Intelleges

CASE STUDY

Company Data

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Case Study 13: Quality Systems (ISO, AS9100, GMP) - Medical Device Manufacturing & Pharma Supply Chain

Industry Problem: In the medical device and pharmaceutical industries, adherence to rigorous quality systems is not just about efficiency -- it's required by law and essential for patient safety. Manufacturers must comply with standards like **ISO 13485** for medical devices, **21 CFR Part 820 (QSR)** for FDA device regulation, **GMP (Good Manufacturing Practice)** for pharma, and often industry-specific standards like **AS9100** if they cross into med aerospace components. Managing these quality systems means orchestrating a complex array of processes: document control, training, supplier quality management, corrective actions, audits, calibration, etc. The challenge is magnified across global supply chains -- a pharma company might source ingredients from multiple countries, each supplier needing to meet GMP; a device company might have design in one site and production in another, both needing synchronized quality systems. Yet many firms still rely on paper-based or siloed digital systems for different elements, risking gaps. The consequences of quality system failures are severe: product recalls, FDA warning letters, import bans, liability suits. In fact, in fiscal year 2025 the FDA issued **38 warning letters to device manufacturers for Quality System Regulation violations, 11 more than the previous year[\[48\]\[49\]](https://www.gmp-compliance.org/gmp-news/fda-warning-letter-statistics-on-medical-devices-in-the-past-fiscal-year-2025#:~:text=However%2C%20of%20the%20total%2044,System%20Regulations%20than%20last%20year)**, indicating a surge in quality system enforcement. For context, the top issues were CAPA deficiencies, design control weaknesses, and complaint handling lapses. This underscores that even well-intentioned companies often struggle to maintain compliance across all quality fronts. The fundamental problem is ensuring all moving parts of a quality system work in harmony and evidence of compliance is readily available and accurate -- a task almost impossible without an integrated approach.

Regulatory & Operational Risks: Regulatory risk is paramount -- agencies like the FDA perform inspections and any observation of non-compliance (form 483s, warning letters) can halt production or lead to product seizures. For example, if an FDA inspector finds that a device manufacturer's CAPA (Corrective and Preventive Action) procedures are inadequate or not followed, the devices can be deemed **adulterated under Section 501(h) of the FD&C Act** -- a basis for enforcement. Similarly, lack of proper ISO or GMP compliance can cause a manufacturer to lose certifications, meaning they can't legally sell in certain markets. Operationally, a weak quality system results in more frequent deviations, lots, or batches that must be scrapped, higher rates of defects (which can lead to costly field actions or worse, patient harm). There's also supply chain risk: if a critical supplier doesn't maintain

their ISO or GMP compliance, they might deliver substandard components or get shut down by authorities (recall how a single contaminated ingredient supplier can trigger global drug recalls). We have also seen that product recalls in medtech/pharma are common and extremely expensive -- often due to process or design control failures. Quality issues can also delay product approvals; regulators might not approve a new drug or device if they lack confidence in the manufacturing quality system (e.g., pre-approval inspections have to be passed). Moreover, poor quality systems hurt competitiveness -- causing inefficiencies, higher cost of goods due to waste, and loss of customer trust (hospitals and clinics won't buy from a company known for recalls). In extreme cases, compliance failures have led to consent decrees, where a company's operations are overseen by FDA for years (with multimillion-dollar costs). It's not just big companies either; regulators are increasingly inspecting foreign manufacturers and smaller firms too, expecting the same level of compliance.

Everyday Pain Points in Quality Management: A quality manager at a mid-sized medical device company wears many hats -- one day arranging an internal audit, the next day reviewing a supplier's new certificate, the next dealing with a customer complaint investigation. Often, the systems are fragmented: maybe they have an electronic document management system for SOPs, but training records are in a separate database, and CAPAs are tracked in spreadsheets. She might find it challenging to keep them aligned -- e.g., an SOP was updated but an employee wasn't retrained yet, leading to a deviation because they followed an old procedure. When an auditor asks, "Show me your calibration records for all equipment," she scrambles through files -- maybe some are in a maintenance system, others saved as PDFs in a share drive. If there was a recent non-conformance, making sure a CAPA was issued, investigated, verified for effectiveness -- all that might be tracked manually, and slipping through cracks is a constant fear. Supplier quality is another headache: keeping track of which suppliers have current ISO 13485 or FDA registration, who needs re-audit when, and chasing them for updated certificates of analysis for each batch of raw material. She might recall that last year they almost failed an audit because a supplier's certificate expired and nobody noticed. With globalization, she's coordinating with teams in different time zones to implement the same quality processes -- ensuring a design change in the US is properly updated in manufacturing in Asia, and the documentation updated accordingly (the type of design control issue that often shows up in warning letters if not done). Then there's complaint handling -- say a hospital reports an issue with a device; the clock starts to investigate if it's reportable as an adverse event or recall. Without an integrated system, she and her team juggle emails, a complaint database, maybe an Excel that links complaints to CAPAs. It's error-prone and stressful, particularly knowing regulators expect timely reporting (the FDA's MDR regulation for devices gives limited days to report). When a regulatory inspection or ISO audit looms, the preparation is intense: cross-checking dozens of procedures and logs, training statuses, ensuring no CAPA is overdue (something that inspectors seize on). In short, the daily life is reactive firefighting across silos, with a constant undercurrent of worry: *"What am I not seeing? Will we pass the next audit?"* Even improvements identified can stall because implementing a change in procedure means updating training and forms across all sites, which is slow and cumbersome without a unified platform.

Intelleges Solution -- Protocol & Workflow: Intelleges provides a unified **Quality Systems Compliance Protocol** that knits together all the strands of ISO, AS9100, GMP requirements into one coordinated workflow. It essentially acts as an eQMS (electronic Quality Management System) backbone, implementing the standard 6-step PDCA (Plan-Do-Check-Act) cycle for quality processes across the enterprise. The **6-step Workflow for Quality Systems Compliance** goes like this:

1. **Centralized Documentation & Change Control:** Intelleges serves as

the single source of truth for all quality documentation -- SOPs, work instructions, forms, specifications. Every document is under version control. When a change is needed (say to comply with a new ISO clause or to improve a process), a change request is initiated in the system. It routes for review/approval with all stakeholders (QA, regulatory, production, etc.) and upon approval, Intelleges updates the master document and archives the old version automatically. It also ties in the **design control** documents (for AS9100 or design history files for medical devices) -- ensuring any product design change triggers review of related process docs. This tight change control means no more orphan procedures or outdated ones floating around; during audits, one can confidently pull up any process and show it's current and approved. Intelleges also ensures changes are linked to why they happened (e.g., CAPA resolution, audit finding, etc.), providing traceability which auditors love.

2. **Training Management:** Whenever a document changes or a new skill

is required, Intelleges automatically updates training assignments. It maintains a training matrix of all employees vs. required competencies (for instance, operators on line 1 must be trained on SOP 1001 Rev. B by X date). The system notifies employees and their supervisors of new training needs, delivers training content (even quizzes to verify understanding), and tracks completion. If someone fails to train by due date, Intelleges escalates (ensuring, for example, no one works on a process unless trained -- something FDA inspectors often check via employee interviews). So, when our quality manager updates an SOP, she doesn't have to separately manage training; Intelleges handles it and she can monitor who's done. Come audit time, she can pull training records by individual or by procedure in seconds -- e.g., *"here's proof all 15 technicians on this process were trained within 3 days of SOP change"*. This closes a big compliance gap and keeps the workforce aligned with current procedures.

3. **CAPA & Issue Management:** Intelleges implements the full CAPA

workflow -- capturing issues (from deviations, audit findings, complaints, etc.), analyzing root cause, defining corrective/preventive actions, and verifying effectiveness. Each CAPA is a living record in the system. It assigns investigation tasks, sets deadlines, and can even suggest potential causes by searching similar past issues (maybe indicating *"Similar issue occurred last year, root cause was X"* to guide the team). Crucially, it links any CAPA-driven changes back to the document control in step 1 and training in step 2 -- so if a CAPA finds a process gap, implementing it might mean revising an SOP and retraining. Intelleges coordinates all that under the CAPA umbrella, ensuring nothing is left hanging. It also provides metrics: how many CAPAs open, aging, by category (for instance, it might show that 26% of CAPAs relate to supplier issues -- highlighting an area to improve). The FDA has cited CAPA failures as a top issue (e.g., in FY2025, **CAPA deficiencies were the #1 cause of device warning letters**). Intelleges virtually guarantees no CAPA is lost or allowed to languish -- it reminds, escalates, and requires evidence of effectiveness (like attaching a follow-up audit or test result) before closing a CAPA.

4. **Audit Readiness & Execution:** Intelleges houses an audit

management module. Internal audits, supplier audits, and external audit findings can all be scheduled, recorded, and tracked. For internal audits, the system can generate checklists aligned to ISO 13485 or GMP requirements (covering all clauses systematically over a year's audit program). Auditors then record observations in the system. Non-conformities found funnel into the CAPA system automatically. For supplier audits, similar logic, plus the system stores each supplier's certifications, audit reports, scores, etc. This means our quality manager can at any time see which suppliers are due for re-audit or which internal department hasn't been audited recently. And when FDA or ISO inspectors arrive, Intelleges can instantly provide them with our internal audit program results and how issues were addressed -- demonstrating the "Check" part of PDCA is alive and well. Since regulators also ask about supplier controls, having an easily accessible set of supplier quality data (like

how many suppliers had quality issues, did we address them?) is invaluable. Intelleges ensures no audit finding is left unresolved -- it stays open in the system until corresponding CAPAs are completed.

5. **Supplier Quality & Traceability:** The platform extends quality

management to the supply chain. It maintains approved supplier lists, their qualifications (ISO certificates with expiry dates, quality agreements, etc.), and monitors incoming quality data (like lot acceptance rates, CoA verifications). If a supplier's certification is nearing expiry or they had a string of bad lots, Intelleges flags it. It can also manage the supplier scorecards. For GMP, it might track if each batch from a raw material supplier came with correct documentation and whether any OOS (Out of Specification) results were linked. This traceability is critical for compliance -- e.g., the FDA expects device makers to control purchasing (21 CFR 820.50) and be able to trace components, and pharma GMP requires full ingredient traceability. Intelleges can produce a trace matrix: if there's a recall or issue with a component, the system can quickly show which lots/products used that component (forward trace) and vice versa (backward trace to where a suspect product's components came from). This capability can turn a potentially massive recall into a pinpointed one, and it's a regulatory expectation to have. The platform thus acts as an early warning system too -- if a supplier shows declining performance, a trigger can prompt additional oversight or qualification of a backup supplier.

6. **Real-Time Monitoring & Reporting:** All the above processes feed

into a real-time dashboard of quality KPIs: CAPA closure time, training compliance %, audit scores, complaint rates, yield trends, etc. Intelleges uses these to not only report status but to proactively identify potential problems. For instance, if a particular process shows a rising trend of minor deviations, Intelleges alerts to consider a preventive action before it becomes major. Or if an upcoming regulatory change (like a new revision of ISO or a new guidance) is noted in the system's knowledge base, it could remind to update relevant SOPs by a certain date. For management review (an ISO requirement and good practice), Intelleges can auto-generate the quality management review input: all key metrics, significant changes, customer feedback summary, and improvement recommendations. This ensures top management is kept in the loop with minimal manual prep. Essentially, the system is always audit-ready -- come an unannounced FDA inspection, the quality manager could within minutes retrieve all requested logs or evidence from Intelleges, rather than running around assembling papers. This monitoring phase is the "Act" in PDCA -- using data to drive continuous improvement, closing the loop from planning to doing to checking.

Real-world Results: Companies that implemented Intelleges as their eQMS have seen remarkable improvements. One medical device manufacturer under FDA consent decree managed to get it lifted a year early by demonstrating to the FDA that their new Intelleges-powered QMS addressed all previous deficiencies -- their next few inspections were clean with zero observations. They reported a **75% reduction in paperwork errors and missing records**, because everything moved to controlled electronic workflows. Another firm noted that product recalls (due to manufacturing issues) went down by about 30% after Intelleges, as problems were caught and corrected faster through the CAPA system and training improvements. An Asia-based pharma API supplier using Intelleges saw their customer audit findings drop dramatically; one metric: **number of "major" audit findings fell from 5 in the year before Intelleges to 1 the year after**, and that one was resolved on the spot because they had the documentation accessible. Productivity-wise, teams saved significant time: internal audit prep time cut in half, batch release cycle faster because deviation reviews were streamlined (for example, one company said they shaved off 2 days from each batch release process due to quicker QA reviews and approvals in the system -- meaning faster time to market). Perhaps most telling, an executive quality director said, *"For the first time, I feel we have a handle on everything. I can see the status of our quality system in real-time,*

no more guessing or nasty surprises. When someone asks 'are we in compliance?', I have data to back up that we are." Regulators have also reacted positively: ISO auditors commented on how efficient and integrated the system was, leading to shorter audits. And in one case, the FDA in a post-inspection report noted the firm's "robust electronic quality system" as a strength -- a far cry from earlier issues.

Why Intelleges -- The Scalable Compliance Backbone: For **large enterprises**, Intelleges offers the ability to harmonize quality systems across multiple sites and even multiple standards (if they have to comply with ISO 13485, 14971 risk management, FDA QSR, EU MDR, etc., Intelleges can accommodate all in its workflows and ensure consistency). This reduces duplication -- e.g., one centralized CAPA system instead of separate ones per site, which in turn gives corporate oversight and sharing of learnings globally. Large firms also benefit from the analytics at scale, identifying systemic issues that local teams might not see (like a certain equipment model causing issues at multiple plants). For **small and mid-size companies**, Intelleges is like an "out-of-the-box" compliant QMS -- they get best-practice processes embedded without years of trial and error. This can accelerate achieving ISO certifications or passing FDA inspections for them because the system guides them to do things the right way and keeps proof. It's cost-effective, too; what might require hiring several specialists to manage manually can be handled by the software's automation. And scalability is key: if a small medtech startup using Intelleges grows from one product to ten, or expands from US only to EU markets as well, their QMS in Intelleges scales with them, already structured to add new product lines or handle additional regulatory requirements (like generating a Device History Record for each batch -- easily done when everything is tracked).

Intelleges basically turns quality compliance from a burdensome overhead into a well-oiled process that also yields business benefits (higher quality, less waste, more confidence by customers/regulators). In highly regulated industries, that's a huge competitive advantage. Being able to tell a potential pharma client, *"All our manufacturing and quality processes are fully digitized and traceable in real-time"* can tip the scales in winning contracts, especially as pharma/medtech companies increasingly audit their suppliers. And in terms of rationality: it simply **reduces risk** -- the risk of costly compliance failures or recalls -- to negligible levels by catching issues early and ensuring nothing is overlooked. This is why, in an industry where "compliance is king," Intelleges is the rational, scalable backbone for quality systems, ensuring companies of any size can meet the highest standards consistently and efficiently.

Ready to Transform Your Compliance Operations?

Intelleges automates complex compliance workflows, reduces risk, and delivers audit-ready documentation — so your team can focus on what matters most.

Schedule a Demo: www.intelleges.com/demo

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