Empower vs OpenLab vs Chromeleon: CDS Comparison Guide

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Executive Summary

Pharmaceutical, biotech, and contract-testing laboratories comparing **empower vs openlab vs chromeleon** are really choosing among the only three chromatography data system (CDS) vendors with meaningful global scale: Waters **Empower** (currently Empower 3.10.0), Agilent **OpenLab CDS** (currently version 3.0; ChemStation Edition is a separate legacy line), and Thermo Fisher Scientific **Chromeleon** (7.4 is the current feature release; 7.3.2 is the current long-term-support release). Thermo Fisher's own competitive literature states that "only three global CDS suppliers" hold more than a 10 percent share of installed base and annual license sales (Source: assets.thermofisher.com, and Mordor Intelligence independently names the same three companies as the businesses that "anchor the field" of a global CDS market it sizes at $587.99 million in 2026, growing at a 7.54 percent compound annual growth rate (CAGR) to $845.53 million by 2031 (Source: mordorintelligence.com) (Source: mordorintelligence.com).

Waters claims the largest footprint by usage: Empower Software is installed on more than 5,000 networks with over 500,000 users worldwide (Source: aws.amazon.com), and Waters' investor materials state that approximately 80 percent of novel drugs submitted to the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), and China's National Medical Products Administration (NMPA) in 2023 used Empower (Source: ir.waters.com). Pricing is largely quote-based for enterprise deployments across all three vendors, but Thermo Fisher publishes a list price of $4,460.00 for a single-instrument Chromeleon Single Edition (SE) license on its webshop (Source: thermofisher.com), while a lab user reported a roughly $3,900 quote for a comparable OpenLab CDS license in 2023 (Source: reddit.com). Waters instead sells Empower primarily through subscription tiers (ES1, ES3, ES5) with no published per-seat price (Source: waters.com.

All three platforms are engineered around 21 CFR Part 11, the FDA regulation that treats electronic records and signatures as equivalent to paper when systems provide secure, computer-generated, time-stamped audit trails and restrict access to authorized users (Source: ecfr.gov). Thermo Fisher markets Chromeleon as explicitly falling "within the scope of 21 CFR Part 11" with over 160 assignable user privileges (Source: documents.thermofisher.com), Waters describes Empower as a "closed system" under Part 11 built on an Oracle relational database (Source: waters.com), and Agilent's OpenLab CDS requires documented confirmation that reviewers actually examined the audit trail (Source: redstar-cms.vn). Yet compliance features do not guarantee compliant use: FDA warning letters reviewed for this report name Empower directly at Indoco Remedies (2024), Mylan Laboratories Nashik (2017), and Tismor Health and Wellness (2019) for unreviewed or deleted audit trail entries (Source: fda.gov), OpenLab at Wisconsin Pharmacal (2025) for missing audit-trail review before batch release (Source: fda.gov), and Chromeleon data quality was central to the Delaware Court of Chancery's 2018 finding that let Fresenius Kabi terminate its roughly $4.75 billion acquisition of Akorn, Inc. after an expert concluded "the data itself is not trustworthy" (Source: courtlistener.com).

On capability, Chromeleon differentiates on multi-vendor instrument control (over 540 instruments, drawn from a broader claim of 525+ modules across 22 manufacturers) and enterprise scalability beyond 1,000 connected users (Source: thermofisher.com; Empower differentiates on breadth of driver support (700+ instrument models) and being marketed as "the first ever cloud-deployable CDS" (Source: waters.com); and OpenLab differentiates on its position inside Agilent's broader instrument and AI ecosystem, including the newer cloud-based OpenLab Sync platform aimed at pharmaceutical quality control (see Capabilities in the Agilent OpenLab CDS section below). No independent, third-party benchmark study comparing the three platforms head to head on performance was located during this research; all efficiency figures originate from vendor marketing rather than peer-reviewed measurement, and should be read as such. For organizations evaluating a CDS migration or validation strategy, the deciding factors in practice are less about raw feature checklists and more about existing instrument fleet composition, in-house Part 11 governance maturity, and the total cost of validation, an area where specialist life-sciences advisory support, distinct from the vendors themselves, is frequently used to structure the technology assessment (Source: intuitionlabs.ai).

Introduction and Background

A chromatography data system (CDS) is the software layer that acquires raw detector signal from high-performance liquid chromatography (HPLC), ultra-performance liquid chromatography (UPLC), and gas chromatography (GC) instruments, integrates and processes the resulting peaks, routes results through review and electronic sign-off, and retains the underlying electronic records for the multi-year periods that Good Manufacturing Practice (GMP) rules require. For a laboratory researching **empower vs openlab vs chromeleon**, the practical choice set is narrow. Waters'

Empower (Empower 3, now at version 3.10.0), Agilent's **OpenLab CDS**, and Thermo Fisher Scientific's **Chromeleon** (7.4 is the current feature release; 7.3.2 is the current long-term-support release) are the platforms that dominate regulated pharmaceutical, biotech, and contract testing labs, and Thermo Fisher's own third-party instrument-control white paper concludes bluntly that the CDS market has consolidated to "only three global CDS suppliers having a significant share (>10% installed base and annual license sales)" (Source: assets.thermofisher.com. Mordor Intelligence's 2026 market analysis reaches the same conclusion independently (see Data Analysis and Evidence below). This concentration is structural, not incidental: each vendor's CDS is built first to control that same company's own instrument line (Waters' ACQUITY and Alliance HPLC systems, Agilent's GC/LC/MS portfolio, Thermo Fisher's Dionex and Vanquish systems), and each has since layered on multi-vendor driver support. Chromeleon CDS natively controls over 540 Thermo Scientific and third-party LC, GC, IC, and MS instruments (Source: thermofisher.com, a historical Thermo Fisher white paper put the multi-vendor figure at over 525 modules from 22 different manufacturers (Source: assets.thermofisher.com), and Waters states Empower drivers cover more than 700 instrument models under a formal Instrument Control Partner Program (Source: waters.com) that includes Thermo Fisher's own LC, GC, and IC drivers (Source: waters.com.

Regulatory Backdrop: 21 CFR Part 11 and Data Integrity

The reason CDS selection is a compliance decision as much as a technical one is 21 CFR Part 11, the FDA regulation establishing when electronic records and electronic signatures are "trustworthy, reliable, and generally equivalent to paper records" (Source: ecfr.gov). Part 11 defines an electronic record broadly, as "any combination of text, graphics, data, audio, pictorial, or other information representation in digital form" (Source: ecfr.gov), which is why raw chromatograms and their audit trails are squarely regulated data. Its closed-system controls require "secure, computer-generated, time-stamped audit trails to independently record" changes to electronic records (Source: ecfr.gov) and require "limiting system access to authorized individuals" (Source: ecfr.gov), the two provisions that every CDS access-control and audit-trail feature is ultimately built to satisfy. FDA's 2003 Part 11 scope and application guidance narrowed enforcement, stating the agency did "not intend to take enforcement action to enforce compliance with the validation, audit trail, record retention, and record copying requirements" while still enforcing the underlying predicate-rule recordkeeping obligations (Source: fda.gov), and pointed firms to "industry guidance such as the GAMP 4 Guide" (the precursor to today's GAMP 5 framework) for validating systems like a CDS (Source: fda.gov).

That enforcement discretion did not stop data-integrity problems from recurring in inspections. FDA's 2018 "Data Integrity and Compliance With Drug CGMP" guidance was, in the agency's own words, "developed in response to an increase in findings of data integrity lapses in recent inspections" (Source: fda.gov). Outside the United States, the European Commission's EudraLex Volume 4 Annex 11 on computerized systems requires that "the application should be validated; IT infrastructure should be qualified" (Source: health.ec.europa.eu), calls for "the creation of a record of all GMP-relevant changes and deletions" (Source: health.ec.europa.eu), and requires firms to "restrict access to computerised system to authorised persons" (Source: health.ec.europa.eu). The UK's Medicines and Healthcare products Regulatory Agency (MHRA) supplies the mnemonic most labs use to judge whether a CDS record satisfies these rules: **ALCOA**, meaning data must be "Attributable, Legible, Contemporaneous, Original, and Accurate" (Source: assets.publishing.service.gov.uk), with guidance further specifying that "users should not be able to amend or switch off the audit trail" (Source: assets.publishing.service.gov.uk).

These are not abstract requirements. FDA's 2017 warning letter to Chongqing Pharma Research Institute found that "you had deleted entire chromatographic sequences and individual injections from your stand-alone computers" (Source: fda.gov), describing a practice where analysts would run extra injections and "delete any undesirable result" (Source: fda.gov). A 2025 warning letter to the Chromatography Institute of America cited the firm for lacking "restricted access and appropriate controls on computerized systems to prevent any potential alteration or deletion of laboratory data" (Source: fda.gov), and its remediation response, that it was merely "looking into installing technology with audit trail capability," was judged by FDA to be inadequate (Source: fda.gov). The Case Studies section below examines how these same failure patterns have played out specifically inside Empower, OpenLab, and Chromeleon deployments.

For a life-sciences and AI consultancy such as intuitionlabs.ai, this comparison sits squarely in the technology-assessment work the firm describes as helping organizations "make informed decisions about technology investments and implementations" (Source: intuitionlabs.ai), alongside "advisory services for maintaining compliance with industry regulations" (Source: intuitionlabs.ai) and, more broadly, the firm's description of its own team as bringing "Regulatory Compliance Know-How" to pharmaceutical and life-science engagements (Source: intuitionlabs.ai). IntuitionLabs does not sell or resell any of the three CDS platforms compared here, and its own service focus is centered on "strategic guidance on digital transformation, AI adoption, and technology roadmapping" (Source: intuitionlabs.ai) rather than laboratory software resale; its perspective, woven through this report, is that of an adjacent advisor helping regulated life-sciences organizations evaluate laboratory and enterprise software choices, not a competing vendor.

Waters Empower

Capabilities

Empower is Waters' flagship CDS, marketed across a deployment spectrum from a single workstation to full enterprise networks, with Waters stating users can "work at the bench, across sites, and even remotely with on-premises or cloud options" (Source: waters.com). As of August 2026, Empower 3.9.0 and above is fully compatible with Windows 11 (Source: waters.com), and the current release, Empower 3.10.0, adds expanded instrument support including multi-angle light scattering (MALS) detectors from Wyatt Technology (Source: waters.com). Peak integration is handled through Waters' proprietary **ApexTrack** algorithm, which the company says can "reduce manual integration, and calculate more precise peak integrations" (Source: waters.com), and **Empower Mobile** extends wireless review and sign-off access "from a tablet or smartphone" (Source: waters.com).

Deployment scales in named tiers: **Empower Personal**, the smallest tier, supports "up to four chromatographic systems" on one workstation (Source: waters.com), and **Empower Workgroup** "allows up to 10 users to connect to an unlimited number of systems" on a small network (Source: waters.com). At the top of the range, Waters markets Empower as "the first ever cloud-deployable CDS," offered as a cloud-deployed Empower Enterprise infrastructure-as-a-service option (Source: waters.com). A newer companion application, **Empower Data Viewer**, runs on the cloud-native waters_connect platform to "view, consolidate, and investigate chromatography data from Empower Software version FR4 SR3 and higher" (Source: waters.com) and includes an artificial intelligence/machine learning (AI/ML) "Anomaly Detection" feature that lets reviewers "compare target results with reference results to identify outliers" (Source: waters.com).

On architecture and compliance, Waters describes Empower as "a closed system" under Part 11 terminology (Source: waters.com), running on Oracle "as the underlying relational database, providing a robust and scalable architecture" (Source: waters.com). Waters' own compliance white paper states plainly that "audit trails are considered the key to the security of a system" (Source: waters.com), and Empower's role-based electronic-signature model can restrict, for example, "someone with pre-defined Chemist privileges" to signing only for review rather than final approval (Source: waters.com). Beyond pure chromatography, **Empower LMS** (Lab Management System) combines Empower CDS "with the added workflow" of Waters' NuGenesis platform for broader sample and instrument data management (Source: waters.com.

Adoption

Empower's installed base is the largest publicly claimed in the category. Waters' investor relations materials cite an overall corporate installed base of "170K+ systems" as of year-end 2024 (Source: ir.waters.com) and a company blog post (hosted on Amazon Web Services) states Empower Software specifically "has more than 500,000 users worldwide, is installed on over 5,000 networks" across 10 languages and more than 70 countries (Source: aws.amazon.com). Most notably for regulatory-affairs teams, Waters states that "approximately 80% of novel drugs submitted to the FDA, EMA, and China NMPA use Empower" as of 2023 (Source: ir.waters.com), a figure that, like the adoption statistics for OpenLab and Chromeleon below, comes from the vendor itself rather than an independent auditor and should be read with that provenance in mind.

Strengths and Limitations

Empower's strengths, on the evidence gathered, center on depth of installed regulatory track record and the breadth of its third-party driver library, which is formally certified for over 700 instrument models across a multi-vendor partner program (see Introduction above). Practitioner sentiment on Reddit's chromatography community frames Empower's rigidity, for instance its inability to let a user alter a sample set once a run has started, as an intentional compliance safeguard rather than a defect: one commenter wrote "this is a feature of Empower not a bug" (Source: reddit.com). The same discussion thread suggests a limitation on the instrument-control side: because "Waters is an LC-focused company," a commenter argued its support for competitor gas chromatography (GC) instruments lags behind its liquid chromatography (LC) driver quality (Source: reddit.com); this is a single practitioner's opinion rather than an independently verified benchmark, but it is a recurring theme in community discussion of cross-vendor CDS choice. On pricing transparency, Empower is a relative weak point: Waters requires a sales quote for its ES1/ES3/ES5 subscription tiers rather than publishing list prices (Source: waters.com, making pre-procurement budgeting harder than for Chromeleon, where at least a single-instrument list price is published (see Data Analysis and Evidence).

Agilent OpenLab CDS

Capabilities

OpenLab CDS is Agilent's chromatography platform, positioned as a single system that can "control your Agilent GC, LC, single quadrupole GC/MS, LC/MS instruments as well as other vendors'" hardware (Source: redstar-cms.vn), with native mass-spectrometry "data acquisition, data processing, and reporting" built into the same environment (Source: redstar-cms.vn). For labs migrating off older platforms, Agilent provides "automated software migration tools" that preserve results, methods, and instrument configuration data from legacy ChemStation, EZChrom, and Galaxie systems (Source: redstar-cms.vn). On compliance, current OpenLab CDS versions require that "audit trails now include confirmation and documentation of audit trail reviews" as part of the electronic record (Source: redstar-cms.vn).

An independent, vendor-neutral technical comparison of business-continuity features names "the current versions of the three most widely used chromatography data systems" as OpenLab CDS 2.8, Chromeleon 7.3.2, and Empower 3.9.0 (Source: wega-it.com), confirming OpenLab CDS 2.8's standing alongside its two rivals as of that assessment. In OpenLab CDS 2.8's networked (client-server) configuration, Agilent Instrument Controllers (AICs) cache project data locally, with "projects and project groups synchronized to the AIC cache every 30 minutes" (Source: wega-it.com). Agilent's newer **OpenLab Sync** platform extends this further with cloud deployment that "centralize[s] system administration, instrument management, along with secure backups" (Source: precedenceresearch.com), and is described as "an AI-enhanced lab execution along with workflow platform designed for pharmaceutical quality" control environments (Source: precedenceresearch.com), offering "technical controls, e-signatures, secure data repositories, along with timestamped audit trails" (Source: precedenceresearch.com). Agilent's newest GC hardware is built for "seamless integration with OpenLab CDS and MassHunter software packages" that "automates tedious data analysis" (Source: precedenceresearch.com). OpenLab's ecosystem history also includes cross-vendor data consolidation: as early as 2010, Agilent's OpenLAB Electronic Lab Notebook (ELN) could automatically ingest "chromatograms and result files from Agilent ChemStation, Waters Empower or other chromatography data systems" (Source: technologynetworks.com), an early sign of the platform's interoperability focus.

Adoption

Agilent's underlying instrument franchise is a strong proxy for OpenLab's installed base, since the CDS is typically sold alongside the hardware. A market-analysis summary states that "Agilent holds the number-one global market position in Gas Chromatography (GC) and then ranks consistently" among the top three in liquid chromatography (LC) and mass spectrometry (MS) (Source: precedenceresearch.com, the same three categories that OpenLab CDS is purpose-built to control. Direct fetches of Agilent's own product and pricing pages were blocked during this research (an access-control response consistent with automated bot protection on agilent.com), so, unlike Empower and Chromeleon, no first-party Agilent installed-base or customer-count statistic could be independently verified for this report; that gap is disclosed rather than filled with an unverified secondary figure.

Strengths and Limitations

OpenLab's Acquisition Failover Mode is a genuine resilience feature, but the same technical comparison that documents it also flags a compliance-relevant limitation: while operating in failover mode, "all actions within the software are executed in the context of the OpenLab system user" rather than an individually authenticated account (Source: wega-it.com), which weakens per-user attribution exactly when Part 11 access controls matter most. Data captured during the outage stays local until reconciled, since results "generated during failover mode remain in the cache on the AIC" and are not saved centrally until a manual sync (Source: wega-it.com), and the same source notes that "Agilent Technologies repeatedly points out that separate procedures must be developed on the customer side" to cover this exceptional operating mode (Source: wega-it.com), effectively pushing part of the compliance burden onto the customer's standard operating procedures (SOPs) rather than the software itself.

User sentiment gathered from a 2023 Reddit thread on replacing legacy ChemStation systems distinguishes two current Agilent CDS product lines: "there's the old OpenLab CDS Chemstation Edition and then there's the new OpenLab CDS 2.x" (Source: reddit.com), with the same commenter describing the newer OpenLab CDS 2.x as "much more user-friendly and feels like they actually contracted with a developer" (Source: reddit.com), a reminder that "OpenLab" today spans a legacy edition and a materially redesigned newer line, an important distinction for buyers comparing quotes.

Thermo Fisher Chromeleon

Capabilities

Chromeleon 7.3.2 is Thermo Fisher's currently marketed CDS release for pharmaceutical laboratories as of August 2026 (Source: thermofisher.com, promoted with a claim of raising "routine testing efficiency by up to 33%" versus prior versions (Source: thermofisher.com). Thermo Fisher markets the platform's data-integrity feature set as "capable of being configured to meet regulatory guidelines from FDA, EMA, MHRA, NMPA, PMDA" (Source: thermofisher.com), reflecting a genuinely global regulatory design target rather than an FDA-only feature set. Instrument control is broad: Chromeleon "controls over 540 Thermo Scientific (LC, GC, IC and MS) and third-party instruments" (Source: thermofisher.com.

At enterprise scale, Chromeleon "is built for on-premise, virtual, or cloud installations" (Source: thermofisher.com) and is designed to "grow beyond 1000+ of connected users/instruments/workstations without affecting performance" (Source: thermofisher.com). It offers a native, "seamless CDS link" to Thermo Fisher's own SampleManager laboratory information management system (LIMS), and for labs on other LIMS platforms, a Chromeleon Software Developer's Kit (SDK) for connection "to any other LIMS or business software" (Source: thermofisher.com). A built-in review-acceleration feature called SmartLink means "one mouse click activates the SmartLink and immediately all active panes reflect the currently displayed" chromatogram or peak (Source: documents.thermofisher.com).

On compliance architecture, Thermo Fisher states directly that "Chromeleon CDS is a system that falls within the scope of 21 CFR Part 11" (Source: documents.thermofisher.com), with role-based security allowing "over 160 different privileges" to be assigned "as appropriate to an unlimited number" of custom roles (Source: documents.thermofisher.com). Before an electronic signature is applied, "all of the source data and settings required to produce the report are automatically locked" and hash-coded against tampering (Source: documents.thermofisher.com). Thermo Fisher traces Chromeleon's lineage back further than either rival platform's current branding: a company white paper states that "1993 saw the introduction of the world's first commercially available chromatography data system" under an earlier product name in the Chromeleon lineage (Source: assets.thermofisher.com).

Adoption

Thermo Fisher's own competitive framing, discussed above, positions Chromeleon as one of just three vendors holding a greater-than-10-percent share of CDS installed base and annual license sales globally (Source: assets.thermofisher.com, a figure dated to 2018 in the source document and not refreshed with a newer independent estimate during this research. Customer testimony collected by Thermo Fisher includes a Charles River Laboratories scientist crediting Chromeleon with letting them "successfully design and perform analytical procedures, control multiple instruments simultaneously" (Source: thermofisher.com), and a published case study with contract research organization Owlstone Medical reports that upgrading to Chromeleon 7.3.2 delivered "processing up to 15 times faster than previous versions" (Source: thermofisher.com).

Strengths and Limitations

Chromeleon's clearest advantage over the other two platforms is public pricing transparency at the entry level: Thermo Fisher's webshop lists a single-instrument Chromeleon Single Edition (SE) license at $4,460.00 (Source: thermofisher.com), a concrete figure neither Waters nor Agilent publishes for their comparable entry tiers. Thermo Fisher also promotes mass-spectrometry-specific productivity tools that claim "up to 10x faster processing" for MS-heavy workflows (Source: thermofisher.com) (a vendor claim, like Empower's and OpenLab's efficiency figures, not independently benchmarked). On the limitations side, community troubleshooting threads on Reddit's chromatography forum describe recurring background-service conflicts in Chromeleon 7.3 installations (spanning local discovery services, SQL Express, and .NET framework dependencies) that sometimes require a full reinstall, with one user advising others to start by "checking that you have all chromeleon services up and running" (Source: reddit.com); this is anecdotal IT-support sentiment rather than a documented defect rate, but it recurs often enough in community discussion to be worth noting for buyers planning their own IT support model.

Feature Comparison

Table 1 below summarizes how Empower, OpenLab CDS, and Chromeleon compare across the dimensions most relevant to a pharmaceutical or biotech buyer, drawing on the vendor facts and citations established in the three vendor sections above.

DIMENSION	WATERS EMPOWER	AGILENT OPENLAB CDS	THERMO FISHER CHROMELEON
Current version (as of Aug. 2026)	Empower 3.10.0, Windows 11 compatible from 3.9.0	OpenLab CDS 3.0; ChemStation Edition is a separate legacy line	Chromeleon 7.4 feature release; Chromeleon 7.3.2 LTS release (latest listed update: MUf)
Deployment models	Workstation to enterprise; on-premises or cloud-deployable	Workstation or networked client-server; confirm supported configurations in the applicable OpenLab CDS release documentation	On-premise, virtual, or cloud; scales beyond 1,000+ connected users/instruments
Instrument control breadth	700+ instrument models via partner program	Agilent and non-Agilent LC, GC, LC/MS, and GC/MS workflows in one environment	540+ instruments; historically 525+ modules from 22 manufacturers
Part 11 / data integrity posture	Closed system; Oracle database; role-based e-signature privileges	Agilent describes technical controls for regulated data acquisition, processing, reporting, and storage	Explicitly designed within Part 11 scope; 160+ assignable privileges
Licensing and indicative pricing	Subscription tiers ES1/ES3/ES5, quote-only, no public price	User-reported quote of roughly $3,900 for a single license, as of 2023	Single Edition (SE), single-instrument list price $4,460.00
LIMS and workflow connections	NuGenesis-based Empower LMS	OpenLab Sync is a separate LES in Agilent’s OpenLab portfolio; assess CDS and LIMS integration requirements separately	Native SampleManager LIMS link plus open SDK

The table makes the underlying trade-off visible: Empower leads on documented adoption scale and third-party driver breadth, OpenLab is tightly coupled to Agilent's own instrument roadmap and is the only platform where public list pricing could not be independently confirmed from a vendor source in this research, and Chromeleon is alone in publishing an entry-level price and is marketed as configurable to meet guidance from five regulatory authorities or frameworks (FDA, EMA, MHRA, NMPA, and Japan's PMDA), rather than treating Part 11 as the sole design target. None of the three vendors publishes enterprise-tier pricing, so the comparable figures above (a published $4,460 Chromeleon SE license versus a reported $3,900 OpenLab quote) describe entry-level, single-instrument configurations, not the networked or cloud deployments most GMP labs eventually adopt.

Performance and Benchmarks

Direct, independent, head-to-head benchmarking of Empower, OpenLab, and Chromeleon on throughput, review time, or system uptime was not located during this research; every performance figure available in vendor literature comes from the vendor whose product it describes, as detailed in each platform's Capabilities and Strengths and Limitations sections above. Thermo Fisher's claimed testing-efficiency and mass-spectrometry processing-speed gains, Waters' ApexTrack integration-accuracy claims, and Agilent's failover-mode resilience design are all self-reported, vendor-published figures rather than measurements from a neutral test lab, and none specify the baseline configuration precisely enough to be reproduced independently.

On enterprise scale, Chromeleon is the platform in this comparison with the most explicit publicly stated numeric ceiling, engineered to scale beyond 1,000 connected users, instruments, and workstations; Waters and Agilent publish deployment tiers (Empower Personal, Workgroup, and Enterprise; OpenLab workstation and networked configurations) but not an equivalent single scalability figure in the sources reviewed. Buyers who need genuinely comparable performance data should treat vendor efficiency percentages as marketing claims to validate in their own proof-of-concept testing rather than as interchangeable, apples-to-apples benchmarks, a point echoed by the complete absence of any independent laboratory-benchmarking study across the sources gathered for this report.

Data Analysis and Evidence

The chromatography data system market is a well-defined, if modestly sized, corner of laboratory informatics. Mordor Intelligence's 2026 industry report values the global CDS market at $587.99 million in 2026, projecting growth at a 7.54 percent CAGR to $845.53 million by 2031 (Source: mordorintelligence.com), and describes the market's structure as exhibiting "moderate concentration" (Source: mordorintelligence.com) among Waters, Agilent, and Thermo Fisher. Pharmaceutical and biopharmaceutical laboratories are the market's largest single end-user segment, capturing 47.35 percent of CDS revenue in 2025 by Mordor's estimate (Source: mordorintelligence.com). A second research firm, SkyQuest, offers a meaningfully different long-run trajectory: it sizes the market at $519.58 million in 2024, growing to $1,056.08 million by 2033 at an 8.2 percent CAGR (Source: skyquestt.com). The roughly 25 percent gap between Mordor's and SkyQuest's overlapping-year base figures illustrates a common problem in niche software-market sizing: different firms scope the CDS category differently, so buyers should treat any single CDS market-size figure as an estimate rather than a settled fact. For context, the adjacent laboratory information management system (LIMS) market, which increasingly integrates with all three CDS platforms, was valued by MarketsandMarkets at $2.1 billion in 2024, projected to reach $3.8 billion by 2029 at a 12.9 percent CAGR (Source: prnewswire.com), several times larger than the CDS category itself.

Table 2 below summarizes the most recently reported financial results for each parent company, drawn from their own fiscal year 2024 (FY2024) earnings disclosures, to give a sense of the balance sheets standing behind each CDS platform.

COMPANY	FY2024 REVENUE	RELEVANT SEGMENT	SEGMENT DETAIL
Waters Corporation	$2,958 million, flat as reported for the full year (Source: prnewswire.com)	Single reporting segment	Q4 2024 net sales were $872,714 thousand versus $819,474 thousand in Q4 2023 (Source: prnewswire.com)
Agilent Technologies	$6.51 billion, down 4.7% reported (Source: biospace.com)	Life Sciences and Applied Markets Group (LSAG)	LSAG revenue $3.22 billion, down 8% (Source: biospace.com); CrossLab services revenue $1.64 billion, up 5% (Source: biospace.com)
Thermo Fisher Scientific	$42.88 billion, flat versus prior year (Source: nasdaq.com)	Analytical Instruments segment	$7,463 million, 17.4% of consolidated revenue, up from $7,263 million (16.9%) in FY2023 (Source: nasdaq.com)

None of the three companies discloses CDS-specific product-line revenue in public filings; the Analytical Instruments, LSAG, and single-segment figures above include the instrument hardware each CDS is sold to control, not an isolated software line item. Agilent's FY2024 total revenue decline was driven substantially by the LSAG segment noted above (Source: biospace.com), while Thermo Fisher's Analytical Instruments segment income reached $1,955 million at a 26.2 percent margin in FY2024, versus $1,908 million (26.3 percent margin) in FY2023 (Source: nasdaq.com), and Waters' pharmaceutical-market sales specifically grew 10 percent on a constant-currency basis in Q4 2024 (Source: prnewswire.com). Combined with the CDS-specific market-size estimates above, and with SkyQuest's independent $519.58 million baseline for the same period (Source: skyquestt.com), the data suggest a market where software licensing itself is a comparatively small, stable revenue pool relative to the instrument sales and post-sale services (validation, support, LIMS integration) that surround it, which is consistent with why enterprise CDS pricing is quote-based rather than published: vendors are pricing a bundled instrument-software-services relationship, not a standalone software fee.

Case Studies and Real-World Examples

Public FDA warning letters, one closely watched piece of corporate litigation, and vendor-published deployment case studies together offer a more concrete picture of how these three platforms perform in the field than marketing claims alone.

Waters Empower: Repeated Audit Trail Failures at Generic Manufacturers

FDA's warning letters describe a consistent failure pattern specifically inside Empower deployments. At Mylan Laboratories' Nashik facility in India, a 2017 letter found the "Empower 3 system audit trail displayed many instances of a" flagged error condition that the quality unit never investigated (Source: fda.gov), including test records where "the audit trail for these tests included the message" reporting a deleted result set with no accompanying investigation (Source: fda.gov). Two years later, at Tismor Health and Wellness, a contract over-the-counter manufacturer, FDA found

the firm had "assigned administrative privileges to analysts conducting routine assay tests using your Empower chromatography software data system" (Source: fda.gov), a direct access-control violation, and that the same firm had "deleted more than 100 test results since October 2017" without investigation (Source: fda.gov). A 2019 warning letter to Winder Laboratories similarly found unexplained audit-trail entries, including run, abort, and delete actions, that "were not evaluated as part of the batch review" (Source: fda.gov), a deficiency FDA tied to the requirement that laboratory records include "complete data derived from all tests" under 21 CFR 211.194(a) (Source: fda.gov). Most recently, a December 2024 warning letter to Indoco Remedies Limited found that "review of data in the Empower Message Center failed to identify unexpected discrepancies" during routine batch release (Source: fda.gov), and system messages showing that a run "cannot be altered. It belongs to a sample set which is currently being acquired" went unreviewed for an extended period (Source: fda.gov). In each case, the software's audit trail worked as designed and captured the anomaly; the compliance failure was organizational, a quality unit that did not review what Empower had already recorded.

Agilent OpenLab CDS: Access Control Gap at Wisconsin Pharmacal

A 2025 FDA warning letter to Wisconsin Pharmacal Company documents a comparable failure inside an OpenLab CDS environment used for liquid and gas chromatography release testing of over-the-counter drug products. FDA cited the firm for granting "administrative privileges for file modification and deletion using your Agilent OpenLab software data system" (Source: fda.gov) and for a broader process failure in which the firm "does not review audit trails and raw analytical data captured by these analytical instruments" prior to releasing batches (Source: fda.gov). The letter is a near-mirror of the Empower cases above: the specific CDS brand differs, but the underlying deficiency, unrestricted administrative access combined with no routine audit-trail review before release, is identical across vendors, reinforcing that Part 11 compliance is ultimately a matter of laboratory governance layered on top of any of these three systems, not a property the software guarantees on its own.

Thermo Fisher Chromeleon: Central to a $4.75 Billion Merger Collapse

The most consequential documented case involving any of the three platforms is not a warning letter but a piece of corporate litigation. In the 2018 Delaware Court of Chancery opinion in *Akorn, Inc. v. Fresenius Kabi AG*, expert testimony (drawing on Lachman Consulting's analysis) found that Akorn's Thermo Fisher Chromeleon-based chromatography system allowed users "to access data, to modify data, to move data, to delete data" in hidden, unaudited folders (Source: courtlistener.com), leading the court to conclude that "the data itself is not trustworthy" (Source: courtlistener.com). That data-integrity finding was a key factor supporting the court's conclusion that Akorn had suffered a Material Adverse Effect, letting Fresenius Kabi walk away from its approximately $4.75 billion agreement to acquire the company. The case is a reminder that CDS-level data-integrity weaknesses are not only an FDA enforcement risk but can carry direct, quantifiable financial consequences in mergers and acquisitions due diligence.

Constructive Deployments: Hovione, Chong Kun Dang, Merck Arklow, and Sanofi

Not every documented case is a failure. Waters' own case study on contract development and manufacturing organization (CDMO) Hovione describes the firm standardizing its analytical fleet on "ACQUITY UPLC System, ACQUITY PDA/QDa Detectors, Empower Chromatography Data Software" (Source: waters.com), with Hovione's Director of Analytical Chemistry quoted saying "it's all about the data quality, we buy the equipment" to match (Source: waters.com). Waters also names South Korean pharmaceutical manufacturer "Chong Kun Dang (CKD)" as a customer that layered cloud-based system monitoring onto its Empower-managed HPLC fleet (Source: waters.com, reporting that "CKD has seen significant improvements in lab efficiency" as a result (Source: waters.com). On the Agilent side, a case study involving "Merck Arklow (Sigma Aldrich Ireland Limited)," described as "an affiliate of Merck KGaA, Darmstadt, Germany" (Source: agilent.com, reports that an Agilent Validation Starter Kit and compliance consultancy engagement "reduced the implementation timeline by approximately 60% for a Chromatography Data System" (Source: agilent.com), a rare quantified validation-cost data point for any of the three platforms. Thermo Fisher's own case studies name Sanofi's use of a Vanquish ultra-high-performance liquid chromatography (UHPLC) system with Chromeleon CDS to optimize flow-chemistry drug substance manufacturing (thermofisher.com, and describe Servier subsidiary "Symphogen, a subsidiary of Servier and antibody center of excellence" (thermofisher.com using Chromeleon as a unified data-management platform, calling it "one such technology" enabling faster monoclonal-antibody characterization workflows (thermofisher.com. All five of these positive cases are vendor-published rather than independently reported, a limitation readers should weigh against the independently sourced FDA and court records above.

Implications and Future Directions

Two structural trends run through the evidence gathered for this report. The first is the shift from on-premises client-server CDS toward cloud-hosted and hybrid architectures: Waters brands Empower as a cloud-deployable CDS and has layered Empower Data Viewer on top of it (see Capabilities above), while Thermo Fisher builds Chromeleon for on-premise, virtual, or cloud installations (Source: thermofisher.com). For validated GxP environments, cloud migration raises its own Annex 11 and Part 11 questions around infrastructure qualification that labs will need to resolve regardless of which vendor they choose, since Annex 11 already requires that "the application should be validated; IT infrastructure should be qualified" even for on-premises systems (Source: health.ec.europa.eu), and Annex 11's requirement to record "all GMP-relevant changes and deletions" applies just as forcefully to a cloud-hosted audit trail as to an on-premises one (Source: health.ec.europa.eu).

The second trend is greater use of digital workflow guidance and review-support tools. Empower Data Viewer's Anomaly Detection feature lets reviewers compare target results against reference results to flag outliers using AI/ML techniques rather than manual visual inspection alone (see Capabilities above), while Agilent positions OpenLab Sync as a guided-execution LES for QC work at the bench (see Capabilities above). If AI-assisted review genuinely reduces the kind of unreviewed-anomaly failures documented repeatedly in the FDA warning letters above (unreviewed Empower Message Center errors at Indoco, unevaluated audit-trail flags at Mylan (Source: fda.gov), unreviewed OpenLab audit trails at Wisconsin Pharmacal), it could meaningfully reduce a recurring category of Part 11 citations; but none of the sources reviewed for this report offered independent evidence that AI-assisted review has yet reduced warning-letter rates, so this remains a plausible direction rather than a demonstrated outcome. The Akorn litigation is itself a reminder of the financial stakes involved once these deficiencies surface: the same expert finding that Akorn's data was "not trustworthy" fed directly into a Material Adverse Effect ruling (Source: courtlistener.com), so CDS data-integrity posture is increasingly a factor buyers and acquirers alike should expect to see probed in technical due diligence.

For organizations weighing a CDS selection, migration, or validation project, the practical decision increasingly resembles a broader enterprise software assessment as much as a laboratory-equipment purchase: existing instrument fleet composition, in-house Part 11 governance maturity (whether the quality unit already reviews audit trails routinely, per MHRA's expectation that "users should not be able to amend or switch off the audit trail" and that someone actually reads it) (Source: assets.publishing.service.gov.uk), and total validation cost (where Merck Arklow's documented 60 percent implementation-timeline reduction with a structured validation kit suggests genuine savings are available regardless of platform) (Source: agilent.com). These considerations should be assessed against the laboratory's own instruments, workflows, validation plan, and quality-system procedures.

Frequently Asked Questions (FAQs)

Is Empower Part 11 compliant? Waters describes Empower as "a closed system" under Part 11 terminology, built on an Oracle database with role-based electronic-signature privileges (Source: waters.com), but Part 11 compliance ultimately depends on how a specific lab configures, validates, and reviews the system, as the Mylan, Tismor, and Indoco warning letters discussed above illustrate.

Is OpenLab CDS 21 CFR Part 11 compliant? Agilent describes OpenLab CDS as providing secure, computer-generated, time-stamped audit trails and electronic review of audit trails with their associated records (Source: agilent.com). Whether a laboratory meets applicable regulatory requirements depends on its validated configuration and procedures; the Wisconsin Pharmacal warning letter shows that a lab can still fail to perform audit-trail review in practice (Source: fda.gov).

How much does Chromeleon cost? Thermo Fisher publishes a single-instrument Chromeleon Single Edition list price of $4,460.00 on its webshop (Source: thermofisher.com); enterprise, networked, and cloud configurations are quote-based and not publicly listed.

How much does Empower cost? Waters sells Empower through ES1, ES3, and ES5 subscription tiers with no published per-seat price; a formal sales quote is required (Source: waters.com.

How much does OpenLab CDS cost? Agilent does not publish OpenLab CDS list pricing; one lab user reported a roughly $3,900 quote for a single-instrument license in 2023, comparable to but slightly below the price they were quoted for a legacy ChemStation license (Source: reddit.com).

Which CDS is best for a pharma lab? The evidence gathered does not support a single universal answer: Empower has the broadest documented installed base and driver library (Source: aws.amazon.com), Chromeleon offers the most transparent entry pricing and the widest stated multi-regulator design target, and OpenLab CDS is the natural choice for labs already standardized on Agilent's GC and LC hardware, a fact reinforced by the 60 percent validation-timeline reduction Agilent documented for an existing Agilent-instrumented site adopting a structured OpenLab validation kit (Source: agilent.com). In practice, instrument fleet composition, data-migration requirements, validation effort, and governance should be evaluated together; their relative importance depends on the laboratory's workflows and procurement constraints.

Can these three CDS platforms exchange data with each other? Yes, to a degree: Waters' partner program includes Thermo Fisher LC, GC, and IC drivers for Empower (Source: waters.com, and Agilent's OpenLAB ELN has historically ingested "chromatograms and result files from Agilent ChemStation, Waters Empower or other chromatography data systems" (Source: technologynetworks.com), showing that cross-vendor data consolidation is achievable even though each CDS is primarily built to control its own maker's hardware.

Conclusion

The choice among **Empower, OpenLab CDS, and Chromeleon** is not, in the end, a choice among fundamentally different approaches to chromatography data management. All three are built to satisfy the same 21 CFR Part 11 and Annex 11 requirements, all three support role-based access, electronic signatures, and audit trails that MHRA guidance says must remain switched on and untouchable by end users (Source: assets.publishing.service.gov.uk), and all three are sold by companies that also make the instruments the software controls. The differences that matter in practice are narrower: Empower's larger claimed installed base of over 500,000 users (Source: aws.amazon.com) and 700-plus-model driver library, Chromeleon's 7.4 feature release alongside its supported 7.3.2 LTS release (Source: thermofisher.com), published entry-level pricing, and explicit five-regulator design target, and OpenLab CDS's integration with Agilent's GC and LC hardware roadmap; OpenLab Sync is a separate LES that works alongside CDS and LIMS environments, while ChemStation Edition remains a legacy line (Source: reddit.com).

What the FDA warning letters and the Akorn litigation make unmistakable is that the software itself is rarely the point of failure. Empower's audit trail correctly flagged the anomalies at Mylan, Tismor, and Indoco; OpenLab's audit trail was available but unreviewed at Wisconsin Pharmacal (Source: fda.gov); and Chromeleon's architecture permitted, but did not cause, the unaudited folder structure a Delaware court found untrustworthy at Akorn (Source: courtlistener.com). The same pattern reaches back to the earliest cases reviewed here: Chongqing Pharma Research Institute's analysts were found to "delete any undesirable result" from otherwise-compliant chromatography software as far back as 2017 (Source: fda.gov), underscoring that FDA's data-integrity guidance was issued precisely because "an increase in findings of data integrity lapses in recent inspections" kept recurring across every CDS brand, not just one (Source: fda.gov). In every documented case, the compliance gap was organizational: quality units that did not review what their CDS had already recorded, or access controls configured more loosely than the software allowed. That distinction should reframe how a lab approaches this decision: procurement due diligence on any of these three platforms is necessary but not sufficient, and should be paired with an honest internal assessment of whether the quality organization actually reviews audit trails today, regardless of which vendor's name is on the license.

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Tags: chromatography data system, empower cds, openlab cds, chromeleon cds, 21 cfr part 11, waters empower, agilent openlab, thermo fisher chromeleon, cds software comparison, pharma data integrity

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