com/trackwise-quality-suite/>
- 3.** No public list price was found on TrackWise Digital or suite pages opened; buyers are directed to contact channels.

Caveat: Aggregator 'starts at' snippets were not confirmed on vendor pages.

pricing · our analysis · high confidence · retrieved 2 Oct 2026 · TrackWise Digital
<https://www.spartasystems.com/trackwise/>
- 4.** DOE purchase order DEAP2607NT02841 obligated USD 5,900 to Sparta Systems, Inc. for TrackWise premium product support and licensing renewal, signed 2007-05-16.

Caveat: 2007 classic TrackWise support renewal is not a 2026 Digital list price. Keyword TrackWise Digital returned no awards.

pricing · procurement · high confidence · published 2007-05-16 · retrieved 2 Oct 2026 · USAspending award DEAP2607NT02841
https://www.usaspending.gov/award/CONT_AWD_DEAP2607NT02841_8900_-NONE--NONE-
- 5.** Norbrook Laboratories Form 483 (inspection Jan–Feb 2020) cites inadequate controls over information logged into the firm's Trackwise system and delayed initiation of deviations in Trackwise per firm SOP — a customer quality-system finding, not a software clearance.

Caveat: Does not identify TrackWise Digital vs classic. Not a warning letter against Honeywell/Sparta. Not an FDA product clearance.

regulatory · regulator record · high confidence · published 2020-02-07 · retrieved 2 Oct 2026 · Norbrook Laboratories Form FDA 483
<https://www.fda.gov/media/185723/download>

MasterControl Quality Excellence

VENDOR	MasterControl
CATEGORY	QMS
PRICING STANCE	Quote-only. Employment disclosed. (Pricing class: quote-only.)
INDEPENDENT REVIEW	Passed 2026-10-03
ONLINE PROFILE	https://www.regdatalab.com/software/mastercontrol-quality-excellence

Welf Ludwig, who runs RegDataLab, works at MasterControl; the two MasterControl profiles (Manufacturing Excellence and Quality Excellence) say so and, like every other profile, draw on public pages only, with no internal MasterControl sales material.

Profile summary

Quality Excellence is MasterControl's cloud eQMS for document control, training, and CAPA and deviation management in regulated manufacturing. Buyers range from startups on the pre-validated Starter package to multi-site pharma companies such as Fagron and U.S. federal agencies, for which the Qx Gov edition holds FedRAMP Moderate authorization. (Quality landing page; FedRAMP Qx Gov page.)

Top claims with sources (5 of 40)

Each claim is followed by its caveat (if the evidence row has one), then topic · source type · confidence · dates · source title, then the source URL. The online profile has the full evidence set.

- 1. Current quality landing page markets the product as MasterControl Quality Excellence, an AI-enhanced QMS trusted by 1,100+ customers.**

Caveat: Customer count is a vendor marketing figure without published methodology.

identity · vendor statement · high confidence · retrieved 3 Oct 2026 · Quality / Quality Excellence landing page
<https://www.mastercontrol.com/quality/>
- 2. QMS overview page equates MasterControl's digital QMS with the product name Quality Excellence and positions it as cloud QMS software.**

Caveat: Vendor positioning.

identity · vendor statement · high confidence · retrieved 3 Oct 2026 · Quality Management Software (QMS) for Life Sciences
<https://www.mastercontrol.com/quality/qms/>
- 3. No public list price; pricing page directs buyers to contact sales for tailored pricing and states named-user licensing for Quality Excellence.**

Caveat: Quote-only. No dollar amounts on the page.

pricing · vendor statement · high confidence · retrieved 3 Oct 2026 · Pricing Options for Every Organization
<https://www.mastercontrol.com/pricing/>
- 4. WebSearch site:fda.gov and site:ema.europa.eu for MasterControl Quality Excellence returned no regulator pages naming the product; openFDA searches returned NOT_FOUND.**

Caveat: Zero hits is not proof of absence from every regulator database. Vendor 483 blogs are not regulator records.

regulatory · regulator record · medium confidence · retrieved 3 Oct 2026 · openFDA drug enforcement search
<https://api.fda.gov/drug/enforcement.json?search=%22MasterControl+Quality+Excellence%22&limit=1>
- 5. Pricing FAQ states MasterControl offerings are cloud-based SaaS and that VxT and Validation on Demand are included, with optional additional validation training.**

Caveat: Vendor FAQ. Scope of 'included' validation evidence not published as a protocol.

architecture · vendor statement · high confidence · retrieved 3 Oct 2026 · Pricing
<https://www.mastercontrol.com/pricing/>

Greenlight Guru QMS

VENDOR	Greenlight Guru
CATEGORY	QMS, medical-device eQMS, not a pharma MES
PRICING STANCE	Public floor: eQMS packages start at \$12,000 per year. Not a full list price. (Pricing class: public-floor.)
INDEPENDENT REVIEW	Passed 2026-10-03
ONLINE PROFILE	https://www.regdatalab.com/software/greenlight-guru

Profile summary

Greenlight Guru is a device-specific eQMS that pairs ISO 13485 quality processes (document control, CAPA, complaints, supplier quality, audits) with design controls, ISO 14971 risk files, and a clinical EDC, sold to medical-device and SaMD companies from first submission to commercial portfolio. The Indianapolis company is backed by JMI Equity, has grown by acquisition (SMART-TRIAL in 2022, Ultralight Labs and Enzyme in 2025), and reports “1,000+ device companies” as customers (Homepage; Platform).

Top claims with sources (5 of 38)

Each claim is followed by its caveat (if the evidence row has one), then topic · source type · confidence · dates · source title, then the source URL. The online profile has the full evidence set.

- The homepage presents Greenlight Guru as medical-device QMS software for quality, product development, and clinical evidence, and claims the platform lowers audit risk by 3.5x.

Caveat: Vendor marketing. No study design for the 3.5x figure.

identity · vendor statement · high confidence · retrieved 3 Oct 2026 · Greenlight Guru homepage
<https://www.greenlight.guru/>
- The platform FAQ describes a suite of product development, eQMS, and eClinical software for medical device companies, not a single undifferentiated module.

Caveat: Vendor FAQ. Does not say every subscription includes all three.

identity · vendor statement · high confidence · retrieved 3 Oct 2026 · Platform | Greenlight Guru
<https://www.greenlight.guru/platform>
- The pricing page states eQMS packages start at \$12,000 per year, and that quality-management and product-development subscriptions start at \$12,000 per year while EDC subscriptions start at \$9,000 per year.

Caveat: A starting floor, not a per-user or module list. Final price 'depends on the products and capabilities you need.'

pricing · vendor statement · high confidence · retrieved 3 Oct 2026 · Greenlight Guru Quality pricing
<https://www.greenlight.guru/quality-pricing>
- Implementation and clinical study-build are priced separately. eQMS and product-development subscriptions are annual. EDC has a 12-month minimum. Validation documentation, a customer success manager, training, and support are included.

Caveat: No rate card for services. No user metric.

pricing · vendor statement · high confidence · retrieved 3 Oct 2026 · Greenlight Guru Quality pricing
<https://www.greenlight.guru/quality-pricing>
- The pricing page says the eQMS is aligned to ISO 13485, FDA QMSR, ISO 14971, and IEC 62304.

Caveat: Alignment claim, not an FDA or EMA certification of the product.

regulatory · vendor statement · high confidence · retrieved 3 Oct 2026 · Greenlight Guru Quality pricing
<https://www.greenlight.guru/quality-pricing>

Dot Compliance eQMS

VENDOR	Dot Compliance
CATEGORY	QMS
PRICING STANCE	Quote-only. (Pricing class: quote-only.)
INDEPENDENT REVIEW	Passed 2026-10-02
ONLINE PROFILE	https://www.regdatalab.com/software/dot-compliance

Profile summary

Dot Compliance is a venture-funded, Salesforce-native eQMS for pharma, biotech, and medical-device companies, sold as a pre-built, pre-validated system with an AI layer called Dottie. Its named customers include a 63-person U.S. pharma manufacturer, a biotech moving from clinical to commercial quality, an Australian testing lab, and a Danish hospital pharmacy that bought it through a public framework (Dot Compliance home).

Top claims with sources (6 of 33)

Each claim is followed by its caveat (if the evidence row has one), then topic · source type · confidence · dates · source title, then the source URL. The online profile has the full evidence set.

- 1.** Doron Sitbon is named Founder and CEO on the about page.

Caveat: None.

identity · vendor statement · high confidence · retrieved 2 Oct 2026 · About us
<https://www.dotcompliance.com/about-us/>
- 2.** Electronic batch management is a named eQMS module, not a documented manufacturing execution system.

identity · our analysis · high confidence · retrieved 2 Oct 2026 · Dot Compliance home
<https://www.dotcompliance.com/>
- 3.** No currency amount for a license, user, or module appears on the vendor home, eQMS, Salesforce, services, or about pages inspected on 2026-10-02.

pricing · our analysis · high confidence · retrieved 2 Oct 2026 · Dot Compliance home
<https://www.dotcompliance.com/>
- 4.** TED notice 814489-2025 states 4 800 000,00 DKK excluding VAT as the estimated value and as the maximum, approximate, and re-estimated value of the AMGROS framework. It does not state the winning tender price.

Caveat: English HTML of a notice whose official language is Danish. The 4.8 million kroner figure is the framework estimate and ceiling, not a list price and not the winning bid. Registration number is printed as 446402605.

pricing · procurement · high confidence · published 2025-12-09 · retrieved 2 Oct 2026 · TED notice 814489-2025
<https://ted.europa.eu/en/notice/814489-2025/html>
- 5.** openFDA returned no 510(k), PMA, device enforcement, or registration listing for applicant or firm name dot compliance.

Caveat: Name search only. Not a determination that the software is or is not compliant.

regulatory · regulator record · high confidence · retrieved 2 Oct 2026 · openFDA device 510(k) search
<https://api.fda.gov/device/510k.json?search=applicant:%22dot+compliance%22&limit=5>
- 6.** Primary customer records are stored on Salesforce, region chosen by the customer; Dottie AI microservices run on AWS in Frankfurt; Dottie queries also go to OpenAI and Google Cloud in the U.S.

Caveat: Vendor list. Does not publish the Salesforce edition or a security white paper.

architecture · vendor statement · high confidence · retrieved 2 Oct 2026 · List of Dot Compliance sub-processors
<https://www.dotcompliance.com/list-of-dot-compliance-sub-processors/>

ComplianceQuest QMS

VENDOR	ComplianceQuest
CATEGORY	QMS
PRICING STANCE	Quote-only on the vendor site. AppExchange USD 30 per user per month is a marketplace plan, not the vendor list price. (Pricing class: marketplace.)
INDEPENDENT REVIEW	Passed 2026-10-02
ONLINE PROFILE	https://www.regdatalab.com/software/compliancequest

Profile summary

ComplianceQuest is a Salesforce-native EQMS built by founders of Pilgrim Software and sold to life-sciences and other manufacturers, with separate supplier, EHS, PLM, and batch-record products on the same platform. Its quality core covers audits, CAPA, change control, equipment, lab OOS investigations, management review, nonconformance, and product inspection, and ComplianceQuest says Gartner named it a Leader in the 2026 QMS Magic Quadrant (Quality page; LLM info).

Top claims with sources (4 of 35)

Each claim is followed by its caveat (if the evidence row has one), then topic · source type · confidence · dates · source title, then the source URL. The online profile has the full evidence set.

- 1.** ComplianceQuest's own LLM info page describes the company as ComplianceQuest, Inc., founded in 2013 by Prashanth Rajendran, Atulya Risal, and Govardhan Muralidharan, headquartered in Tampa, Florida, and delivered 100% as SaaS on Salesforce rather than on CQ-hosted infrastructure.

Caveat: Vendor page written for AI systems.

identity · vendor statement · high confidence · retrieved 2 Oct 2026 · LLM Info Page: ComplianceQuest
<https://www.compliancequest.com/llm-info/>
- 2.** The same page separates QualityQuest (core QMS) from ProductQuest (PLM), BatchQuest (EBR), SafetyQuest (EHS), and PartnerQuest (supplier management).

Caveat: An older EQMS landing page still lists Supplier inside the EQMS module list. The split is the vendor's current product-family wording, not a contract schedule.

identity · vendor statement · high confidence · retrieved 2 Oct 2026 · LLM Info Page: ComplianceQuest
<https://www.compliancequest.com/llm-info/>
- 3.** The vendor QMS pricing page states that ComplianceQuest does not publish fixed QMS software pricing and prices through a quote and demo, varying by users, modules, sites, integrations, and compliance scope.

Caveat: No currency amount appears on this page. Percentages on the page (99% retention, 48% cost of quality, 46% fewer audit findings) have no study design.

pricing · vendor statement · high confidence · published 2026-01-16 · retrieved 2 Oct 2026 · QMS Software Pricing | ComplianceQuest
<https://www.compliancequest.com/qms-software-pricing/>
- 4.** The Salesforce AppExchange EQMS listing, publisher ComplianceQuest, Inc., shows a paid default plan of USD 30 per user per month, described by the listing as the lowest license type, with a 30-day trial, and says detailed pricing including volume discounts comes from sales.

Caveat: This is a marketplace plan for the lowest license type, not the enterprise quote on compliancequest.com/qms-software-pricing/. It is not a full-suite list price.

pricing · vendor statement · high confidence · published 2014-07-11 · retrieved 2 Oct 2026 · Enterprise Quality Management System (EQMS) by ComplianceQuest
<https://appexchange.salesforce.com/appxListingDetail?listingId=a0N3000000B5PNxEAN>

IQVIA SmartSolve eQMS

VENDOR	IQVIA
CATEGORY	QMS
PRICING STANCE	Quote-only. (Pricing class: quote-only.)
INDEPENDENT REVIEW	Passed 2026-10-03
ONLINE PROFILE	https://www.regdatalab.com/software/iqvia-smartsolve

Profile summary

IQVIA SmartSolve eQMS is the enterprise eQMS in IQVIA's Safety & Regulatory Compliance line, built on the Pilgrim Quality Solutions product that IQVIA absorbed in 2017. IQVIA sells it to pharmaceutical, in vitro diagnostics, and medical device quality teams, and the U.S. CDC has run it since 2006 (SmartSolve eQMS hub; CDC record in section 7).

Top claims with sources (5 of 54)

Each claim is followed by its caveat (if the evidence row has one), then topic · source type · confidence · dates · source title, then the source URL. The online profile has the full evidence set.

- 1.** Current live product name is IQVIA SmartSolve eQMS, a cloud-based enterprise QMS for pharmaceutical, IVD, and medical device companies, distinct from other products named SmartSolve.

Caveat: Vendor product page.

identity · vendor statement · high confidence · retrieved 3 Oct 2026 · QMS for Life Sciences | SmartSolve eQMS
<https://www.iqvia.com/solutions/safety-regulatory-compliance/quality-compliance/smartsolve-eqms>
- 2.** Florida Sunbiz shows PILGRIM QUALITY SOLUTIONS, INC. (P93000023245) filed 29 Mar 1993, status INACTIVE after CORPORATE MERGER filed 22 Dec 2017 effective 31 Dec 2017, Tampa address.

Caveat: State register detail page.

identity · regulator record · high confidence · published 2017-12-22 · retrieved 3 Oct 2026 · Florida Sunbiz detail — Pilgrim Quality Solutions, Inc.
<https://search.sunbiz.org/Inquiry/CorporationSearch/SearchResultDetail?inquirytype=EntityName&directionType=ForwardList&searchNameOrder=PILGRIMQUALITYSOLUTIONS%20P930000232451&aggregatId=domp-p93000023245-aff19540-daff-479a-bf3e-b3be5399a229&searchTerm=PILGRIM%20QUALITY%20SOLUTIONS&listNameOrder=PILGRIMQUALITYSOLUTIONS%20P930000232451>
- 3.** MedTech FAQ states pricing is modular by sites/processes and buyers should request a tailored quote; no list price on the page.

Caveat: Quote-only. Not a fee table.

pricing · vendor statement · high confidence · retrieved 3 Oct 2026 · SmartSolve eQMS for MedTech FAQ
<https://www.iqvia.com/solutions/safety-regulatory-compliance/quality-compliance/smartsolve-eqms/smartsolve-for-medtech>
- 4.** No public currency list price was found on the inspected SmartSolve product pages; commercial motion is demo/RFP/contact.

pricing · our analysis · high confidence · retrieved 3 Oct 2026 · SmartSolve eQMS hub
<https://www.iqvia.com/solutions/safety-regulatory-compliance/quality-compliance/smartsolve-eqms>
- 5.** openFDA device 510(k) queries for SmartSolve and Pilgrim Quality Solutions returned NOT_FOUND / no matches.

Caveat: Not a full FDA database audit. Not a statement that FDA rejected the product.

regulatory · regulator record · high confidence · retrieved 3 Oct 2026 · openFDA device 510(k) search
https://api.fda.gov/device/510k.json?search=device_name:%22SmartSolve%22&limit=3

Ennov QMS

VENDOR	Ennov
CATEGORY	QMS
PRICING STANCE	Quote-only. (Pricing class: quote-only.)
INDEPENDENT REVIEW	Passed 2026-10-02
ONLINE PROFILE	https://www.regdatalab.com/software/ennov-qms

Profile summary

Ennov QMS is the quality-process module (deviation, CAPA, change control, complaints, audits) of the quality suite sold by Ennov, a Paris vendor whose wider portfolio covers RIM, clinical, and pharmacovigilance software. Its published buyers are multi-site life-sciences manufacturers: a CDMO (Delpharm, 16 sites), a biotech (HTL Biotechnology), and an unnamed radiopharmaceutical maker (Ennov QMS).

Top claims with sources (5 of 34)

Each claim is followed by its caveat (if the evidence row has one), then topic · source type · confidence · dates · source title, then the source URL. The online profile has the full evidence set.

- The Quality Suite page presents Ennov Doc, Ennov Process, and Ennov Training as separate pillars, and says the suite is AI-powered and aligned to 21 CFR Part 11, GxP, Annex 11, and ISO.

Caveat: Annex 11 and ISO wording is a vendor claim. AI behavior is not specified. Ennov Process versus Ennov QMS is not defined as a rename.

identity · vendor statement · high confidence · retrieved 2 Oct 2026 · Ennov Quality Suite
<https://en.ennov.com/solutions/quality/>
- Ennov says it was founded in 1999, serves clinical, regulatory, quality, pharmacovigilance, and commercial use, and claims ISO/IEC 27001 and ISO 9001:2015 for software development and operations plus a 100% customer-audit success rate.

Caveat: Certificate numbers and the body were not on the page. Audit-success rate has no method. Street address not on this page.

identity · vendor statement · high confidence · retrieved 2 Oct 2026 · About the Company | Ennov
<https://en.ennov.com/about/>
- No currency amount, per-user fee, or per-site fee is stated on the QMS page, which ends in a contact form.

pricing · our analysis · high confidence · retrieved 2 Oct 2026 · QMS Software | Ennov
<https://en.ennov.com/solutions/quality/qms/>
- About-page commercial language says cost-effective and an unmatched price-performance ratio, without a number.

Caveat: Not a price.

pricing · vendor statement · high confidence · retrieved 2 Oct 2026 · About the Company | Ennov
<https://en.ennov.com/about/>
- The QMS page says Ennov QMS fully complies with FDA 21 CFR Part 11 for electronic signature, audit trail, and records management.

Caveat: Vendor compliance claim. Not an FDA certification.

regulatory · vendor statement · high confidence · retrieved 2 Oct 2026 · QMS Software | Ennov
<https://en.ennov.com/solutions/quality/qms/>

LabWare LIMS

VENDOR	LabWare
CATEGORY	LIMS
PRICING STANCE	Quote-only for a current price. (Pricing class: quote-only.)
INDEPENDENT REVIEW	Passed 2026-10-02
ONLINE PROFILE	https://www.regdatalab.com/software/labware-lims

Profile summary

LabWare LIMS is an enterprise LIMS for regulated QC and QA labs, sold on one platform with LabWare ELN and deployed self-hosted or as LabWare-run SaaS. LabWare says 21 of the top 25 pharmaceutical companies use it, and U.S. federal labs from NIH to the Army buy it through GSA schedules and direct orders.

Top claims with sources (5 of 39)

Each claim is followed by its caveat (if the evidence row has one), then topic · source type · confidence · dates · source title, then the source URL. The online profile has the full evidence set.

- 1.** LabWare LIMS is positioned as an enterprise LIMS for routine QC and complex studies, with a vendor claim of more than 30 years and over 30,000 labs.

Caveat: Vendor marketing census, not audited.

identity · vendor statement · high confidence · retrieved 2 Oct 2026 · LabWare LIMS product page
<https://www.labware.com/lims>
- 2.** LabWare was founded in 1987 in Wilmington, Delaware, by Vance Kershner, who remains President and CEO. Headquarters and all R&D are in Wilmington.

Caveat: Conflicts with a 1978 founding line on the CompassRed release boilerplate.

identity · vendor statement · high confidence · retrieved 2 Oct 2026 · About LabWare
<https://www.labware.com/about>
- 3.** No current public list price was found on the product, SaaS, cloud, self-hosted, or services pages opened on 2026-10-02.

Caveat: Absence on the pages opened, not proof that no price file exists elsewhere.

pricing · our analysis · high confidence · retrieved 2 Oct 2026 · LabWare LIMS product page
<https://www.labware.com/lims>
- 4.** 2009 USDA APHIS delivery order bought 20 LabWare LIMS version 6.0 concurrent-user licenses, part 2100.60, at \$4,750 each, obligation \$95,000.

Caveat: Historical version 6.0 order under GSA FSS GS07F5446R. Not a 2026 list price. Recipient LABWARE HOLDINGS, INC. Historical version 6.0 only. Parent schedule GS07F5446R ended 2024-10-31 and is not a 2026 price.

pricing · procurement · high confidence · published 2009-11-16 · retrieved 2 Oct 2026 · USAspending AG32KWD100027
https://www.usaspending.gov/award/CONT_AWD_AG32KWD100027_12K3_GS07F5446R_4730
- 5.** ECA Academy on 10 January 2024 paraphrased an FDA Form 483 from a 19-27 October 2023 inspection at Dr. Reddy's Laboratories as criticizing controls over LabWare LIMS.

Caveat: Site observation, not a vendor finding.

regulatory · press · medium confidence · published 2024-01-10 · retrieved 2 Oct 2026 · ECA Academy, FDA Form 483 calibration note
<https://www.gmp-compliance.org/gmp-news/fda-form-483-calibration-of-analytical-instruments>

STARLIMS

VENDOR	STARLIMS
CATEGORY	LIMS
PRICING STANCE	Quote-only. (Pricing class: quote-only.)
INDEPENDENT REVIEW	Passed 2026-10-03
ONLINE PROFILE	https://www.regdatalab.com/software/starlims

Profile summary

STARLIMS is a long-established commercial LIMS, formerly Abbott Informatics, now independent and backed by Turn/River Capital since January 2026. It sells a Quality Manufacturing LIMS to pharma, biotech, and device QC labs, a SaaS edition for small batch manufacturers, and a separate catalog of SDMS, LES, ELN, analytics, and environmental-monitoring products; its public-sector base runs from U.S. federal health agencies to European police forensic labs.

Top claims with sources (5 of 80)

Each claim is followed by its caveat (if the evidence row has one), then topic · source type · confidence · dates · source title, then the source URL. The online profile has the full evidence set.

- 1.** The live site positions STARLIMS as LIMS and lab informatics platforms for R&D, QC and manufacturing, public health, and clinical diagnostics.

Caveat: Vendor homepage.

identity · vendor statement · high confidence · retrieved 3 Oct 2026 · STARLIMS homepage
<https://www.starlims.com/>
- 2.** Homepage counters say founded 1986, 2,000+ laboratories, 700+ customers, and 85+ countries.

Caveat: Vendor counters. Conflict with the 1,100-customer press line.

identity · vendor statement · high confidence · retrieved 3 Oct 2026 · STARLIMS homepage counters
<https://www.starlims.com/>
- 3.** QM Essentials is a subscription cloud LIMS for SMB batch manufacturers in pharma, food and beverage, and consumer goods, with a minimum of five users, batch login, environmental monitoring, and outsource samples, and optional Stability Studies and Advanced Analytics 2.0.

Caveat: No dollar rate. Five users is a minimum seat count, not a price.

pricing · vendor statement · high confidence · retrieved 3 Oct 2026 · QM Essentials
<https://www.starlims.com/qm-essentials/>
- 4.** No opened commercial page states a dollar list price, a per-user fee, or a rate card. Public obligations are buyer-specific and are not scaled to a unit price.

Caveat: A later price list could exist behind a form that was not submitted.

pricing · our analysis · high confidence · retrieved 3 Oct 2026 · QM Essentials and hosting pages, read with the award payloads
<https://www.starlims.com/qm-essentials/>
- 5.** openFDA device-event search on brand name STARLIMS returned 23 reports. The sample is a malfunction report for STARLIMS CLINICAL SOLUTION, manufacturer ABBOTT INFORMATICS CORPORATION, report 3006130047-2021-00001, received 20210812.

Caveat: MAUDE-style device reports, not warning letters or Form 483s. openFDA says results are unvalidated.

regulatory · regulator record · high confidence · published 2026-09-22 · retrieved 3 Oct 2026 · openFDA device event API, brand STARLIMS
https://api.fda.gov/device/event.json?search=device.brand_name:%22STARLIMS%22&limit=5

LabVantage LIMS

VENDOR	LabVantage
CATEGORY	LIMS
PRICING STANCE	Quote-only. (Pricing class: quote-only.)
INDEPENDENT REVIEW	Passed 2026-10-03
ONLINE PROFILE	https://www.regdatalab.com/software/labvantage-lims

Profile summary

LabVantage LIMS is a browser-based enterprise LIMS sold as one platform with ELN, LES, and SDMS, and pitched to pharma QC buyers as a pre-validated, pre-configured Pharma LIMS on SaaS or on-premises. Its public buyers include NIH, the Defense Health Agency, CBP's forensic labs, and public agencies in Ireland, Wales, Finland, and Norway.

Top claims with sources (5 of 59)

Each claim is followed by its caveat (if the evidence row has one), then topic · source type · confidence · dates · source title, then the source URL. The online profile has the full evidence set.

1. LabVantage LIMS is marketed as a flexible HTML5 browser-based laboratory information management system for testing, sample storage, research data, analytical/diagnostic testing, and manufacturing quality data.

Caveat: Vendor product page. Platform also blends ELN, LES, and SDMS on the same page.

identity · vendor statement · high confidence · retrieved 3 Oct 2026 · LabVantage LIMS product page

<https://www.labvantage.com/informatics/lims/>
2. On the LIMS page the vendor presents LIMS, ELN, LES, and SDMS as capabilities of one LabVantage platform rather than as four unrelated products.

Caveat: Product-boundary caution: this dossier still treats ELN, LES, SDMS, LIS, and biobanking as separate named offerings when claims are about those modules.

identity · vendor statement · high confidence · retrieved 3 Oct 2026 · LabVantage LIMS product page

<https://www.labvantage.com/informatics/lims/>
3. No public list price for LabVantage LIMS was found on the vendor pages opened; commercial contact is quote-driven.

Caveat: Absence of a list price is not proof of a hidden public price elsewhere.

pricing · our analysis · high confidence · retrieved 3 Oct 2026 · LabVantage LIMS product page

<https://www.labvantage.com/informatics/lims/>
4. USAspending spending_by_award keyword LabVantage (award types A–D, 2007-10-01 through 2026-10-03) returned 88 results.

Caveat: Keyword search, not a complete census of every federal LabVantage use.

pricing · procurement · high confidence · retrieved 3 Oct 2026 · USAspending spending_by_award API (keyword LabVantage)

https://api.usaspending.gov/api/v2/search/spending_by_award/
5. openFDA 510(k) applicant LabVantage, device-event text LabVantage, and drug-enforcement product_description LabVantage each returned NOT_FOUND.

Caveat: Clean NOT_FOUND for these three openFDA queries only. They are not a Form 483 citation-dataset search and not a warning-letter index search. Those checks are recorded separately and were not completed. Absence is not proof facilities do not use the software.

regulatory · our analysis · high confidence · retrieved 3 Oct 2026 · openFDA 510(k) / MAUDE / enforcement checks

<https://api.fda.gov/device/510k.json?search=applicant:LabVantage&limit=1>

Thermo Scientific SampleManager LIMS

VENDOR	Thermo Fisher Scientific
CATEGORY	LIMS
PRICING STANCE	Quote-only. (Pricing class: quote-only.)
INDEPENDENT REVIEW	Passed 2026-10-03
ONLINE PROFILE	https://www.regdatalab.com/software/thermo-samplemanager

Profile summary

SampleManager LIMS is Thermo Fisher's manufacturing and process-development LIMS, with LES, SDMS, and a notebook built in and a direct link to Chromeleon CDS. It sells to pharma, CDMO, food, petrochemical, water, and contract-testing QC labs, and Thermo Fisher runs it across its own Pharma Services network, including Patheon.

Top claims with sources (4 of 38)

Each claim is followed by its caveat (if the evidence row has one), then topic · source type · confidence · dates · source title, then the source URL. The online profile has the full evidence set.

- The current SampleManager product page describes it as informatics for lab, data, process, and compliance management, and says SDMS, ELN, and LES functionality is additional built-in function.

Caveat: Vendor page. Those three names stay function labels, not a second product and not proof of separate SKUs.

identity · vendor statement · high confidence · retrieved 3 Oct 2026 · SampleManager LIMS Software product page
<https://www.thermofisher.com/us/en/home/digital-solutions/lab-informatics/lab-information-management-systems-lims/solutions/samplemanager.html>
- The ELN page identifies Labguru as Thermo Fisher's chosen ELN, able to integrate with Thermo Scientific LIMS, and does not say Labguru is the notebook built into SampleManager.

Caveat: Separate ELN. The same text was returned for core-eln.html.

identity · vendor statement · high confidence · retrieved 3 Oct 2026 · Electronic Lab Notebook (ELN) / Labguru
<https://www.thermofisher.com/us/en/home/digital-solutions/lab-informatics/electronic-lab-notebook-el.html>
- Catalog INF-11000 shows Price (USD) as Request A Quote and describes one solution as LIMS and SDMS plus process execution called procedural ELN (LES). It also calls SampleManager the world's most widely deployed LIMS.

Caveat: No numeric list price. The deployment claim has no method.

pricing · vendor statement · high confidence · retrieved 3 Oct 2026 · SampleManager LIMS Software catalog INF-11000
<https://www.thermofisher.com/order/catalog/product/INF-11000>
- Purchase order N3904023P0075 to Thermo Lab Systems Inc. obligates USD 131,771.72 for THERMOFISHER SAMPLEMANAGER LICENSES, signed 2023-03-02, Navy Portsmouth Naval Shipyard office, firm fixed price, PSC 7A21.

Caveat: Not a list price. Place of performance Philadelphia matches the recipient address.

pricing · procurement · high confidence · published 2023-03-02 · retrieved 3 Oct 2026 · USAspending award N3904023P0075
https://www.usaspending.gov/award/CONT_AWD_N3904023P0075_9700_-NONE-_NONE-

Autoscribe Matrix Gemini LIMS

VENDOR	Autoscribe Informatics
CATEGORY	LIMS
PRICING STANCE	Quote-only. (Pricing class: quote-only.)
INDEPENDENT REVIEW	Passed 2026-10-02
ONLINE PROFILE	https://www.regdatalab.com/software/autoscribe-matrix-gemini

Profile summary

Matrix Gemini is a configurable, no-code LIMS from a small UK vendor, Autoscribe Informatics, now owned by Instem through its 2025 purchase of Xybion. It sells to QC labs across industries, including pharma QC and stability, with an Express edition for small labs, and holds public contracts with the University of Glasgow's veterinary diagnostic lab and a USDA research lab.

Top claims with sources (5 of 38)

Each claim is followed by its caveat (if the evidence row has one), then topic · source type · confidence · dates · source title, then the source URL. The online profile has the full evidence set.

- 1.** Matrix Gemini LIMS is Autoscribe's flagship LIMS, configured without custom coding, with desktop and browser use, and deployment on a local server, a remote site, or in the cloud.

Caveat: Vendor product page. Compliance sentence on the same page is marketing, not a certificate.

identity · vendor statement · high confidence · retrieved 2 Oct 2026 · Matrix Gemini LIMS

<https://www.autoscribeinformatics.com/lims-laboratory-information-management-system/matrix-gemini>
- 2.** Core named LIMS products are Matrix Gemini LIMS and Matrix Gemini LIMS Express; Matrix Tracker is a separate tracking-only product that excludes testing and analytical results.

identity · vendor statement · high confidence · retrieved 2 Oct 2026 · Laboratory Information Management System (LIMS)

<https://www.autoscribeinformatics.com/lims-laboratory-information-management-system>
- 3.** Matrix Gemini LIMS Express is an off-the-shelf introductory LIMS described as competitively priced and low cost, with no currency amount, and with a Part 11-oriented audit trail.

Caveat: No price figure. 'Competitively priced' is not a list price.

pricing · vendor statement · high confidence · retrieved 2 Oct 2026 · Matrix Gemini LIMS Express

<https://www.autoscribeinformatics.com/lims-laboratory-information-management-system/matrix-gemini-lims-express>
- 4.** No public list price was found on the flagship, Express, About, or Instem pages opened on 2026-10-02.

Caveat: Procurement figures below are not list prices.

pricing · our analysis · high confidence · retrieved 2 Oct 2026 · Matrix Gemini LIMS

<https://www.autoscribeinformatics.com/lims-laboratory-information-management-system/matrix-gemini>
- 5.** Matrix Gemini v6.0, announced 12 October 2021, added 64-bit support, a new calculation engine, and further multi-language user interfaces.

Caveat: 2021 release. Not evidence of the 2026 build.

architecture · vendor statement · high confidence · published 2021-10-12 · retrieved 2 Oct 2026 · Autoscribe Demonstrates Matrix Gemini LIMS v6.0 at Lab Innovations

<https://www.autoscribeinformatics.com/resources/press-releases/autoscribe-demonstrates-matrix-gemini-lims-v6-0-at-lab-innovations>

Agilent SLIMS

VENDOR	Agilent
CATEGORY	LIMS (vendor also describes ELN and LES in the same product)
PRICING STANCE	Quote-only. (Pricing class: quote-only.)
INDEPENDENT REVIEW	Passed 2026-10-02
ONLINE PROFILE	https://www.regdatalab.com/software/agilent-slims

Profile summary

Agilent SLIMS is a combined LIMS, ELN, and lab execution system that Agilent bought with Genohm in 2018, built for biobanks and NGS labs and now pitched to pharma QC through stability studies and a direct OpenLab CDS handoff. Its best-documented public buyer is the UK Health Security Agency, which runs it as a critical dependency in its genome-sequencing labs.

Top claims with sources (5 of 24)

Each claim is followed by its caveat (if the evidence row has one), then topic · source type · confidence · dates · source title, then the source URL. The online profile has the full evidence set.

- Agilent SLIMS is described as a combined LIMS and ELN in one laboratory execution system, and the FAQ says SLIMS means a smart laboratory information management system.

Caveat: Vendor marketing page. Copyright line says 2025. No publication date.

identity · vendor statement · high confidence · retrieved 2 Oct 2026 · The best of LIMS & ELN in one software | Agilent SLIMS
<https://explore.agilent.com/AgilentSLIMS>
- The 2 May 2018 release calls SLIMS a LIMS and ELN for biobanks, research labs, and NGS, and John Sadler says its architecture is aligned with OpenLab rather than identical to it.

Caveat: 2018 positioning. Current pages add LES language.

identity · press · high confidence · published 2018-05-02 · retrieved 2 Oct 2026 · Acquisition of Genohm, 2 May 2018
https://documents.epfl.ch/groups/e/ep/epflmedia/www/20180502_Genohm/Final%20Press%20Release%20Genohm%20Acquisition.pdf
- No public list price was found on the SLIMS pages opened on 2026-10-02.

Caveat: A price could exist on a blocked www.agilent.com page or behind a form.

pricing · our analysis · high confidence · retrieved 2 Oct 2026 · Agilent SLIMS explore page
<https://explore.agilent.com/AgilentSLIMS>
- The August 2022 GSA document for contract GS-07F-0564X does not name SLIMS, LIMS, or Genohm and does not print a SLIMS price.

Caveat: Text read from the Internet Archive capture of that same file, archived 2024-06-26. The awarded-SIN table prints 531490L, which does not match cover SIN 532490L. Neither line is SLIMS.

pricing · procurement · high confidence · published 2022-08 · retrieved 2 Oct 2026 · GSA Authorized FSS Price List, August 2022, GS-07F-0564X
<https://www.agilent.com/cs/library/support/Sales-Services-Terms/GS07F0564X-authorized-FSS-price-list-august-2022-Agilent-TermsOfUse.pdf>
- The explore page says SLIMS can be hosted on an Agilent server, at a cloud provider, or on a customer server, that deployment is 100 percent remote, and that the client is a web browser.

Caveat: No cloud vendor, database, or version is named.

architecture · vendor statement · high confidence · retrieved 2 Oct 2026 · Agilent SLIMS explore page
<https://explore.agilent.com/AgilentSLIMS>

Sapio GMP LIMS

VENDOR	Sapio Sciences
CATEGORY	LIMS
PRICING STANCE	Quote-only. (Pricing class: quote-only.)
INDEPENDENT REVIEW	Passed 2026-10-03
ONLINE PROFILE	https://www.regdatalab.com/software/sapio-gmp-lims

Profile summary

Sapio GMP LIMS is the GMP packaging of Sapio Sciences' cloud lab informatics platform, launched in June 2024 with QC, environmental monitoring, and stability modules and extended to electronic batch records in October 2024. Sapio's installed base is in biotech and pharma R&D, and Sapio says 8 of the top 10 pharma companies use its software; GMP manufacturing QC is the market its investor named as an expansion target in 2022, and no named GMP plant deployment is public yet.

Top claims with sources (6 of 43)

Each claim is followed by its caveat (if the evidence row has one), then topic · source type · confidence · dates · source title, then the source URL. The online profile has the full evidence set.

- The current public product page is headed Sapio GMP LIMS and describes a no/low-code GMP LIMS for regulated manufacturing, including pharmaceuticals.

Caveat: Vendor product page. No version number on the page.

identity · vendor statement · high confidence · retrieved 3 Oct 2026 · GMP-Compliant Lab Informatics
<https://www.sapiosciences.com/solutions/gmp-lims/>
- On 25 June 2024 Sapio announced Sapio GMP LIMS as available, including QC LIMS, environmental monitoring programs, and stability management, and claimed 21 CFR Part 11 and EU Annex 11 compliance.

Caveat: Vendor newsroom. Compliance wording is not a regulator certificate.

identity · press · high confidence · published 2024-06-25 · retrieved 3 Oct 2026 · Sapio Sciences Introduces Sapio GMP LIMS
<https://www.sapiosciences.com/news/sapio-gmp-lims-unmatched-flexibility-sapio-sciences/>
- The QC page's dollar ranges are labeled annual value for a representative lab, not a software price.

Caveat: Illustrative vendor ROI. Not a quote and not an audited saving.

pricing · vendor statement · high confidence · retrieved 3 Oct 2026 · GMP QC LIMS with Self-Service Process Configuration
<https://www.sapiosciences.com/solutions/qc-lims/>
- The public pricing page asks for a proposal and lists LIMS add-ons and bundles with no currency amounts. GMP LIMS is not a priced bundle title on that page.

Caveat: Quote-only. Footer ELN Bronze signup was not followed.

pricing · vendor statement · high confidence · retrieved 3 Oct 2026 · Sapio Pricing
<https://www.sapiosciences.com/sapio-pricing/>
- The QC page attributes report generation to ELaiN, described as the AI co-scientist built into the platform, and names Claude, Copilot, ChatGPT, and Gemini.

Caveat: Platform assistant named on a QC page. Not evidence that ELaiN is a GMP module.

architecture · vendor statement · high confidence · retrieved 3 Oct 2026 · GMP QC LIMS with Self-Service Process Configuration
<https://www.sapiosciences.com/solutions/qc-lims/>
- The general Sapio LIMS page lists cloud or on-premise options and says the LIMS is GLP, GCP, and GMP compliance ready. It does not state a GMP LIMS version.

Caveat: General LIMS page. The GMP solution pages do not repeat the on-premise sentence.

architecture · vendor statement · high confidence · retrieved 3 Oct 2026 · Laboratory Information Management System (LIMS)
<https://www.sapiosciences.com/products/lims/>

BIOVIA ONE Lab LIMS

VENDOR	Dassault Systèmes
CATEGORY	LIMS
PRICING STANCE	Quote-only. A £576 G-Cloud rate is a different BIOVIA service and is not this price. (Pricing class: quote-only.)
INDEPENDENT REVIEW	Passed 2026-10-02
ONLINE PROFILE	https://www.regdatalab.com/software/biovia-one-lab

Profile summary

BIOVIA ONE Lab LIMS is Dassault Systèmes' LIMS, sold as one part of a ONE Lab suite that puts LIMS, procedure execution (LES), and ELN on a single data model, with review by exception for batch release. It targets large R&D and QA/QC organizations in life sciences, consumer goods, and energy and materials that want to consolidate several ELNs and LIMS into one platform.

Top claims with sources (6 of 26)

Each claim is followed by its caveat (if the evidence row has one), then topic · source type · confidence · dates · source title, then the source URL. The online profile has the full evidence set.

- 1.** ONE Lab LIMS is described as digitalizing samples, laboratory tasks, studies, and instrument metrology, and as able to take the place of a traditional LIMS while adding procedure execution on one data model.

Caveat: Vendor product page.

identity · vendor statement · high confidence · retrieved 2 Oct 2026 · ONE Lab LIMS
<https://www.3ds.com/products/biovia/one-lab/lims>
- 2.** The parent ONE Lab page positions the suite for life sciences, consumer packaged goods, and energy and materials, across research, development, and QA/QC, and says it removes barriers between ELN, LIMS, LES, equipment, and inventory.

Caveat: Vendor positioning of the suite, not of the LIMS SKU alone.

identity · vendor statement · high confidence · retrieved 2 Oct 2026 · BIOVIA ONE Lab
<https://www.3ds.com/products/biovia/one-lab>
- 3.** No public list price for ONE Lab LIMS was found on the product pages or in the Essentials brochure.

pricing · our analysis · high confidence · retrieved 2 Oct 2026 · ONE Lab LIMS
<https://www.3ds.com/products/biovia/one-lab/lims>
- 4.** UK G-Cloud 14 lists Chemical, Materials and Bioscience - BIOVIA from DASSAULT SYSTEMES UK LIMITED at £576 a user a year. The listing describes BIOVIA Unified Lab and ScienceCloud, not ONE Lab LIMS by name.

Caveat: This is a catalog price for the titled service. It is not a demonstrated ONE Lab LIMS list price. Framework printed as G-Cloud 14.

pricing · procurement · high confidence · retrieved 2 Oct 2026 · Chemical, Materials and Bioscience - BIOVIA, Digital Marketplace
<https://www.applytosupply.digitalmarketplace.service.gov.uk/g-cloud/services/547426717364799>
- 5.** ONE Lab is offered cloud and on premise, and Dassault says both use the same code stream.

Caveat: No residency regions or RPO/RTO on this page. TCO is qualitative.

architecture · vendor statement · high confidence · retrieved 2 Oct 2026 · BIOVIA ONE Lab
<https://www.3ds.com/products/biovia/one-lab>
- 6.** Dassault says it provides ONE Lab validation kits and that cloud automation performs initial validation steps so the customer receives an environment ready for final validation.

Caveat: No protocol or GAMP category published on the page.

architecture · vendor statement · high confidence · retrieved 2 Oct 2026 · BIOVIA ONE Lab
<https://www.3ds.com/products/biovia/one-lab>

ADJACENT PRODUCT

Benchling Notebook

VENDOR	Benchling
CATEGORY	Adjacent ELN
PRICING STANCE	No public commercial list price. (Pricing class: quote-only.)
INDEPENDENT REVIEW	Passed 2026-10-03
ONLINE PROFILE	https://www.regdatalab.com/software/benchling-notebook

Profile summary

Benchling Notebook is the cloud ELN at the center of Benchling's R&D platform, where biotech and biopharma scientists record experiments and link them to registered samples, inventory, and results. It is adjacent because it is a research notebook, not a QC LIMS or an MES (Benchling sells batch execution separately as Bioprocess for process development), and its buyers run from free academic labs and startups to large biopharma R&D groups, with enterprise pricing quote-only.

Top claims with sources (5 of 32)

Each claim is followed by its caveat (if the evidence row has one), then topic · source type · confidence · dates · source title, then the source URL. The online profile has the full evidence set.

- 1.** The Notebook page presents Benchling Notebook as an electronic lab notebook and says the product is more than an ELN because it can model biomolecules, small molecules, cell lines, animals, and reagents.

Caveat: Vendor positioning. Modeling those entities is also described on the separate Registry page.

identity · vendor statement · high confidence · retrieved 3 Oct 2026 · Online Lab Notebook (ELN) Software
<https://www.benchling.com/notebook>
- 2.** The pharma LIMS page says Benchling is more than a LIMS and lists Notebook as one module among Molecular Biology, Registry, Inventory, Workflows, Lab Automation, and Studies.

Caveat: Vendor category marketing. It does not isolate a GMP QC LIMS product. This profile keeps Notebook adjacent and does not treat the page as proof that Notebook is a LIMS.

identity · vendor statement · high confidence · retrieved 3 Oct 2026 · Modern LIMS for pharma
<https://www.benchling.com/lims-for-pharma>
- 3.** The pricing page publishes no dollar amount and describes a customized quote for products, add-ons, validation support, and services.

Caveat: Quote-only. Not a list price.

pricing · vendor statement · high confidence · retrieved 3 Oct 2026 · Benchling Pricing
<https://www.benchling.com/pricing>
- 4.** Benchling states that the academic plan is free and includes Notebook and Molecular Biology, and that Inventory and Registry are not part of that academic plan.

Caveat: A free tier for a named subset. Not the enterprise price. The page also says AI is free to try for verified academic accounts.

pricing · vendor statement · high confidence · retrieved 3 Oct 2026 · Benchling for Academics
<https://www.benchling.com/academic>
- 5.** A 2026-10-03 web search did not return an FDA warning letter that names Benchling as the inspected software.

Caveat: Not a full FDA corpus query. A failed or empty search is a gap, not proof that no inspected firm uses the software.

regulatory · our analysis · low confidence · retrieved 3 Oct 2026 · Web search for FDA warning letters naming Benchling
<https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters>

ADJACENT PRODUCT

Tulip frontline operations platform

VENDOR	Tulip
CATEGORY	Adjacent frontline / composable operations platform
PRICING STANCE	Essentials \$100 and Professional \$250 per interface per month, billed annually. Enterprise and Regulated Industries quote-only. Not a plant-wide MES price. (Pricing class: public-floor.)
INDEPENDENT REVIEW	Passed 2026-10-03
ONLINE PROFILE	https://www.regdatalab.com/software/tulip

Profile summary

Tulip is a no-code frontline operations platform whose pharma app suite, marketed as a composable MES, covers weigh and dispense, eBR review by exception, packaging, sampling, and equipment logbooks. It stays adjacent because the suite is a set of customer-configured apps rather than a plant-wide GMP system of record, and its buyers are pharmaceutical and biotech manufacturers that want guided operator workflows, electronic records, and faster change, starting at a published \$100 per interface per month with the 21 CFR Part 11 tier quote-only.

Top claims with sources (4 of 22)

Each claim is followed by its caveat (if the evidence row has one), then topic · source type · confidence · dates · source title, then the source URL. The online profile has the full evidence set.

- 1.** Tulip's pharma page markets the product as an MES for pharmaceutical manufacturing and also calls it composable, no-code, and cloud-native.

Caveat: Vendor category language. This profile keeps the product adjacent. The older industry URL redirected to this page.

identity · vendor statement · high confidence · retrieved 3 Oct 2026 · Composable MES for Pharmaceutical and BioTech Manufacturing
<https://tulip.co/solutions/composable-mes-for-pharma/>
- 2.** The pharma library describes a composable app suite for electronic batch records, including blending, tableting, weigh and dispense, packaging, sampling, and review by exception.

Caveat: Template library, not a customer deployment.

identity · vendor statement · high confidence · retrieved 3 Oct 2026 · Composable MES for Pharma library suite
<https://library.tulip.co/suites/composable-mes-for-pharma>
- 3.** Essentials is listed at \$100 per month per interface, billed annually, with a 10-interface minimum, and the feature list does not include Part 11 e-signatures.

Caveat: Vendor-site unit price. The card still says Contact Sales. This profile does not multiply the unit price into an annual contract total.

pricing · vendor statement · high confidence · retrieved 3 Oct 2026 · Tulip Plans and Pricing
<https://tulip.co/plans/>
- 4.** Professional is listed at \$250 per month per interface, billed annually, with a 10-interface minimum, and adds HTTP and SQL connectors, an on-premise connector host, and the Tulip API.

Caveat: Vendor-site unit price. Not a regulated-tier price. Connector types are not a named ERP certification.

pricing · vendor statement · high confidence · retrieved 3 Oct 2026 · Tulip Plans and Pricing
<https://tulip.co/plans/>

ADJACENT PRODUCT

TraceLink serialization (SNM / SOM)

VENDOR	TraceLink
CATEGORY	Adjacent SNM / SOM
PRICING STANCE	Quote-only. (Pricing class: quote-only.)
INDEPENDENT REVIEW	Passed 2026-10-03
ONLINE PROFILE	https://www.regdatalab.com/software/tracelink-serialization

Profile summary

TraceLink is a serialization and DSCSA compliance network: Serial Number Manager issues serial numbers, and Serialized Operations Manager records serialized packaging, warehouse, and distribution events across manufacturers, CMOs, 3PLs, and trading partners. It is adjacent to MES because it runs beside packaging and warehouse systems with no batch record or batch release, and it is bought by pharmaceutical manufacturers, CMOs, contract packagers, and distributors that must exchange serialized data with governments and trading partners.

Top claims with sources (5 of 18)

Each claim is followed by its caveat (if the evidence row has one), then topic · source type · confidence · dates · source title, then the source URL. The online profile has the full evidence set.

- 1. TraceLink's serialization index describes a multi-product solution for meeting serialization requirements in dozens of markets and scaling over millions of units.**
Caveat: Vendor positioning. The page names several products rather than one SKU.
identity · vendor statement · high confidence · retrieved 3 Oct 2026 · TraceLink Serialization
<https://www.tracelink.com/products/product-orchestration/serialization>
- 2. Serial Number Manager generates, imports, replenishes, and provisions serialized identifiers for saleable units, bundles, cases, and pallets, including GS1 SGTIN and SSCC, CN-EDMC, and Russia Crypto Codes.**
Caveat: Vendor capability list. Not a certificate that a national system accepted a file.
identity · vendor statement · high confidence · retrieved 3 Oct 2026 · Serial Number Manager
<https://www.tracelink.com/products/product-orchestration/serialization/serial-number-manager>
- 3. SNM and SOM pages have no dollar price. Both say contact us.**
Caveat: Quote-only. The SOM URL was checked separately and also has no price.
pricing · vendor statement · high confidence · retrieved 3 Oct 2026 · Serial Number Manager and Serialized Operations Manager
<https://www.tracelink.com/products/product-orchestration/serialization/serial-number-manager>
- 4. The about page says Integrate-Once eliminated billions in integration cost and does not provide a method or a currency.**
Caveat: Marketing scale claim. Not a price and not a measured saving.
pricing · vendor statement · low confidence · retrieved 3 Oct 2026 · About TraceLink timeline
<https://www.tracelink.com/about>
- 5. The about page's current chapter describes an agentic supply-chain operating system on OPUS, which is broader than serialization.**
Caveat: Company strategy. This profile does not treat OPUS agents as a serialization feature unless a serialization page says so. They do not.
architecture · vendor statement · high confidence · retrieved 3 Oct 2026 · About TraceLink
<https://www.tracelink.com/about>

ADJACENT PRODUCT

Waters NuGenesis SDMS

VENDOR	Waters
CATEGORY	Adjacent SDMS, not a LIMS
PRICING STANCE	Quote-only. (Pricing class: quote-only.)
INDEPENDENT REVIEW	Passed 2026-10-03
ONLINE PROFILE	https://www.regdatalab.com/software/waters-nugenesis-sdms

Profile summary

NuGenesis SDMS is Waters' scientific data management system: it captures, catalogs, and archives instrument output, including Empower CDS chromatography data, and is the repository under the NuGenesis LMS analytical ELN. It is adjacent rather than a LIMS because it stores and retrieves lab data and hands selected results to a LIMS or ERP, and Waters sells it to pharmaceutical, biotechnology, and environmental labs that must retain data under GLP, GxP, cGMP, and 21 CFR Part 11.

Top claims with sources (5 of 18)

Each claim is followed by its caveat (if the evidence row has one), then topic · source type · confidence · dates · source title, then the source URL. The online profile has the full evidence set.

- 1.** Waters describes NuGenesis SDMS as an automated data repository and the foundation of NuGenesis LMS, and lists GLP, GxP, cGMP, 21 CFR Part 11, Sarbanes-Oxley, and EPA CROMERRR as standards it helps meet.
Caveat: Vendor compliance list. Not a regulator certificate.
identity · vendor statement · high confidence · retrieved 3 Oct 2026 · NuGenesis SDMS product page
<https://www.waters.com/nextgen/us/en/products/informatics-and-software/lms-and-data-management/nugenesis-software/nugenesis-sdms.html>
- 2.** The SDMS page says the product captures printouts, raw spectra and chromatograms, documents, Windows and UNIX content, and JCAMP-DX, and that it supports retention, retirement, and legal hold.
Caveat: Marketing page. No file-format matrix was attached.
identity · vendor statement · high confidence · retrieved 3 Oct 2026 · NuGenesis SDMS product page
<https://www.waters.com/nextgen/us/en/products/informatics-and-software/lms-and-data-management/nugenesis-software/nugenesis-sdms.html>
- 3.** The SDMS marketing page publishes no dollar price.
Caveat: Quote-only on the vendor page. Not a finding that a GSA schedule has no price. That schedule page did not load.
pricing · vendor statement · high confidence · retrieved 3 Oct 2026 · NuGenesis SDMS product page
<https://www.waters.com/nextgen/us/en/products/informatics-and-software/lms-and-data-management/nugenesis-software/nugenesis-sdms.html>
- 4.** The SDMS page includes InSpector as a vendor-independent viewer for NMR, MS, chromatography, and related techniques, and it says the system can scale from one laboratory to a global enterprise.
Caveat: No cloud, region, or uptime figure is on the page. Release notes describe Windows and Oracle, which is a different and more on-premises picture.
architecture · vendor statement · high confidence · retrieved 3 Oct 2026 · NuGenesis SDMS product page
<https://www.waters.com/nextgen/us/en/products/informatics-and-software/lms-and-data-management/nugenesis-software/nugenesis-sdms.html>
- 5.** A 9.0 note on the releases page calls SDMS the LMS base kit and distinguishes an LMS option kit, and a 9.0.2 note distinguishes a customer Oracle 19c license from a Waters embedded Oracle 12.2 license on Windows.
Caveat: Support-matrix language for named versions, not a 2026 architecture white paper. Confirm the row before relying on the October 2020 date.
architecture · vendor statement · medium confidence · retrieved 3 Oct 2026 · NuGenesis Software releases overview
<https://help.waters.com/help/en/product-support/nugenesis-software-support-solutions/nugenesis-software-releases-overview.html>

ADJACENT PRODUCT

IDBS Polar

VENDOR	IDBS
CATEGORY	Adjacent R&D informatics platform, not a separate GMP LIMS or plant MES
PRICING STANCE	Quote-only. (Pricing class: quote-only.)
INDEPENDENT REVIEW	Passed 2026-10-03/04
ONLINE PROFILE	https://www.regdatalab.com/software/idbs-polar

Profile summary

IDBS Polar is Danaher's biopharma R&D informatics platform: one cloud system that combines an ELN (Explorer), a spreadsheet-style LES (Advance), and LIMS-style inventory and genealogy, built for work from preclinical through process development, scale-up, and tech transfer. It is adjacent because its LIMS functions live inside an R&D platform rather than a standalone GMP QC LIMS and it runs no commercial batch records, and IDBS sells it to biopharma R&D and process-development groups in either a GxP or a non-GxP configuration.

Top claims with sources (4 of 28)

Each claim is followed by its caveat (if the evidence row has one), then topic · source type · confidence · dates · source title, then the source URL. The online profile has the full evidence set.

- 1.** The current Polar page calls the product an enterprise lab informatics platform with ELN, LES, and LIMS capabilities for research through development, not a standalone LIMS or MES.

Caveat: Vendor positioning. LIMS is described as a capability of this platform.

identity · vendor statement · high confidence · retrieved 3 Oct 2026 · IDBS Polar product page
<https://www.idbs.com/polar/>
- 2.** On 4 December 2020, in a release datelined Guildford, IDBS announced Polar as BioPharma Lifecycle Management software for drug development and manufacturing in biopharma research.

Caveat: 2020 category launch. The history page's 'world's first' phrase is marketing.

identity · vendor statement · high confidence · published 2020-12-04 · retrieved 3 Oct 2026 · IDBS launches Polar, 4 December 2020
<https://www.idbs.com/2020/12/idbs-launches-polar-in-a-new-product-category-that-aims-to-streamline-and-speed-up-biopharmaceutical-development/>
- 3.** Polar's own page assigns ELN to Explorer, LES to Advance, and LIMS-style inventory to a module named Inventory, all inside one platform.

Caveat: Does not isolate a separate GMP LIMS product. Kept adjacent.

capabilities · vendor statement · high confidence · retrieved 3 Oct 2026 · IDBS Polar product page
<https://www.idbs.com/polar/>
- 4.** A Cytiva executive is quoted in the IDBS launch release about siloed development knowledge. The quote does not say Cytiva deployed Polar.

Caveat: Endorsement hosted by IDBS, not a customer case study.

customers · vendor statement · high confidence · published 2020-12-04 · retrieved 3 Oct 2026 · IDBS launches Polar, 4 December 2020
<https://www.idbs.com/2020/12/idbs-launches-polar-in-a-new-product-category-that-aims-to-streamline-and-speed-up-biopharmaceutical-development/>

ADJACENT PRODUCT

Körber PAS-X Track & Trace

VENDOR	Körber
CATEGORY	Adjacent serialization, not PAS-X MES
PRICING STANCE	Quote-only. (Pricing class: quote-only.)
INDEPENDENT REVIEW	Passed 2026-10-03
ONLINE PROFILE	https://www.regdatalab.com/software/korber-pas-x-track-and-trace

Profile summary

PAS-X Track & Trace is Körber's level 3 serialization and aggregation site manager: it sits between packaging-line controllers and ERP, MES, and serial-number repositories, and V3 (March 2025) runs on-premise, in the customer's cloud, or as Körber-managed SaaS. It is adjacent because it handles serialization and aggregation, not batch execution, which Körber sells separately as PAS-X MES, and it is sold to pharmaceutical and biotech manufacturers that must serialize for market-specific anti-counterfeiting rules.

Top claims with sources (5 of 31)

Each claim is followed by its caveat (if the evidence row has one), then topic · source type · confidence · dates · source title, then the source URL. The online profile has the full evidence set.

1. On 4 March 2025 in Lüneburg, Körber launched the latest PAS-X Track & Trace version, described as minimizing total cost of ownership through lifecycle management and vendor-agnostic integration.

Caveat: Vendor release. TCO is named but not quantified.

identity · press · high confidence · published 2025-03-04 · retrieved 4 Oct 2026 · Körber releases new cloud-native PAS-X Track & Trace

<https://www.koerber.com/en/about-us/news-and-press/new-cloud-native-pas-x-track-trace>
2. Körber product owner René Reuter called the latest PAS-X Track & Trace a lean, functionally complete, cloud-native solution aimed at lower TCO and lifecycle management.

Caveat: Quote of René Reuter, Product Owner Software, Körber Business Area Pharma. Marketing quote, not a customer result.

identity · press · high confidence · published 2025-03-04 · retrieved 4 Oct 2026 · Körber releases new cloud-native PAS-X Track & Trace

<https://www.koerber.com/en/about-us/news-and-press/new-cloud-native-pas-x-track-trace>
3. No public list price, currency amount, or license metric for PAS-X Track & Trace was on the V3 release, the packaging page, the factsheet page, or the track-and-trace hub.

Caveat: The 90 percent infrastructure claim is not a price. Quote-only.

pricing · our analysis · high confidence · retrieved 4 Oct 2026 · PAS-X Track & Trace pages inspected for a price

<https://www.koerber.com/en/about-us/news-and-press/new-cloud-native-pas-x-track-trace>
4. The same Track & Trace section claims infrastructure and update costs can fall by up to 90 percent and that uptime is near-zero downtime.

Caveat: No baseline, sample, or method. Not a price.

pricing · vendor statement · low confidence · retrieved 4 Oct 2026 · Packaging and serialization

<https://www.koerber.com/en/solutions/software-and-ai/life-sciences-mes/digital-manufacturing/packaging-and-serialization>
5. The PAS-X Track & Trace section of the packaging page says it integrates ERP, MES, and packaging lines to manage serialized and aggregated products and handles coding requirements including GS1 and 21 CFR Part 11.

Caveat: Undated marketing page. Part 11 wording is a vendor claim, not an FDA certificate. DSCSA and EU FMD are not named in this section.

regulatory · vendor statement · high confidence · retrieved 4 Oct 2026 · Packaging and serialization

<https://www.koerber.com/en/solutions/software-and-ai/life-sciences-mes/digital-manufacturing/packaging-and-serialization>

SOURCES AND REFRESH

Sources and refresh

DATASET DATE	2026-10-04
PRODUCTS	33 (MES 9, QMS 10, LIMS 8, adjacent 6)
SOURCED CLAIMS	1,182
EXCLUDED	Körber PAS-X MES is held back: its dossier did not pass independent review on 4 Oct 2026. PAS-X Track & Trace is a separate product and is included.

Where the sources are

This guide prints the top claims for each product with full source URLs. The online edition carries the complete record: full profiles, every sourced claim, and each product's sources note, which lists every source and what it supports. The same data is available to AI agents through the RegDataLab MCP tools `software_search_products`, `software_get_product`, `software_compare`, `software_list_evidence`, and `software_get_sources`.

Online edition: <https://www.regdatalab.com/software>

Refresh

This edition reflects the dossiers as of 2026-10-04. Each research refresh produces a new edition from the same dataset, dated to that refresh.