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ABBREVIATION	MEANING
ALCOA+	Attributable, Legible, Contemporaneous, Original, Accurate (+ Complete, Consistent, Enduring, Available)
BI	Business Intelligence
CAPA	Corrective and Preventive Action
CC	Change Control
CI	Continuous Improvement
CMC	Chemistry, Manufacturing & Controls (regulatory module area)
CSA	Computer Software Assurance (FDA risk-based approach)
CSV	Computer System Validation
DMI	Digital Maturity Index (10-dimension framework used in this study)
DI	Data Integrity
eBMR / eBPR	Electronic Batch Manufacturing / Packaging Record
eCTD	Electronic Common Technical Document (regulatory submission format)
EDMS	Electronic Document Management System
EMA	European Medicines Agency
FDA	U.S. Food and Drug Administration
GAMP 5	Good Automated Manufacturing Practice (ISPE guidance, 5th ed.)
GDPR	General Data Protection Regulation (EU)
GMP	Good Manufacturing Practice
GxP	Good "x" Practices (GMP, GDP, GCP, etc.)
HA	Health Authority (regulator)
IDMP	Identification of Medicinal Products (ISO standards)
IT	Information Technology
KPI	Key Performance Indicator
LIMS	Laboratory Information Management System
MES	Manufacturing Execution System
MHRA	Medicines and Healthcare products Regulatory Agency (UK)
OT	Operational Technology (shop-floor/automation systems)
PQS	Pharmaceutical Quality System
QMS	Quality Management System
QRM	Quality Risk Management
RA	Regulatory Affairs
RBAC	Role-Based Access Control
RIM	Regulatory Information Management (system)
SaaS	Software as a Service (cloud delivery model)
SoA	Statement of Applicability (supplier assurance content)
SOP	Standard Operating Procedure
SPOR	Substance, Product, Organisation and Referentials (EMA data domains)
WHO	World Health Organization

DEDICATION

*To **Mr. Brendan Mcguire** — thank you for your steady support, clear advice, and quiet belief when it mattered most. Your encouragement kept this work moving, your questions sharpened my thinking, and your patience helped me finish well. This dissertation is dedicated to you with gratitude.*

Measuring Digital maturity in QA/RA and its Regulatory readiness in Pharmaceutical Industry: A cross organizational study

1. ABSTRACT

This study looks at how digital maturity in pharma QA/RA work shows up in day-to-day practice and how it links to regulatory readiness. A 10-dimension Digital Maturity Index (DMI) was used as the overall lens; six dimensions were studied live in interviews (Strategy & Governance, Technology Infrastructure, Data Integrity & Records, Process Automation & Workflow, Compliance Readiness/Assurance, Continuous Improvement), and four were considered in the background (People & Capability, Supplier/Cloud Assurance, Master Data/Interoperability, Performance & Insight). Conducted six semi-structured interviews (P1–P6) across QA/MES and RA operations. Transcripts were coded line-by-line; themes were compared across cases; each dimension was rated 1–4 with a one-line reason. Findings are clear. Controls are steady**:** people describe draft → review → approve, role-based access, "supersede, not delete", and audit-trail checks. These behaviours sit at level-3 and relate to smoother submissions and stable audits. Differences in readiness come from flow, not from the basic control layer. Where MES/workflows stop on exceptions and manual pockets sit outside systems (e.g., RA reuse/notifications in spreadsheets), cycle-time increases and people do double work. Where teams added small pre-checks or used auto-routing, clock-stops reduced and movement was faster. Technology is mostly stable, but integration gaps (e.g., RIM↔EDMS duplicate typing) and one paper-heavy site explain delays. In RA, one case showed level-4 assurance due to a full change → submission → approval trace. The study suggests practical fixes that can be done this quarter: write a short rationale in periodic reviews; add pre-checks at the common stop points; align 8–10 master-data fields between systems; keep a tidy supplier pack; and make the weekly pipeline data-led with two simple KPIs. These small steps connect digital maturity to everyday readiness: fewer queries**,** fewer clock-stops**,** shorter cycle-time, and smoother approvals**.**

Keywords: digital maturity, QA/RA, data integrity, process automation, regulatory readiness, eCTD, master data.

2. INTRODUCTION

Term	Plain definition	Source
Digital maturity	Alignment of people, process, data and technology to deliver reliable, compliant outcomes and improvement.	MIT Sloan; ISPE
PQS (ICH Q10)	Lifecycle quality system: management responsibility, monitoring, change control, CAPA, KM.	ICH Q10
QRM (ICH Q9(R1))	Systematic risk management to protect patient safety and product quality; proportional formality.	ICH Q9(R1)
Part 11	US rule for trustworthy electronic records and signatures.	eCFR 21 CFR Part 11
EU Annex 11	EU GMP expectations for computerized systems in GMP activities.	EudraLex Vol 4 Annex 11
CSA	Risk-based assurance for production and quality system software.	FDA CSA draft
Data integrity (ALCOA+)	Complete, consistent, enduring records with defined governance and controls.	MHRA; WHO

Table 1: Terms used with definition and sources

Pharmaceutical companies are accelerating digital transformation to improve quality, speed, and compliance, yet the evidence shows that outcomes depend as much on strategy and organisation as on the technologies themselves. Within this context, Quality Assurance (QA) and Regulatory Affairs (RA) sit at the sharp end of regulation because electronic records and signatures used in quality and regulatory systems must meet explicit legal requirements in the United States under 21 CFR Part 11. In Europe, EU GMP Annex 11 governs the use of computerised systems for GMP activities, emphasising validation, data integrity, security, and lifecycle control for software that supports manufacturing and quality operations. To align digital work with business value and regulatory expectations, industry groups promote Pharma 4.0™, which adapts Industry 4.0 ideas to the regulated life-sciences environment and encourages connected processes, data flow, and cross-functional ways of working. Regulators have likewise encouraged more risk-based approaches for software used in production and quality systems, with the FDA's Computer Software Assurance (CSA) draft guidance focusing effort on activities that matter most for product quality and patient safety. In parallel, the revised ICH Q9(R1) codifies modern quality risk management principles and clarifies appropriate levels of formality and decision-making in risk assessments across the product lifecycle.

Guidance on data integrity from the UK MHRA highlights ALCOA+ attributes and governance practices needed to ensure data are complete, consistent, and reliable across both paper and digital processes. The WHO expands on these expectations with detailed advice on good data and record management practices, underscoring that reliable data underpin effective quality systems and regulatory trust. Against this backdrop, this study defines digital maturity in QA/RA as the degree to which people, processes, data, and technology are integrated to produce reliable, compliant outcomes and continuous improvement rather than simply the presence of tools or automation.

This view is consistent with the ICH Q10 Pharmaceutical Quality System (PQS), which frames quality as a lifecycle system of management responsibility, process performance and product quality monitoring, corrective action and change management, and knowledge management. The combination of PQS thinking, risk-based assurance, and data-integrity expectations implies that "going digital" requires coherent governance, clear roles, trustworthy data, capable processes, and appropriate validation—across functions, not just within IT or validation teams.

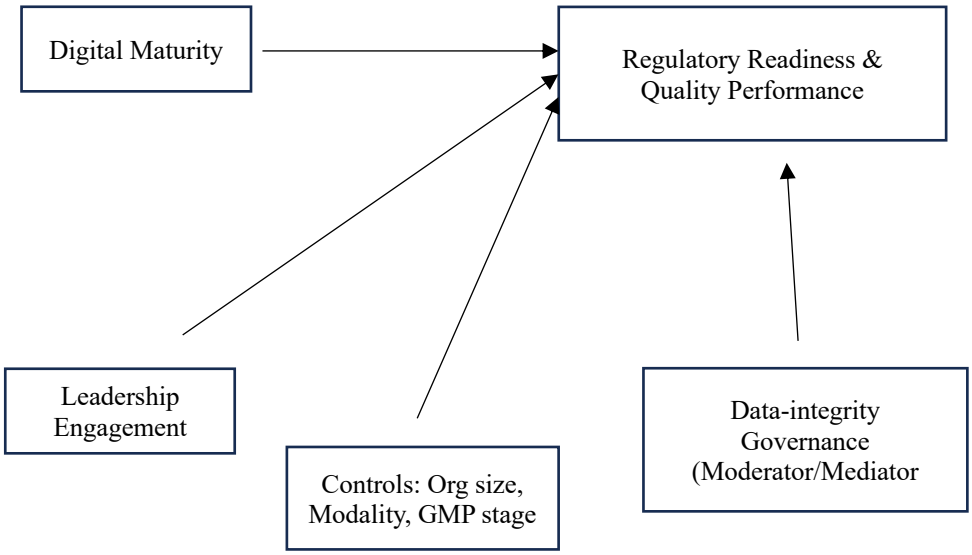

Fig 1: Conceptual framework: Digital Maturity (IV) → Regulatory Readiness & Quality Performance (DV) with moderators and controls

However, many well-known digital transformation models are enterprise-level and do not directly address the day-to-day realities of QA/RA teams operating under GxP, leading to uneven progress and limited comparability of capability between organisations. Managers therefore lack a concise, QA/RA-focused way to benchmark digital capability, identify barriers and enablers, and connect maturity to indicators that matter for inspection readiness and quality performance. The practical risk is that organisations over-invest in documentation-heavy activities or isolated technologies while under-investing in governance, data stewardship, change control, and learning mechanisms that sustain compliant, value-adding digital

operations. This study addresses that gap by examining digital maturity in QA and RA across multiple pharmaceutical organisations, using an applied assessment aligned with PQS, risk management, and data-integrity principles to make results both rigorous and usable. This study uses a ten-dimension Digital Maturity Index (DMI) tailored for QA/RA; six dimensions are rated live in interviews, and all ten inform analysis and discussion.

2.1 AIM

The aim is to characterise current levels of digital maturity in QA/RA and explore how maturity relates to regulatory readiness and quality performance so leaders can prioritise improvements with confidence.

2.2 OBJECTIVES

- Develop a concise, QA/RA-focused digital-maturity assessment that is practical to administer across organisations.
- Apply the assessment across several organisations to compare maturity patterns (strengths and weaknesses).
- Examine relationships between maturity levels and indicators of readiness and performance (e.g., audit/inspection outcomes, cycle times, data-integrity signals).
- Identify key enablers and barriers (governance, data practices, skills, change control) and propose actionable recommendations for QA/RA leaders.

2.3 SCOPE

The scope is limited to QA and RA (including close interfaces such as Quality Systems, Validation/CSV, and Regulatory Operations) within pharmaceutical organisations and does not extend to clinical, R&D, or commercial domains, ensuring depth and relevance to regulated quality and compliance work. This focus is justified because QA/RA functions operationalise PQS concepts and are directly accountable for risk-based controls, documented evidence, and the integrity of quality records that underpin regulatory confidence. By framing digital maturity through PQS, risk management, and data-integrity lenses, the work aims to help organisations balance compliance obligations with the agility and learning needed to sustain improvement in a highly regulated setting.

3. LITERATURE REVIEW

Digital maturity describes how well an organisation aligns people, processes, data, and technology to achieve strategic goals, and multiple studies show that strategy and leadership—not tools alone—drive successful digital outcomes. In regulated life-sciences contexts, this alignment must sit inside the Pharmaceutical Quality System (PQS), which articulates management responsibility, monitoring, change management, and knowledge management across the product lifecycle. Quality risk management (QRM) formalises how risks to patient safety and product quality are identified, analysed, controlled, and reviewed, and the 2023 revision of ICH Q9(R1) clarifies concepts such as formality, subjectivity, and hazard identification to strengthen decision-making in practice. Together PQS and QRM imply that digitalisation in Quality Assurance (QA) and Regulatory Affairs (RA) is about capability and governance as much as systems, because reliable, risk-based decisions depend on both technology and the organisational context around it.

2.1 Regulatory backbone (Part 11 & Annex 11)

Regulatory requirements for electronic records and computerised systems create the boundary conditions for digital work in QA/RA, with 21 CFR Part 11 in the US defining when electronic records and signatures are trustworthy and equivalent to paper. FDA's scope and application guidance reinforces how Part 11 should be interpreted in practice, emphasising validation, audit trails, security, and record retention as core expectations for compliant systems. In Europe, EU GMP Annex 11 sets specific expectations for computerised systems used in GMP activities, requiring validation of applications, qualification of IT infrastructure, robust access and change control, and risk-based lifecycle management. The European Commission has also launched a revision process for Annex 11 to reflect new technologies and harmonise expectations across Member States and PIC/S, signalling continued regulatory attention to digital controls. For QA/RA leaders, these baselines mean that "going digital" cannot be separated from assurance activities and governance over time, or from the data policies that sustain integrity and trust in records.

Document	Purpose	Scope	Key expectations	Notes
21 CFR Part 11	Trustworthy e-records/signatures	Quality & regulatory records in US settings	Validation, audit trails, security, retention	Guidance clarifies scope/application
EU GMP Annex 11	Computerized systems in GMP	GMP activities, Europe	Lifecycle validation, access/change control, supplier oversight	Revision underway
FDA CSA (draft)	Risk-based assurance	Prod/QS software	Critical thinking, focus on impact, proportionate testing	Complements GAMP® practice
ICH Q9(R1)	Quality risk management	All lifecycle stages	Formality, subjectivity, hazard ID and control	Revised 2023
MHRA Data Integrity	Integrity governance & controls	GxP data lifecycle	ALCOA+, roles, periodic review	Culture emphasized
WHO GDRP	Good data & record management	GxP contexts, global	Design for trustworthy records	TRS 996 Annex 5

Table 2: Regulatory & guidance landscape (Part 11, Annex 11, CSA, Q9(R1), MHRA, WHO)

Electronic Common Technical Document (eCTD) is now the default way many authorities receive regulatory submissions, and it sets clear expectations for how quality and regulatory data are structured, traceable, and maintained over time. eCTD breaks the dossier into standard modules and requires consistent metadata and lifecycle operations, which means RA teams must manage documents and changes in a repeatable, auditable way that aligns with quality systems. Because eCTD lifecycles track new versions, replacements, and withdrawals, weak control of document status or naming inside QA/RA quickly shows up as errors when building or updating sequences. For QA/RA digital maturity, this matters because good RA practice in eCTD depends on good QA practice around change control, data integrity, and role-based access to shared records. If RA cannot rely on validated sources of truth from the PQS (e.g., current specifications, change approvals, stability summaries), submission work slows and rework grows, which hurts readiness and credibility with regulators. Authorities also publish technical conformance guides for eCTD packaging and validation, so teams that standardise their internal processes and metadata reduce errors and speed up sequence assembly. Viewed this way, RA operations provide a practical lens on digital maturity in QA/RA: when PQS artefacts are controlled and findable, eCTD flows smoothly; when ownership or data quality is weak, issues surface at submission time.

2.2 Risk-based assurance & data integrity (CSA, GAMP® 5, MHRA/WHO)

Recent guidance encourages a sharper risk-based approach to software assurance so effort focuses where it most affects quality and patients, notably in FDA's Computer Software Assurance (CSA) draft guidance for production and quality system software. Under CSA, critical thinking and proportional testing are emphasised over documentation volume, aligning with the broader QRM direction in ICH Q9(R1) and signalling a more outcome-oriented view of compliance. This evolution complements industry practice around computerised systems (e.g., GAMP® 5 Second Edition), which likewise emphasises risk-based, patient-centred, and modernised approaches to assurance while recognising agile and cloud technologies. The practical implication for digital maturity is that organisations need capabilities that integrate regulatory logic into everyday decisions—prioritising efforts by risk, maintaining traceability, and designing processes with assurance in mind from the outset. Data integrity expectations further shape digital maturity by defining how data are generated, processed, reviewed, and retained to remain complete, consistent, and accurate throughout the lifecycle. The UK MHRA guidance sets out ALCOA+ principles and governance measures such as role-appropriate access, supplier oversight, and periodic review, linking integrity to culture as well as controls. The WHO has also issued detailed guidance on good data and record management practices, reinforcing that design of systems and processes must support trustworthy records, not merely their storage. Because QA/RA functions rely on the credibility of records to demonstrate control and compliance, digital maturity in these areas necessarily includes robust data governance and behaviours that protect integrity alongside technical controls.

Digital quality management systems (eQMS) are now common in pharma, but their value depends on how well they are embedded in the Pharmaceutical Quality System (PQS) and quality-risk management (QRM) rather than on software features alone. When eQMS workflows mirror good practice in change control, deviation/CAPA, and management review, they shorten feedback loops and improve the visibility of risk-based decisions that inspectors expect to see. Where digital records are set up with ALCOA(+) attributes in mind, teams can trace who did what, when, and why, which strengthens both day-to-day oversight and inspection readiness. Guidance on good data and record management from the WHO adds that systems must be designed so that trustworthy records are the natural output of routine work, not a separate documentation burden after the fact. In this context, "Quality 4.0" ideas—using analytics, connectivity, and automation to support quality—work best when the basics are strong: clear ownership of master data, consistent role-based access, and routine periodic review of records and audit trails. Pharma 4.0™ materials emphasise the same point: readiness

and maturity should come before scale, so organisations avoid automating poor processes or weak governance. Put simply, eQMS enables better quality only when paired with disciplined process design, risk-based assurance, and a culture that treats data as a product of the process rather than an afterthought.

2.3 Pharma 4.0™ & maturity design principles

The Pharma 4.0™ initiative adapts Industry 4.0 ideas to the regulated pharmaceutical context and explicitly embeds PQS elements, advocating "readiness and maturity" before scaling advanced technologies across the lifecycle. ISPE materials stress that Pharma 4.0 is not an IT project but a cross-functional operating model requiring cultural, organisational, and process changes as well as digital enablers, with PQS as a prerequisite and driver of sustained value. Within this framing, updated guidance on GAMP® 5 provides a risk-based approach to computerised systems that protects patient safety, product quality, and data integrity while encouraging innovation, aligning practice with CSA and QRM principles. Survey work and practitioner articles within the Pharma 4.0™ community indicate that maturity grows fastest where there is executive sponsorship, clear use-cases, and cross-functional collaboration, whereas siloed projects and unclear benefits slow adoption. These insights support the view that achieving digital maturity in QA/RA requires an operating model that connects people, processes, data, and technology with PQS and QRM as the backbone. Beyond pharma-specific initiatives, the broader literature on maturity models offers design principles for building sound, usable assessments that can be applied in domain contexts such as QA/RA.

Design principle	Application in this study
Clear dimensions & levels	10 dimensions with four levels; six-dimension rubric used for interviews.
Operational criteria	Plain-language evidence statements to support consistent scoring and benchmarking.
Domain language	QA/RA terminology aligned to PQS/QRM and Pharma 4.0™.
Validation & iteration	Pilot the rubric; refine based on saturation and coding feedback.

Table 3: Maturity-model design principles and how applied to this study

Reviews of maturity-model practice emphasise that models should define coherent dimensions and levels, provide unambiguous criteria, be validated for reliability, and use language that practitioners recognise so results can inform improvement. Design-science work lays out phases for development and application—problem identification, design of constructs and scales, evaluation, and iteration—so that a model achieves both rigour and relevance. These meta-guidelines are valuable in regulated settings because they ensure a maturity measure

remains transparent and auditable, which is essential when results are used to justify prioritisation and to demonstrate improvement over time. In parallel, "Quality 4.0" literature frames how digital technologies, analytics, and connected systems extend traditional quality management, provided organisations strengthen data foundations, governance, and skills. Quality 4.0 narratives consistently argue that technology must be integrated with culture and methods if value is to be sustained, which mirrors Pharma 4.0™ and GAMP/CSA emphasis on risk-based, outcome-oriented practice. For QA/RA specifically, this means that any maturity lens should illuminate not only tool deployment but also leadership, behaviours, and learning mechanisms that convert data into decisions under regulatory guardrails.

2.4 Operational enablers & metrics for QA/RA digital maturity

Many QA/RA systems now run on hosted or cloud platforms, so supplier assurance becomes part of everyday maturity rather than a one-off procurement task. Regulators expect a risk-based approach where you assess how the service can affect product quality or patient safety and then tailor qualification, testing, and oversight accordingly. EU GMP Annex 11 calls out supplier competence and service management, which includes things like change notification, incident handling, and clear responsibilities between the company and the provider. PIC/S guidance for computerised systems in GxP adds practical advice on contracts, audit rights, and shared controls, which is important when security and backup are partly owned by the vendor. From a data-integrity view, hosted systems still need ALCOA(+) outcomes, so you check that the platform supports reliable audit trails, time synchronisation, controlled user roles, and export of records for inspection. Under CSA thinking, you test and document what matters most: if a vendor change cannot affect a quality decision, you avoid paperwork churn; if it can, you plan proportionate checks and keep evidence easy to follow. Mature teams therefore keep a simple supplier-oversight plan with risk ranking, contact points, change notifications, and periodic reviews, so assurance is continuous instead of reactive.

Readiness is easier to manage when QA/RA use a few practical indicators that link maturity to day-to-day work rather than big transformation slogans. Change-control cycle time in QA-owned steps shows whether processes and digital workflows are helping decisions move with the right checks rather than causing backlogs. The coverage and quality of periodic review for critical systems (including user access and audit-trail checks) shows how well integrity is being protected in routine operations, not only during projects. Simple checks on audit-trail review quality—for example, whether reviews include rationale and follow-up actions—tell you if the control is meaningful or just a tick-box. Management-review inputs and actions (e.g., CAPA on-time closure, deviation trends, training effectiveness) indicate whether data are being turned

into decisions that improve quality and compliance over time. Because these indicators are already mentioned in PQS guidance, teams can adopt them without inventing new frameworks, and they fit well with maturity-model levels in your DMI. When combined with a small set of rubric ratings (1–4) for the six dimensions you use in interviews, these indicators create a clear line from maturity to outcomes that inspectors and managers both understand.

Digital maturity depends on people and process as much as on platforms, so change management and capability building need to target risk-based decisions, not only "how to click" in the system. "Quality 4.0" materials emphasise that analytics and automation pay off when staff know how to frame problems, read trends, and act on evidence inside PQS guardrails. Industry overviews of digital transformation also show that strategy and leadership drive results, which means roles, decision rights, and training plans must be explicit for QA/RA—not assumed to "come with the tool". Pharma 4.0™ guidance calls for readiness and maturity before scale, which in practice means stabilising ownership, measures, and routines (like periodic review and risk-based assurance) before adding complexity. PQS guidance points to knowledge management and management responsibility, so teams should capture what "good" looks like for evidence, audit-trail review, and supplier oversight in short, reusable playbooks. When these people-and-process basics are in place, digital tools have a stable home: data are trustworthy, workflows are clear, and improvements compound over time instead of slipping back after go-live.

2.5 Inspection readiness & findings

Inspectors expect QA and RA teams to show that computerised systems are fit for purpose and are being controlled across their whole process, not just at the time of validation. They also expect to see risk-based thinking in how you plan testing, manage suppliers, and review records, so that effort focuses on what could affect product quality and patients. Across the public guidance, three themes repeat again and again: lifecycle control for systems, data integrity in routine work, and clear roles with suppliers. Lifecycle control means you think about risk from design to retirement and you can show why your level of validation and oversight is enough for the job the system does. EU GMP Annex 11 says risk management should be applied throughout the lifecycle and that validation and IT qualification must be justified and documented. The FDA's Computer Software Assurance (CSA) draft guidance adds that you should use critical thinking to decide what to test and how much evidence is needed, based on impact. This helps teams avoid piles of documents that add no value and instead build proof that matches real risk.

Data integrity is the second theme, and it sits right at the centre of inspection readiness because decisions rely on trustworthy records. MHRA's guidance sets out ALCOA(+) and calls for practical controls like role-appropriate access, time-stamped audit trails, and periodic review with actions when issues are found. PIC/S guidance on data integrity echoes this and asks firms to assess data criticality and vulnerability so they can prioritise the right checks. WHO guidance also says that systems should be designed so that good records happen by default in daily work, not as an extra step later. Inspections often find weak spots when teams use spreadsheets or manual hand-offs to bridge systems without proper version control, access control, or change history. Supplier oversight is the third theme and is now a daily job because many QA/RA systems sit in the cloud or are managed by vendors. Annex 11 expects evidence of supplier competence, change notification, incident handling, and clear responsibilities between you and the provider. PIC/S guidance points to contracts, audit rights, and shared controls, which matter when backups, patches, or monitoring are partly owned by the vendor. Under CSA, you still focus your checks on what could change a quality decision, but you keep assurance continuous with a simple, risk-based plan. Public summaries and training slides from inspectorates show that common findings continue to include weak periodic review, poor audit-trail review quality, unclear roles for master data, and validation that is heavy on documents but light on risk reasoning. Where periodic reviews exist, issues are raised when reviews are tick-box and do not include a rationale, follow-up actions, or checks that actions were closed.

Findings also appear when there is no plan for supplier changes or when teams cannot show how vendor updates are assessed for impact on quality decisions. These findings line up with the core guidance and are avoidable with the right routines. For QA/RA digital maturity, this means inspection readiness is built into everyday work by a few simple routines. First, keep a short risk-based assurance plan for each critical system, so you can show why your testing and reviews are enough and what you will do when the system or process changes. Second, run periodic reviews that include users and roles, audit-trail samples with rationale, and status of open actions, and make sure reviews are recorded and followed up. Third, keep a living supplier oversight plan with contacts, change notifications, incident rules, and clear responsibilities, so you do not scramble when something changes. Finally, make sure management review sees short, honest signals about these controls, so leaders can help remove barriers and allocate time where it matters most. These steps take little time once they are part of the calendar, and they make inspections less stressful because evidence is already in place. The near-term update to Annex 11 is also a signal that expectations will keep moving with technology, but the basics will stay the same: risk-based control, integrity, and clarity on who

does what. The concept/consultation paper notes the goal to align approaches across EU and PIC/S and to address newer technologies while keeping the focus on product quality, patient safety, and data integrity. Planning for this now—by tightening risk reasoning, integrity checks, and supplier roles—will help teams stay ready as the detailed text evolves.

2.5.1 Master data & interoperability for QA/RA

Master data and shared identifiers help QA and RA teams keep records straight across systems, which reduces rework and speeds up decisions. In Europe, the IDMP standards and the EMA SPOR services define how data about substances, products, organisations, and reference lists should be managed and shared. The aim is to make medicine information easy to exchange and unambiguous across regulators and companies, which is vital for reliable submissions and safety work. For digital maturity, this means QA/RA need clear owners for these data and simple rules that keep names, codes, and statuses consistent in all places where they are used. The eCTD format also rewards consistency because it relies on standard modules and metadata to organise and track dossier lifecycles. If documents and data in PQS systems are controlled and findable, RA can assemble, update, and re-use content with fewer errors. If naming or status is inconsistent across systems, eCTD validation and lifecycle operations will surface errors that then have to be fixed under time pressure. This is one reason why RA and QA must align on change control, document status, and master data rules, not just on templates. IDMP and SPOR are not only about RA submissions; they also help quality teams because clean master data make it easier to link changes, deviations, and CAPA to the right products and sites. Using common IDs across eQMS, document systems, and RA tools means reports and metrics line up without manual reconciliation, which reduces the risk of mistakes. EMA materials explain that these services support data quality and consistency across regulatory activities, which is exactly what QA/RA need for routine work.

So, adopting simple SPOR-aligned fields in local systems can give benefits before any big integration project is done. A practical way to start is to define a small set of shared fields for QA/RA processes, such as product ID, strength, dosage form, and a standard site or company identifier. Keep a short master data guide that says who owns each field, how it is created or changed, and where it is used, and check these fields during periodic review. If you cannot integrate systems yet, use a controlled reference list or a simple lookup table to keep values aligned across tools. This keeps the data stable while you plan long-term integration or IDMP alignment in stages. Linking master data to readiness indicators also helps teams see progress. For example, if product IDs are consistent, change-control cycle time goes down because reviewers can find related records faster. If organisation and site codes are consistent, supplier

oversight and periodic review are easier to track because systems agree on which supplier or site is in scope. If document status and names are standardised, eCTD assembly is smoother and fewer fixes are needed late in the process. These are small wins that add up to strong evidence during inspections and faster RA timelines. Finally, teams should remember that IDMP has several standards behind it and that public summaries explain the basics even if the full standards are not free. At a high level, the goal is to uniquely identify medicinal products and related data elements so everyone is talking about the same thing in the same way. Using EMA's open SPOR guidance and aligning local fields to those concepts is enough to get started and already improves data quality across QA/RA. This is a simple, low-cost step that supports both submissions and quality operations while you build broader digital maturity. In the DMI, Master data & interoperability are treated as part of Data & Information Management.

2.6 DMI & conceptual model

Bringing these strands together, this study employs a custom Digital Maturity Index (DMI) for QA/RA that synthesises maturity-model design principles with Pharma 4.0™ and PQS/QRM expectations to make assessment results both rigorous and usable. The DMI spans ten linked capability areas that reflect organisational and technical needs in regulated quality work—strategy and governance, culture and skills, process design and automation, data and information management, technology and architecture, validation and assurance, risk and security, performance measurement, cross-functional integration, and continuous improvement—so that maturity goes beyond tools to the systems that sustain compliant value. Levels are expressed on a pragmatic four-step scale to simplify benchmarking across organisations, with explicit criteria to evidence progress and support consistent scoring and prioritisation.

A maturity model is only useful if people interpret it the same way and it produces stable results over time, so validation needs to address both content (does it cover the right ideas?) and reliability (do different raters score it similarly?). Design-science work suggests starting with clear constructs and levels, then testing the draft with practitioners to check whether criteria are unambiguous and evidence is easy to recognise in real processes. Reviews of information-systems maturity models add that domain language matters: using terms familiar to QA/RA (e.g., management review, periodic review, supplier assurance) improves face validity and reduces scoring noise. A practical approach is to pilot the rubric with a small number of interviews, compare how two raters apply the levels, and refine criteria where disagreements cluster, which improves inter-rater consistency without making the tool complex.

Cross-case comparison is strengthened when the rubric asks for short, concrete evidence examples at each level—for instance, "risk-based test rationale linked to product impact" or "audit trail review with documented rationale"—so scorers are not guessing. Finally, periodic calibration sessions help keep scoring aligned as the organisation learns; calibration also creates a simple audit trail that shows how the model was maintained, which examiners and inspectors appreciate. These steps make a QA/RA-centred maturity model easier to apply, defend, and improve over time.This structure aligns to PQS elements and QRM logic so that higher maturity requires, for example, risk-based assurance for software that affects the quality system, traceable data-integrity controls, and cross-functional ways of working consistent with Pharma 4.0™. The DMI artefact operationalises these ideas into a 10-dimension framework and applies an adapted four-level scoring scheme, making the literature-to-practice link explicit for QA/RA benchmarking in this project.

Dimension	Abbrevations
Strategy & Governance	Defined digital QA/RA strategy; roles; decision rights
Culture & Skills	Training; competency framework; engagement
Process Design & Automation	Digitalised change control; workflow maps
Data & Information Mgmt	Data ownership; master data; integrity controls
Technology & Architecture	eQMS, validated tools; integrations
Validation & Assurance	Risk-based CSA-aligned approach; critical thinking
Risk & Security	Access control; supplier assurance; business continuity
Performance Measurement	KPIs; management review outputs
Cross-functional Integration	QA/RA with Ops/IT collaboration routines
Continuous Improvement	CAPA learning loops; retrospectives

Table 4: DMI dimensions with abbrevations

Within regulated contexts, evidence consistently points to barriers such as siloed functions, legacy processes, unclear ownership, skill gaps, and over-reliance on documentation as a proxy for assurance, which together can decouple digital tools from compliant value. The most persistent barriers in QA/RA digitalisation come from gaps in process ownership and data stewardship rather than from technology limits. Teams often rely on manual "bridges" such as spreadsheets or email to connect systems, which creates version control problems and undermines the integrity of the record, especially when access controls or change histories are unclear. Supplier assurance for hosted or cloud solutions can also be uneven, and without a risk-based vendor oversight plan—covering service levels, incident response, and audit rights—organisations struggle to demonstrate control over critical quality records. Training is another barrier: many programmes focus on "how to click" in the system rather than "how to make risk-based decisions" with the data, which weakens Compliance Readiness even when

the software is validated. On the other hand, the literature points to enablers that have repeatable impact: executive sponsorship tied to PQS outcomes, a single accountable owner per QA/RA workflow, routine periodic review of users and audit trails, and a CSA-style approach that focuses testing and documentation on what affects product quality and patients. These enablers reinforce one another because clear governance makes it easier to define evidence, allocate resources, and keep improvement moving after the go-live of a digital tool. In short, leadership, ownership, and risk-based routines are the multipliers that turn digital tools into reliable quality outcomes.

Conversely, enablers include executive sponsorship, clear use-cases tied to PQS outcomes, robust data governance, proportionate risk-based assurance, and cross-functional teaming that shortens feedback loops between QA/RA and operational units. Quality 4.0 programmes further show that capability building in analytics and problem-solving enhances adoption by giving teams the skills to interpret data and take action within compliant guardrails. Across the sources, the pattern is that maturity arises from reinforcing loops between governance, skills, processes, assurance, and data, rather than from individual technologies in isolation. The literature also indicates that measurement matters: models with clear criteria, transparent evidence requirements, and reliable level definitions produce results that can guide investment and withstand scrutiny during audits and inspections. For QA/RA, this implies using maturity evidence that links to PQS processes (e.g., management review outputs, change-control metrics, data-integrity checks) and to risk-based assurance records for systems that influence quality decisions. Open regulatory consultations, such as the EU's Annex 11 revision, further underscore the importance of auditable, risk-based lifecycle management for computerised systems—an area where maturity measures can demonstrate readiness and drive improvement. Given these findings, a domain-specific maturity model that sits on PQS/QRM foundations, integrates data-integrity governance, and reflects Pharma 4.0™ operating principles is well-justified as a lens for cross-organisational comparison in QA/RA.

Across the sources, there is strong guidance on data integrity, risk-based assurance, and readiness for digital quality, but far less open, detailed material focused specifically on QA and RA as the unit of analysis across organisations. Enterprise-level maturity models are common, yet they often miss the day-to-day decision points and evidence needs that define QA/RA success during inspections and routine operations. This gap justifies a lean, QA/RA-specific model that connects PQS and QRM logic to plain-language criteria and evidence examples so that scores are comparable and actionable across sites and companies. By grounding the model in Pharma 4.0™ principles and in design-science guidance for maturity models, the measure

aims to be rigorous without being complicated, and—most importantly—useful for planning and tracking improvement in regulated quality work.

In summary, the literature converges on five points that motivate the present study: first, strategy and governance are the primary drivers of digital success in regulated settings; second, regulatory baselines for electronic records and computerised systems require assurance and integrity to be designed into processes and culture; third, risk-based approaches (CSA, QRM, GAMP® 5) shift focus from paperwork to outcomes; fourth, maturity-model design research provides clear principles for building usable, auditable assessments; and fifth, Pharma 4.0™ and Quality 4.0 indicate that cross-functional integration and data-driven behaviours are central to sustained value. These conclusions collectively justify a QA/RA-specific Digital Maturity Index that is anchored in PQS/QRM and data-integrity expectations, aligned with Pharma 4.0™ thinking, and constructed following maturity-model design principles so that results can meaningfully inform readiness and improvement priorities across organisations.

For practicality, the interview applies six core dimensions—Strategy; Technology infrastructure; Data integrity; Process automation; Compliance readiness (assurance); Continuous improvement—while the full 10-dimension DMI is provided in Appendix A and used to interpret results across cases.

4. METHODOLOGY

4.1 Research Design and Approach

This study adopts a qualitative, multiple-case comparative design to understand how pharmaceutical organisations develop digital maturity within Quality Assurance (QA) and Regulatory Affairs (RA) functions. A comparative case approach supports in-depth exploration of local context while enabling pattern identification across sites, which suits complex organisational phenomena such as QA/RA digitalisation.

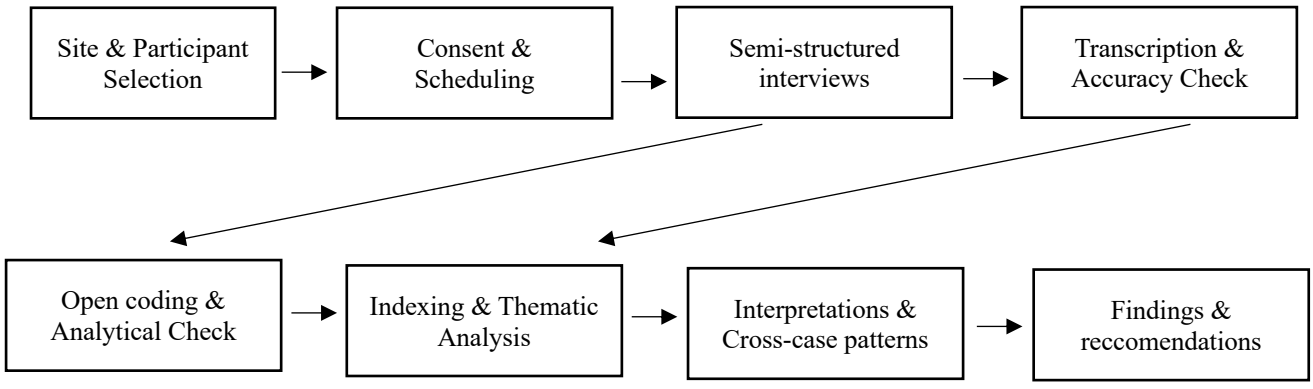

Fig 2: Study design flow

The lens is anchored to openly available practice frameworks—ICH Q10 Pharmaceutical Quality System, ICH Q9(R1) Quality Risk Management, FDA Computer Software Assurance (CSA), and ISPE Pharma 4.0™—to ensure relevance to regulated work without converting this research into a compliance audit. These references act as sensitising concepts for questions and analysis rather than prescriptive checklists, maintaining methodological flexibility while remaining aligned to PQS and risk-based principles. This study takes a qualitative, interpretivist stance and uses a multiple-case strategy focused on real practice in regulated QA/RA. It follows a mainly inductive/abductive logic: codes and themes are developed from interviews while being sensitised by established concepts (PQS, QRM, CSA, Pharma 4.0). The method choice is mono-method qualitative (semi-structured interviews), with a cross-sectional time horizon across five organisations. Analysis uses the Framework Method with a case-by-theme matrix so patterns can be compared transparently.

4.2 Setting and Participants

The field comprises GMP-regulated pharmaceutical organisations operating in or serving the Irish market, reflecting typical QA/RA contexts where electronic records and computerised systems are central to decision-making. Participants are professionals directly engaged in QA, RA, computerised systems validation/assurance, digital quality systems, manufacturing IT/OT that supports quality processes, or cross-functional digital-transformation roles interfacing with QA/RA. To protect confidentiality and encourage candour, all organisations and individuals are pseudonymised, and no identifiable product or company names are reported.

4.3 Inclusion and Exclusion Criteria

Inclusion requires a minimum of two years' experience in a GxP-relevant QA/RA or closely interfacing role and current or recent involvement with quality-system processes, data integrity, change control, regulatory operations, or validation/assurance activities. Participants must be able to discuss how digital practices are governed and used within QA/RA or adjacent functions (e.g., Quality Systems or Regulatory Operations) to ensure information-rich interviews. Exclusion applies to roles with no substantive QA/RA interface, to purely commercial or discovery R&D posts, and to consultants whose non-disclosure obligations would prevent meaningful discussion even under anonymisation. Focusing eligibility in this way targets practitioners who can speak to the intersection of compliance, process, data, and technology in regulated environments.

Inclusion	Exclusion
≥2 years GxP experience in QA/RA or interfacing function	No substantive QA/RA interface, or NDA prevents discussion
Current/recent involvement in quality systems, DI, change control, regulatory ops, or validation/assurance	Purely commercial or discovery R&D roles with no quality-systems interface

Table 5: Inclusion and exclusion criteria for participants

4.4 Sampling Technique

Sampling is purposive and criterion-based to recruit information-rich cases that meet the inclusion criteria rather than statistically representative samples. The planned sample is six participants across five organisations, which balances breadth with depth and reflects the approved scope in the institutional ethics submission. Sample sufficiency is assessed using code saturation (no new codes emerging) and meaning saturation (no new insights about existing codes), documented through a running log that links interviews to coding developments. Evidence shows that many thematic domains stabilise within a small number of expert interviews, with meaning saturation sometimes requiring additional cases depending on heterogeneity, which supports the present plan.

4.5 Materials

Two instruments are used: a semi-structured interview guide and a researcher-developed Digital Maturity Instrument (DMI) rubric tailored to QA/RA. The interview guide is derived from the research questions and sensitising frameworks (PQS, QRM, CSA, Pharma 4.0™), then piloted to refine prompts, flow, and probes following open guidance on interview-protocol development. For data collection, the DMI rubric focuses on six dimensions expressed in accessible terms—Strategy**,** Technology Infrastructure**,** Data Integrity**,** Process Automation**,** Compliance Readiness**,** and Continuous Improvement**—**each discussed with concrete examples and a simple Likert rating to support cross-case comparison. The rubric is used as a conversational scaffold and descriptor, not as a compliance scorecard, aligning with risk-based assurance principles and lifecycle quality thinking. The study also includes the full 10-dimension DMI (with a four-level scale) in Appendix A to document conceptual completeness and traceability to maturity-model design literature. The interview protocol was built directly from the research questions and the six live rubric dimensions—Strategy, Technology Infrastructure, Data Integrity, Process Automation, Compliance Readiness, and Continuous Improvement—so the conversation flows from goals to everyday practice. A short pilot with two colleagues in QA/RA was used to check that prompts were clear, focused, and not leading, and small wording changes were made where people asked for clarification. The protocol also

includes a simple Likert rating for each dimension (1–4), but ratings are discussed after the narrative to avoid steering answers too early. The final version balances consistency across interviews with enough flexibility to follow lines of inquiry that are especially relevant for a participant's role.

4.5.1 Digital Maturity Index (DMI): instrument and scoring

During the interview after the narrative for each theme, 1–4 rating is assigned and guided by short evidence cues. 1 = ad hoc/incidental, 2 = emerging/informal, 3 = defined/consistent, 4 = optimised/continuous improvement. Ratings are based on recent, concrete examples discussed in the interview; if evidence is mixed, lower score is recorded and note a one-line rationale. Single total score was not computed; instead, the per-dimension profile across cases and link it to readiness/performance signals collected at the end of each interview was compared.

4.6 Methods

Data are collected via one-to-one semi-structured interviews conducted face-to-face or using secure videoconferencing where travel or scheduling constraints apply. Synchronous online interviewing is established as a feasible method that preserves depth and rapport while offering practical advantages for multi-site qualitative studies. Interviews are expected to last 30–45 minutes, are audio-recorded with permission, and are professionally transcribed or transcribed by the researcher with accuracy checks and optional participant verification of quoted extracts for factual correctness. Field notes are completed immediately after each interview to capture contextual details, early interpretations, and follow-up prompts for subsequent participants where appropriate. Most interviews will be done on secure video calls to fit busy schedules across multiple sites, and prior research shows that synchronous online interviewing can achieve depth and rapport similar to in-person sessions when basics like audio quality and privacy are managed. Participants are asked to join from a private space, to use headphones where possible, and to avoid naming specific products or companies during examples, which protects both confidentiality and focus.

Before the first question, consent checks that recording is working, and reminds the participant that they can skip any question or pause the session at any time, which reduces pressure and builds trust. When network issues occur, the protocol is to stop, note the timestamp, and resume or reschedule rather than risk losing the thread of the conversation, because the quality of the transcript matters for coding later. Alongside the maturity discussion, participants are asked for practical readiness and performance signals from the last 12–24 months (e.g., inspection

experience, QA change-control cycle time, CAPA on-time) so the maturity narrative is anchored to observable results.

4.7 Data Analysis

Analysis follows the Framework Method, which supports systematic comparison across cases using a structured matrix while retaining links to the full transcript for auditability. The process comprises familiarisation, open coding, development of a working analytical framework aligned to the research questions and the six DMI dimensions, indexing of all transcripts, charting into a case-by-theme matrix, and interpretive analysis of patterns and relationships. Where needed to deepen specific lines of inquiry, reflexive thematic analysis techniques are used within Framework categories, maintaining transparency about coding decisions and theme development. All analytic artefacts are version-controlled and stored securely; no research data are transferred outside the EU/EEA without appropriate legal safeguards in accordance with GDPR. After familiarising with all transcripts, the first two interviews are open-coded line by line, letting codes emerge from the data before tightening them into an analytical framework mapped to the six rubric dimensions and any new themes that appear. The framework is then written as a short codebook with code names, plain definitions, and example quotes, which makes later coding faster and more consistent. Each transcript is indexed to the agreed codes, and a case-by-theme matrix is built with one row per organisation and one column per analytical category, so it is easy to scan patterns and exceptions.

For example, the “Data Integrity” column might hold short summaries like “periodic review conducted but only for one system; supplier oversight plan draft in progress,” with a link to the supporting line numbers in the transcript. Where a theme needs deeper interpretation, reflexive thematic analysis techniques are used within the relevant column to explore nuance without losing the cross-case view. This combination—Framework for structure, reflexive techniques for depth—keeps analysis transparent and auditable for examiners while still making room for insight. These signals are charted in the case-by-theme matrix so we can compare maturity ratings with readiness/performance notes at a glance. The final 1–4 ratings are entered in the case/theme matrix with a one-line rationale and quote line numbers. Profiles are read rather than totals and interpret them alongside readiness/performance signals (inspection experience, QA change-control cycle time, CAPA on-time)

4.8 Trustworthiness and Rigour

Rigour is supported through credibility, dependability, confirmability, and transferability, with explicit procedures mapped to each criterion. Credibility is enhanced by iterative probing, the common six-dimension rubric to keep interviews on comparable ground, and limited member checking for factual accuracy of quotations. Dependability is supported by an audit trail including protocol versions, the interview schedule, codebook iterations, the Framework matrix, and decision logs that explain analytical refinements. Confirmability is addressed through reflexive memos, supervisory review of emergent themes, and storage of de-identified excerpts that substantiate key claims. Transferability is aided by thick description of roles, process contexts, and site characteristics at an abstracted level to protect anonymity while allowing readers to judge applicability. Reporting will follow COREQ to improve completeness and transparency of qualitative reporting. The researcher keeps brief reflexive memos after each interview and coding session, noting assumptions, surprises, and how prior experience with QA/RA might shape interpretation, and these memos are reviewed during supervision to check for blind spots. Credibility is supported by using concrete probes and asking for examples; when appropriate, the researcher confirms factual details in quotes with participants ("member checking lite") to avoid misrepresentation. Dependability is strengthened by saving protocol versions, codebook iterations, and matrix snapshots with dates, so that a clear audit trail shows how the analysis developed over time. Confirmability is addressed by anchoring interpretations to multiple excerpts across cases rather than to single striking quotes, which helps separate signal from noise. Saturation is documented in a short log that notes when no new codes appeared ("code saturation") and when further interviews stopped adding meaning to existing codes ("meaning saturation"), which is a transparent way to justify the sample size for a focused qualitative study.

4.9 Ethical Considerations, Data Protection, and Confidentiality

Prior ethics approval is obtained, and participants provide written informed consent after receiving an information sheet that outlines purpose, procedures, risks, benefits, voluntary participation, and data rights. Personal data are handled lawfully, fairly, and transparently under the EU GDPR, with encryption at rest and in transit, role-based access, and retention and deletion aligned with institutional policy. Anonymity is maintained by pseudonymising organisations and individuals; any inadvertently disclosed proprietary names or sensitive commercial details are redacted during transcription. Because interviews may reference computerised systems and assurance approaches, the consent form clarifies that this research is not an audit and that no compliance judgements will be issued, which reduces perceived risk

for participants. Ethical handling of data is consistent with data-integrity expectations in regulated environments, reinforcing ALCOA(+) principles and good record management practices. All recordings and transcripts are stored on institution-approved, encrypted storage with access limited to the researcher and supervisor, and no files are kept on personal devices, which reduces the chance of accidental disclosure. Pseudonym keys that link participant IDs to names are stored in a separate, encrypted file so that a transcript on its own cannot be traced back to a person. Data are retained only for the period set out in the institution's policy for student research and are then securely deleted; if there is a need to keep de-identified excerpts for examination or publication, those are kept without any direct identifiers. Under the EU General Data Protection Regulation (GDPR), participants have rights to access and, in some cases, to erasure; the information sheet explains these rights clearly and provides a contact point for questions or requests. Good record management practices from MHRA and WHO are used as a design lens—especially around traceability of changes and control of access—so that ethical handling supports data-integrity expectations too. The consent form also makes clear that this study is not an audit and that no compliance judgements will be issued, which lowers perceived risk and encourages honest, specific examples.

4.10 Limitations of the Methodology

The small, purposive sample of six participants across five organisations prioritises depth over statistical generalisability, which is appropriate for qualitative inquiry but limits external validity claims. Self-report bias is possible; mitigation includes probing for concrete examples, seeking negative cases, and triangulating across cases using the common six-dimension rubric to structure comparisons. Researcher subjectivity is managed through reflexive memoing, supervisory dialogue, and a transparent analytical framework that links interpretations to evidence. Despite these limitations, the comparative design, systematic Framework analysis, and explicit attention to trustworthiness provide a credible basis for the study's conclusions and recommendations.

5. FINDINGS AND ANALYSIS

This chapter presents findings using the Digital Maturity Index (DMI) and a thematic analysis of interviews. Results are organised by the six live-rated dimensions (1–4): Strategy, Technology infrastructure, Data integrity, Process automation, Compliance readiness (assurance), and Continuous improvement. Notes from the other four DMI dimensions (Leadership & governance, Culture & change, Integration & interoperability, Analytics & decision support) are included where relevant. Ratings are reported as a profile, not a single

total, and are read alongside readiness/performance signals (inspection experience, QA change-control cycle-time trend, CAPA on-time trend, submission timelines) and themes were refined across all six interviews.

DMI dimension (live-rated)	P 1	Reason (P1)	P 2	Reason (P2)	P 3	Reason (P2)
Strategy	**3**	Director approvals link projects to compliance aims; KPI cadence not shown in this interview.	**3**	QA head + cross-functional steering; goals = compliance & efficiency; monthly/bi-weekly reviews.	**3**	Daily team huddle + cross-functional meeting; events review cadence; customer calls to resolve issues.
Technology infrastructure	**3**	Broad stack (QMS, MES, LIMS/Empower, e-logs); backups/second server; some platform transition.	**3**	SAP/QMS, LIMS, EDMS in daily use; some logs still paper during migration.	**2**	Hybrid environment: current site still largely paper, migrating to eBMR/eBPR; uses MasterControl QMS, MES, LIMS, JD Edwards, "Antares"; MES slows/hangs at peaks.
Data integrity	**3**	Execute→review→approve; audit-trail reviews pre-release/periodic; role-based access; minor lab lifecycle gaps.	**3**	ALCOA+, e-signatures, periodic audit-trail checks; role-based access; DI "walks/spot checks".	**3**	Three-step flow (operator→production review→QA review); role-based access; passwords rotate ~60 days; events + training if DI issues.
Process automation	**2**	MES stops runs if any step is missed → delays/training overhead.	**3**	Auto-routing speeds CAPA/deviation approvals; some day-to-day logs still paper.	**2**	Line clearance and some logbooks still manual; MES stoppages 1–2×/month; delays 30 min–2–3 h at busy times.
Compliance readiness (assurance)	**3**	Risk-based CSV; quarterly internal audits; periodic checks vs new guidance.	**3**	Risk assessment before go-live; validation; periodic reviews vs HPRA/EMA; internal audits.	**3**	Validation for new systems; risk assessment for changes (EDMS small change = simple test; new MES module = full validation); internal/external/customer/supplier audits.
Continuous improvement	**3**	Procedure reviews + trainer-supported go-lives; KPI specifics not discussed.	**3**	Monthly/bi-weekly steering; training emphasis; transition "in progress".	**3**	Weekly huddles; monthly metrics (CAPA on-time ~92%); regular Gemba walks; barcode scanning introduced for line clearance.

DMI dimension (live-rated)	P 4	Reason (P4)	P 5	Reason (P5)	P 6	Reason (P6)
Strategy	3	Weekly pipeline + monthly cross-function;	3	Weekly pipeline + monthly cross-function; first-cycle focus.	3	Manager sets; weekly pipeline; first-time-right focus.

		fast-track for inspections/launches.				
Technology infrastructure	3	EDMS/RIM + publisher stable; integration gaps/duplication; peak slowdowns.	3	EDMS/RIM + publisher stable; integration gaps/duplication; peak slowness.	3	EDMS stable; some RIM↔EDMS double entry; publisher slows at peaks.
Data integrity	3	Draft→peer→approve; version control; pre-submission audit-trail; monthly RA spot checks; supersede, not delete.	3	Draft→peer→approve; pre-publish QC/audit-trail; DI sweep; supersede (no delete).	3	Draft→peer→approve; pre-submission audit-trail; monthly RA spot checks; supersede.
Process automation	2	Templates/routing automated; content reuse & country tracking partly manual; workflow stops; 1–2 h delay (up to a day).	3	Validations/workflows help; naming pre-check reduced rejects; smoother re-submits.	2	Routing ok; reuse/notifications in spreadsheet; workflow stops; fix <1–24 h.
Compliance readiness (assurance)	3	Validation for new; risk-assessed for small; internal/customer/authority audits (Part 11/Annex 11 focus).	4	Traceable change→submission→approval chain; robust query handling; audit-ready.	3	Validation for new; risk-based tests for small; audits check traceability/SOP.
Continuous improvement	3	Monthly KPIs/lessons-learned; metadata rules cut queries; early readiness checks reduced clock-stops.	3	Monthly KPIs + lessons-learned; templates/pre-checks improved first-time-right.	3	Dashboards; lessons-learned; refreshers; early checks cut clock-stops.

*1 = ad hoc/incidental
*2 = emerging/informal
*3 = defined/consistent
*4 = optimised/continuous improvement

Table 6: DMI ratings for participants response

Matrix Snapshot

Across six participants, Data integrity is consistently level-3 (three-step review, role-based access, pre-release/periodic audit-trail checks), and Compliance readiness is level-3 for most, with P5 showing level-4 due to a traceable change→submission→approval chain and a tight query process. Process automation remains the main split (P1=2, P2=3, P3=2, P4=2, P5=3, P6=2): MES/workflow stops and manual pockets (line-clearance; RA content reuse and country tracking in spreadsheets) slow flow, while QMS auto-routing helps at P2 and pre-checks help P5. Technology reads 3–3–2–3–3–3 (P3 is still paper-heavy during migration; RA tools are stable but not fully integrated and can slow at peaks). Early readiness signs match this: P1 faster submissions/fewer document observations; P2 quicker internal approvals/easier retrieval; P3 high CAPA on-time (~92%) but time loss when MES stalls; P4 fewer queries/clock-stops and faster approvals; P5/P6 show approvals around 3–4 months with lower queries and clock-stops.

5.1 Participants

Six semi-structured interviews were planned across regulated quality roles. Anonymity is maintained by using participant IDs and removing company/product names. All participants work under GxP conditions and use a mix of QMS, MES, LIMS and EDMS/e-logbook tools.

Participant 1 (Project Quality Engineer (>8 years exp)). Works across QA and validation. Everyday systems include TrackWise/Q-Plus (QMS), MES, LIMS/Empower, and electronic logbooks. Described strong data-integrity routines (execute → review → approve; audit-trail review pre-release/periodic) and some MES friction when steps are missed. Reported faster submissions and fewer documentation observations since digitalisation.

Participant 2 (QA Manufacturing Specialist (>4 years exp)). Supports manufacturing QA workflows. Uses SAP/QMS, LIMS, EDMS; runs a hybrid paper + digital setup during migration. Auto-routing in QMS has reduced approval chasing and made evidence easier to retrieve during audits.

Participant 3 (Quality Operations Specialist (>4 years exp)). Operates in a paper-heavy site that is migrating to eBMR/eBPR. Uses MasterControl (QMS), MES, LIMS, JD Edwards (warehouse) and a serialization/track-and-trace suite (e.g., Antares) on the packaging side. Reports daily huddles and cross-functional reviews; MES can be slow at peaks; CAPA on-time ≈ 92%; barcode scanning introduced for line clearance.

Participant 4 (Regulatory Affairs Specialist (>2 years)). Works on CMC submissions and variations, coordinating with QA/Production/QC. Uses EDMS/RIM for documents/metadata, publishing for eCTD build/validation, and QMS for change/CAPA links; data also pulled from LIMS and a registrations database. Described weekly pipeline and monthly cross-functional reviews, stable EDMS/RIM, but integration gaps (duplicate entries; version-link issues) and peak slowdowns in publishing. Reported three-step review (draft → peer → approve), pre-submission audit-trail checks, and monthly RA spot checks. Readiness signals include fewer queries, fewer clock-stops, and faster approvals for similar scope.

Participant 5 — Regulatory Operations (2+ years). Runs document assembly and lifecycle management across EDMS/RIM and publishing. Confirms weekly pipeline, monthly cross-function and a first-cycle focus. Reports stable tools with integration gaps and peak-time slowness; a small naming pre-check reduced rejects and smoothed resubmits. Assurance reads strong: a traceable chain from change → submission → approval, structured query handling and tidy records. Approvals are around three to four months, with queries four to six and clock-stops reduced after fixes.

Participant 6 — Regulatory Operations (1 year). Works on assembly and submissions with an emphasis on day-to-day routing and quality checks. Confirms manager-set priorities and the

same weekly pipeline rhythm with a first-time-right mindset. EDMS is stable; some double entry remains between RIM and EDMS; the publisher slows at peaks. Integrity controls mirror others: supersede, pre-submission audit-trail checks and monthly spot checks. Workflow stops still happen on missing fields or signatures, but returns are generally fixed within hours to a day depending on volume. Approvals run three to four months with lower query counts after early checks were added.

These brief profiles help interpret the ratings that follow and explain differences in technology maturity and process flow across sites. Readiness/performance notes (inspection experience, cycle-time, CAPA on-time, submission timelines) are used later when comparing maturity profiles.

5.2 Thematic analysis

Research shows that a clear thematic analysis reads each transcript closely, codes line-by-line, clusters similar codes into sub-themes, and then reviews these against the whole dataset and a guiding framework to produce stable themes. In this study, the analysis followed those steps and used the Digital Maturity Index (DMI) as a lens to check fit without forcing the data. A short codebook (code name, plain definition, tiny quote) was maintained to keep decisions transparent and to make later interviews comparable. Themes are reported in plain English with brief quotes; each theme ends with a 1–4 rating link and a readiness note (inspection experience, QA change-control cycle-time trend, CAPA on-time trend, submission timelines). This keeps the reasoning auditable while staying close to what participants actually described.

Procedure. Transcripts were read repeatedly, then coded line-by-line. Codes were merged into sub-themes and refined through constant comparison across participants. The working analytical framework was aligned to the six live DMI dimensions (Strategy, Technology infrastructure, Data integrity, Process automation, Compliance readiness, Continuous improvement), with the other four DMI dimensions used qualitatively where relevant (Leadership & governance, Culture & change, Integration & interoperability, Analytics & decision support). A case-by-theme matrix was built so patterns and exceptions could be scanned at a glance, and so the 1–4 ratings and readiness signals could be viewed together for within-case and cross-case interpretation.

Trustworthiness. Consistency was supported by keeping a dated codebook, noting one-line rationales beside every rating, and linking each claim to short evidence excerpts. Where evidence was mixed, the lower score was taken and the reason recorded. Reflexive notes were kept after each interview and coding session, and limits are stated clearly when the sample is still small or where metrics were not available.

5.3 Theme A — Strategy: compliance-first, shared ownership

Both participants describe formal ownership of digital work tied to compliance and efficiency goals. Participant 1 highlighted director approvals across Quality, Finance, Manufacturing and Lab before projects proceed, which shows cross-functional governance but did not evidence KPI-style management review. Participant 2 described QA leadership with cross-functional steering (monthly for general items; bi-weekly when critical), which keeps priorities moving and reduces approval chasing. Participants 3–6 reinforce the same picture. P3 described a daily team meet, a cross-functional check-in, and an events review to chase open points; P4 (RA) works to a weekly pipeline and monthly cross-function call, with fast-track near inspections/launches. P5 and P6 (RA ops) also keep a first-time-right focus under weekly pipeline reviews. Ownership is clear and cadence is regular, which keeps priorities moving even when timelines are tight.

Illustrative quotes: "All directors need to approve the project …" (P1). "Steering meets bi-weekly for critical items …" (P2). "At nine o'clock we have a team meeting and plan the day." (P3) "Weekly pipeline, monthly cross-function; if a launch is near we fast-track." (P4) "We review the pipeline every week; aim is first-cycle approval." (P5) "My manager sets priorities; weekly check keeps us on time." (P6)

Interpretation: Strategy is defined/consistent rather than optimised: decisions have owners and cadence, but did not hear strong examples of quantified targets or management-review actions linked to DMI dimensions.

Readiness link: Regular reviews reduce last-minute rush and support smoother approvals/inspections.

5.4 Theme B — Technology: broad stack; resilience vs transition

Participant 1 runs a broad digital stack (QMS, MES, LIMS/Empower, e-logs) with backups and a second server for resilience; some platform change is underway (e.g., TrackWise→Q-Plus). Participant 2 uses SAP/QMS, LIMS, EDMS, with paper kept as backup during migration to avoid downtime. P3 works in a paper-heavy site that is moving to eBMR/eBPR and reports MES slowdowns at peaks. P4–P6 (RA) say EDMS/RIM/publisher are stable, yet there are integration gaps and double entry (RIM↔EDMS); the publisher can slow when many builds run together. Most cases remain level-3 infrastructure (stable, usable), with P3 level-2 until migration completes.

Illustrative quotes: "We are completely digitalised … backups, second server …" (P1). "We're moving logs to digital; paper remains during transition." (P2). "Our company is still paper-based; we are moving to eBMR/eBPR." (P3) "EDMS/RIM are stable; integration gaps

make me check versions manually." (P4) "Publisher is fine, but at peak loads it slows down." (P5) "Some fields don't flow; I type the same data twice." (P6)

Interpretation: Stable platforms make dossier work and evidence retrieval quicker during audits/submissions

Readiness link: Better RIM/EDMS/QMS mapping would cut queries and rechecks.

5.5 Theme C — Data integrity: layered ALCOA+, tighten lifecycle edges

Both participants describe execute → review → approve with role-based access and audit-trail reviews. Participant 1 notes pre-release audit-trail for some systems and periodic checks for others (monthly/six-monthly); a recurring lab issue ("unfinished channels") shows lifecycle edges to tidy. Participant 2 cites ALCOA+, e-signatures, and periodic DI checks, including walk-throughs/spot checks. P3 confirmed a three-step flow (operator → production review → QA approval), role-based access, and training after DI events; passwords rotate on a set schedule. P4–P6 described draft → peer → approve, no delete (use supersede), pre-submission audit-trail checks, and monthly spot checks in RA folders. Small fixes (metadata rules, checklists, refreshers) followed incidents.

Illustrative quotes: "QA performs audit-trail review … no one can delete data." (P1). "We check audit trails monthly." (P2). "Draft, then production review, and QA approval—roles are fixed." (P3) "Before submission we review audit trails and signatures." (P4) "Approved docs are never deleted; we supersede with a new version." (P5) "We do a pre-submission audit-trail check and monthly RA spot checks." (P6)

Interpretation: Integrity practices are steady at level-3; moving 3→4 needs clearer periodic-review rationales and recorded follow-ups.

Readiness link: Strong DI routines align with fewer documentation observations and smoother submissions.

5.6 Theme D — Process automation: depth vs flow/usability

Participant 1's MES is strict—if any step is missed, the run stops until resolved. That protects quality but adds friction and depends on trainer support at go-live. Participant 2 reports auto-routing in QMS that speeds approvals, though some logs are still paper. Flow breaks at exceptions. P3 still uses manual line-clearance and sees MES stoppages (1–2×/month, 30–180 min). In RA (P4–P6), routing is automated but content reuse and country tracking often sit in spreadsheets; workflows stop when a required field or signature is missing. P5 added a small naming pre-check that reduced rejects; P6 fixes returns within hours/day depending on volume.

Illustrative quotes: "If any single point is missed, the machine stops." (P1). "Auto-notifications move CAPA faster." (P2). "If MES stops, clearing it can take thirty minutes to hours." (P3) "Reuse and country notifications still sit in a spreadsheet." (P4) "The pre-check

on names cut many publishing rejects." (P5) "When a field is missed, workflow stops and comes back to me." (P6)

Interpretation: Automation exists, but **exception paths** are the bottleneck; each stop causes rework and time loss.

Readiness link: Map top stops and shift reuse/notifications into the system to shorten cycle-time.

5.7 Theme E — Compliance readiness: risk-based assurance as routine

Both describe **risk-based validation/assurance** before go-live and **internal audits** to stay aligned with expectations. P1 mentioned quarterly audits and checks vs updated guidance; P2 cited risk assessment + validation against HPRA/EMA expectations. P3, P4 and P6 described validation for new systems and risk-assessed testing for small changes, with internal/external audits focused on Part 11/Annex 11, traceability and SOP use—steady level-3. P5 showed a tight, traceable chain from change → submission → approval and structured query handling, which reads as level-4 assurance.

Illustrative quotes: "We perform CSV before using software … internal audits every three months." (P1). "We validate and review against HPRA/EMA." (P2). "For small template updates we test light; big changes get full checks." (P3) "Audits look for Part 11/Annex 11 controls and traceability." (P4) "We can trace a change through to submission and approval." (P5) "Internal audits check signatures, history and SOP steps." (P6)

Interpretation: Assurance is proportionate and routine; documenting the risk-based reasoning more clearly will help other sites move toward level-4.

Readiness link: Clear assurance records reduce back-and-forth in inspections and submissions.

5.8 Theme F — Continuous improvement: routines present; KPI visibility varies

Participant 1 reports procedure reviews, trainer-supported transitions, and quarterly audits; KPI detail (e.g., CAPA on-time) wasn't discussed. Participant 2 has monthly/bi-weekly steering, visible governance cadence, and training focus during transition. P3 reports weekly huddles, Gemba, and monthly KPIs (e.g., CAPA on-time ≈92%) plus barcode scanning to cut errors. P4–P6 run monthly dashboards, lessons-learned, and short refreshers; small fixes such as metadata/naming rules and early readiness checks reduced queries and clock-stops in RA.

Illustrative quotes: "We review procedures and run internal audits." (P1). "Steering reviews progress every month/fortnight." (P2). "Our KPIs show CAPA on-time around ninety-two percent." (P3) "Dashboards and lessons-learned help us avoid repeats." (P4) "Templates and pre-checks improved first-time-right in publishing." (P5) "Refresher trainings and early checks lowered clock-stops for us." (P6)

Interpretation: CI sits at level-3: routines with visible benefits. Publishing two simple KPI trends into the steering forum would make learning loops stronger.

Readiness link: Fewer repeats and steadier audits where fixes are tracked to closure.

5.9 Preliminary synthesis

With six interviews, the pattern is clear. Teams run defined/consistent controls for Data integrity and Assurance (draft→review→approve, RBAC, "supersede not delete," audit-trail checks), which links to steadier audits and smoother submissions. The bottleneck is process-automation flow. Where MES or workflow stops on exceptions and manual pockets remain (paper line-clearance; RA reuse/notifications in spreadsheets), cycle-time stretches and people do double work. Where auto-routing or small pre-checks exist (e.g., P2's QMS routing; P5's naming pre-check), internal movement is faster. Technology is broadly stable across five contexts; one site is still paper-heavy mid-migration, and RA shows integration gaps that create duplicate typing and occasional version-link checks. Implication. Raising readiness is practical: (1) lift DI/assurance from 3→4 by recording periodic-review rationales and making risk-based test decisions explicit in records; (2) smooth exception paths and remove manual pockets (map common stops, shift reuse/notifications into system, keep brief go-live refreshers). These actions directly tie to fewer queries/clock-stops, shorter QA/RA cycle-time, and more confident inspections. Findings across six roles show a stable baseline in Data integrity and Assurance (level-3), with Process automation and system integration as the main constraints. The most frequent pain-points are MES/workflow stops and spreadsheet-based reuse/notifications. Where routing and pre-checks are used, movement is quicker and queries/clock-stops fall. The next chapter links these patterns to the literature and sets out focused actions to move from defined/consistent (3) to optimised/continuous improvement (4) in high-impact areas.

6. DISCUSSION

Across the six interviews (P1–P6), the overall picture is steady: teams have defined and consistent controls for digital work (three-step review, role-based access, "supersede not delete," audit-trail checks before release and on a schedule), and this baseline connects to smoother submissions and steady audits. The main differences show up in flow, not in basic control: where MES/workflows stop on exceptions and where manual pockets still sit outside systems (paper line-clearance on the floor; content reuse and country notifications in RA spreadsheets), the cycle-time stretches and people do double work. Sites with practical helpers—like auto-routing in QMS or a small pre-check before publishing—move faster and see fewer queries/clock-stops. Technology is mostly stable across roles, but integration gaps (for example, duplicate typing between RIM and EDMS, or version-link checks) create small mismatches and rechecks; one site is still paper-heavy during migration and reports MES

slowdowns at peaks. Strategy comes through as compliance-first with regular cadence: weekly pipeline reviews and monthly cross-functional catch-ups are common, ownership is clear, and launches/inspections get fast-tracked. Continuous-improvement routines (huddles, dashboards, lessons learned, short refreshers) do exist and are helping in small ways—metadata/naming rules, barcode scanning, and early readiness checks have already reduced errors and clock-stops in several places. Pulling this together, the results answer both parts of the study aim: the maturity profile is around level-3 for Data Integrity and Assurance in most cases, while Process Automation and system integration are the bottlenecks that explain the readiness differences (queries, clock-stops, cycle-time, approval timelines). The most practical path from 3 → 4 is not a big tool change; it is (a) make periodic reviews meaningful by writing a short rationale and recording follow-ups, and (b) smooth the exception paths by moving spreadsheet work into the system and adding a few pre-checks where stoppages are common. These small steps line up with the readiness signals reported here: faster internal movement, fewer corrections, shorter queues, and fewer surprises during inspections or submissions.

6.1 Limitations and credibility checks

This is a small qualitative study with six interviews; several readiness numbers are self-reported (not direct system exports), and one site is mid-migration, so the technology picture there will evolve. Vendor names were kept generic for confidentiality, which limits technical detail. To support credibility, the analysis used a codebook, a case × theme matrix, and a single-rater 1–4 score with the rule to take the lower score when evidence was mixed, plus a one-line rationale beside every rating. Short quotes were used to anchor interpretations, and routine patterns were reported cautiously. Future work should extend roles/sites, add document/dashboard review for the quantitative signals, and re-check the same dimensions after key fixes (pre-checks, integration, review rationales) are in place.

DMI theme / dimension	Core finding (P1–P6)	Answers RQ1 (maturity profile)	Answers RQ2 / Aim (maturity → readiness)
1) Strategy & Governance	Compliance-first; weekly pipeline + monthly cross-function; fast-track near launches/inspections.	Level-3 (clear owners, regular cadence).	Regular cadence reduces last-minute scrambles → smoother approvals/inspections.
2) Technology Infrastructure	Tools mostly stable; integration gaps (RIM↔EDMS duplicate entry); publisher slows at peaks; one paper-heavy site mid-migration.	Mixed: mostly 3, one 2.	Gaps cause re-checks/mismatches → extra review time and small delays.
3) Data Integrity & Records	Draft → review → approve, RBAC; supersede not delete; pre-release/periodic audit-trail checks; small fixes after incidents.	Level-3 across cases.	Consistent controls align with fewer documentation observations and smoother submissions.
4) Process Automation & Workflow	Stops on exceptions; manual pockets (paper line-clearance; RA reuse/notifications in sheets). Pre-checks help.	Split 2/3 depending on stops.	Stops create delay/double work; pre-checks & routing reduce clock-stops.
5) Compliance Readiness / Assurance (CSV/CSA)	Validation for new; risk-based testing for small; audits focus Part 11/Annex 11; RA (P5) has traceable chain.	Mostly 3; P5 = 4.	Clear, proportionate assurance reduces back-and-forth at inspection/submission.
6) Continuous Improvement & Learning	Huddles/dashboards/lessons-learned; short refreshers; small fixes (metadata/naming rules, barcode, early checks) reduce errors.	Level-3 routines.	Visible small wins (↓queries, ↓clock-stops) → faster internal movement.
7) People & Capability (Training & Change)	On-the-job refreshers work; targeted coaching around error types beats long classes; capability varies with role.	Level-3 (structured but practical).	Better micro-training before known pain points → fewer errors/rework.
8) Supplier / Cloud & SaaS Assurance	Vendor systems in play; assurance relies on risk-based docs + change impact; supplier evidence sometimes fragmented.	Level-2/3 (varies by team).	Weak supplier evidence slows audits and change closures.
9) Master Data & Interoperability (IDMP/SPOR, metadata)	RA highlights duplicate typing and occasional version-link checks; master data rules reduce queries.	Level-2/3 (rules exist; integration gaps remain).	Clean master data reduces queries/clock-stops and re-formatting loops.
10) Performance & Insight (KPIs & dashboards)	Dashboards exist but not always used in weekly decisions; numbers shared after the fact.	Level-2/3 (available, not fully embedded).	When KPIs drive the weekly forum, flow improves and surprises drop.

Table 5: DMI with core findings and answers to research questions

6.2 Non-Live DMI Dimensions in the Findings

People & Capability (training & change).

Evidence came from the warm-up and "improvement" prompts (who trains whom, what refreshers work, what changed after errors). Extraxts were coded mainly inside Theme F (Continuous improvement) and Theme D (Process automation) when training cut workflow stops. Across cases this reads as level-3: short refreshers close to the work, targeted coaching

around common error types, and on-the-job support at go-live. The readiness link is straightforward—better micro-training near risky steps → fewer mistakes and less rework. A practical lever is 15-minute micro-refreshers before known pain points and logging completion near the task rather than in a general LMS report.

Supplier / Cloud & SaaS Assurance:

Vendor-related assurance surfaced in the assurance/audit questions (what evidence is checked, how change impact is shown, what auditors ask for). Extraxts were analysed in Theme E (Compliance readiness). Maturity sits level-2/3 depending on how tidy the supplier documentation is. When supplier evidence is fragmented, audit prep slows and change closures stretch. The quick fix is to keep a standard supplier assurance pack (statement of applicability, test summary, DI/Part 11 controls) linked in QMS/EDMS, so it is ready during audits and for impact assessments.

Master Data & Interoperability (IDMP/SPOR, RA metadata).

This dimension appeared mainly in the RA interviews (P4–P6): duplicate typing between RIM↔EDMS, occasional version-link checks, and the positive effect of metadata rules. Theme B (Technology) and Theme D (Process) were coded because they directly affect integration and flow. Overall the picture is level-2/3: rules exist, but gaps remain. Readiness improves when a golden source is declared and 8–10 high-risk fields are mapped to auto-flow; this reduces queries, reformatting loops, and clock-stops.

Performance & Insight (KPIs & dashboards).

Metrics came up in both Theme A (Strategy cadence) and Theme F (CI). Most teams have dashboards, but numbers are not always used in weekly decisions, so this reads level-2/3. Where two simple measures are reviewed in the pipeline—change-control cycle-time (median) and CAPA on-time %—people move earlier, and last-minute escalations drop. The lever is to put those two KPIs on the weekly board with a 10-minute actions review so the cadence becomes data-informed, not just a meeting.

7. RECOMMENDATIONS

R1. Strategy & Governance.

Keep the existing weekly pipeline and monthly cross-functional forum, but make them lightly data-led so decisions move faster. Add just two measures to the weekly agenda—change-control median cycle-time and CAPA on-time %—and close each meeting with one small action, an owner, and a due date. This keeps focus on ageing items and prevents last-minute scrambles when launches or inspections approach. Assign the QA lead to chair, with the RA lead as co-owner, so both quality and regulatory work stay aligned. Within four to eight weeks, trend both measures and drop anything that adds noise. The expected effect is fewer fire-drills,

a steadier release rhythm, and cleaner hand-offs between teams. The main risk is metric overload; keep the list to two and review definitions quarterly so people trust the numbers.

R2. Technology Infrastructure.

Tools are stable but hand-offs create re-typing and checks, especially between RIM and EDMS. Map 8–10 high-risk fields (product ID, strength, dosage form, version, status, country) to flow automatically or be selected from a controlled list instead of typed. Where the publishing tool slows at peak times, schedule heavy builds off-peak and post a simple fallback so evidence still moves when systems are busy. Own this jointly between RA Ops and IT/CSV so validation is proportionate and change records are clear. The outcome is fewer mismatches, fewer last-minute corrections, and faster eCTD builds. The risk is tool limits; when full integration isn't ready, use a read-only lookup table in EDMS or RIM as an interim step, then replace it when the interface lands.

R3. Data Integrity & Records.

Controls exist—draft → review → approve, role-based access, "supersede, not delete"**,** and audit-trail checks—but the review quality needs to be visible. In every periodic review, add one or two lines explaining why the result is correct and what changed since the last cycle; sample a few audit-trail entries and user roles each time, and close small actions in the same record. This turns a tick-box into a traceable decision and removes doubt during audits. Make the system owner responsible, with a data-steward who checks for the rationale line before closing. In two cycles you should see fewer repeat findings and more confidence when records are inspected. Keep it lightweight: a clear sentence beats a long essay and keeps reviewers engaged.

R4. Process Automation & Workflow.

Readiness gaps come from exception paths**:** MES holds on missed steps and RA workflows that stop for missing fields or signatures while reuse/notifications live in spreadsheets. Pick the top three stops, add a pre-check or inline rule for each (for example, a naming/metadata checker before eCTD build; a brief step verification before MES release), and move any tracker that drives decisions from a spreadsheet into a controlled form or module. Own this with the process lead (QA for CC/CAPA, RA for publishing) and involve IT/OT only where rules touch systems. Measure clock-stops and first-time-right before and after. Expect shorter cycle-time and less rework without changing platforms. Allow exception notes with approval to avoid over-tight rules that block real work.

R5. Compliance Readiness / Assurance (CSV/CSA).

Validation is already proportionate; what is missing in places is visible reasoning. Add a short risk paragraph in each protocol or change record stating the potential impact on

product/decision, the tests selected, and why that depth is enough. Train approvers to look for this paragraph and sample one page per month for quality. This simple note reduces back-and-forth with auditors and speeds change closure because the logic is on the page. CSV/QA should own the template tweak; system owners provide the content. Keep it brief and specific so it does not become boilerplate. Over a quarter, you should see fewer validation queries and clearer links between change, evidence, and approval.

R6. Continuous Improvement & Learning.

Teams already run dashboards, lessons-learned and refreshers, and small fixes (metadata rules, barcode, early checks) are working. To lock these gains, run a 15-minute "fixes closed" huddle once a month. Show just three items: the problem, the fix, and a tiny proof (for example, queries per submission before/after). Save the single slide in EDMS and reference it in the pipeline meeting so actions do not drift. This short routine keeps attention on real outcomes, reduces repeat issues, and gives auditors a simple, credible story. Time-box the huddle so it stays useful, and rotate the presenter so learning spreads across roles.

R7. People & Capability (Training & Change).

Replace long classroom sessions with micro-refreshers delivered just before high-risk tasks (e.g., line-clearance, initial eCTD build, critical MES steps). A 10–15 minute walkthrough, one page of "do's and don'ts," and a buddy check on the first run after a change cut the common errors that trigger stops. Capture one or two frequently asked questions and update the one-pager; record attendance close to the work (EDMS note or shift board) rather than only in the LMS. The expected result is better first-time-right and faster clearance of holds. The risk is low uptake; schedule refreshers at shift start or right before the build so people actually attend.

R8. Supplier / Cloud & SaaS Assurance.

When evidence is scattered, audits slow down. Keep a standard supplier pack for each critical service in EDMS: a short scope/SoA, a test summary, a note on Part 11/Annex 11 controls, the approved change-notice route, and current contacts. Review the pack every six months and link it from QMS records so it is reachable during audits and impact assessments. The QA supplier-owner should maintain the pack with procurement/IT. This is light admin with a high payoff: faster responses, fewer follow-up emails, and clearer shared control. If a vendor is slow, request read-only access or a summary letter as an interim measure while the full pack is assembled.

R9. Master Data & Interoperability (IDMP/SPOR, metadata).

RA interviews showed duplicate typing between RIM and EDMS and version-link checks; master-data rules already reduced some queries. Declare golden sources for key product and site identifiers, enforce simple naming/ID rules, and align 8–10 fields across QMS/EDMS/RIM. If full integration is not available, publish a controlled reference list so users

pick values instead of typing them. Pilot the alignment on one product set, review mismatches weekly for a month, then roll out. Cleaner master data directly reduces RA queries, prevents re-formatting loops, and speeds country notifications. The risk is local variations; allow a small mapping table with an expiry date and review it until systems are aligned.

R10. Performance & Insight (KPIs & dashboards).

Dashboards exist but are not always used in weekly decisions. Build a small visual board with four tiles—change-control median**,** CAPA on-time**,** queue age by step**,** and RA queries per submission—and end the weekly pipeline with a 10-minute actions review: one action per tile or "no action" if the trend is acceptable. Keep definitions fixed so trends are real, and remove any tile that nobody uses. This avoids data walls and turns numbers into movement. Over a quarter you should see queue age come down, queries per submission fall, and a cleaner link between what leaders see each week and the improvements on the floor and in RA operations.

8. CONCLUSION

This dissertation set out to understand how digital maturity in QA and RA shows up in real work and how it relates to regulatory readiness. Six interviews across QA/MES and RA operations produced a consistent picture. The control layer is strong: people described draft → review → approval, role-based access, "supersede not delete," and audit-trail checks before release and on a schedule. This defined and consistent behaviour aligns with smoother submissions and steadier audits. Differences in readiness came from flow at exceptions and system hand-offs**,** not from the presence or absence of tools. On the shop floor, MES holds after a missed step protect quality but can be slow to clear; in RA, content reuse and country tracking often live in spreadsheets, and workflows stop for missing fields or signatures. Where small helpers exist—auto-routing in QMS or a simple pre-check before a publishing build—movement is faster and there are fewer queries and clock-stops. Technology itself is mostly stable, but integration gaps (for example, duplicate typing between RIM and EDMS and version-link checks) and one paper-heavy site mid-migration explain much of the variation. Strategy looks similar across contexts: compliance-first with weekly pipeline reviews and monthly cross-functional catch-ups, plus fast-track when inspections or launches are close. Continuous-improvement routines are visible: huddles, dashboards, lessons learned and short refreshers, with small fixes like naming or metadata rules and barcode scanning already making a difference. These findings answer the research questions directly. RQ1 (maturity profile). Across cases the live DMI dimensions settle near level-3 for Data Integrity and Assurance**,** while Process Automation and Technology hand-offs show mixed levels (2–3) depending on exception handling and integration. RQ2 (maturity → readiness). Readiness improves when the control layer is visible (short rationales in periodic reviews; proportionate, risk-based

testing written down) and when exception paths are smoothed (pre-checks, fewer spreadsheets, clearer hand-offs). These are modest, practical moves that any site can make this quarter. They do not require a platform change; they require attention to how work actually flows and how evidence is shown. The ten-dimension DMI helped interpret this because it kept people, process, data, and technology in view. The six live dimensions captured day-to-day practice; the other four explained why some places moved faster (better micro-training, tidier supplier packs, cleaner master data, and KPIs used in weekly decisions). The contribution is therefore both descriptive and practical: it gives a plain view of what level-3 looks like in QA/RA, shows the levers that move behaviour toward level-4, and links them to signals managers care about—queries, clock-stops, cycle-time, and approval timelines. These findings answer the research questions directly. For RQ1 (maturity profile): across the cases, the live DMI dimensions settle around level-3 for Data Integrity and Compliance

Readiness, while Process Automation and technology hand-offs vary between level-2 and level-3 depending on how well exceptions are handled and how clean the integrations are. For RQ2 (maturity → readiness): readiness improves when the control layer is visible—for example, periodic reviews include a short rationale and proportionate, risk-based testing is written down—and when exception paths are smoothed with small pre-checks, fewer spreadsheets, and clearer hand-offs. These are modest fixes that any site can make this quarter; they do not require a new platform. Using the ten-dimension DMI helped to interpret the picture: the six live dimensions captured everyday practice, and the other four (people capability, supplier assurance, master data, and KPIs) explained why some teams moved faster and had fewer issues. The contribution of this study is therefore both descriptive and practical: it shows what "level-3" looks like in QA/RA, identifies the levers that move behaviour toward level-4, and links those levers to signals that matter—fewer queries and clock-stops, shorter cycle-times, and quicker, steadier approvals.

9. LIMITATIONS

This is a small qualitative study based on six interviews, so the findings are indicative, not generalisable. Several readiness signals (e.g., approval timelines, queries per submission) were self-reported, not exported from systems, so recall or impression bias is possible. One site was mid-migration (paper-heavy), meaning the technology picture there is changing; results capture a moving target. To protect confidentiality, vendor and product names were kept generic, which limits technical detail. The DMI scores used a single rater with a "score low if mixed evidence" rule; this keeps the bar honest but may under-rate borderline cases. Finally, the work sits mainly in an Irish/European regulatory context; practices are similar elsewhere but not identical. These limits set fair boundaries for the claims while keeping the practical value of the results.

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