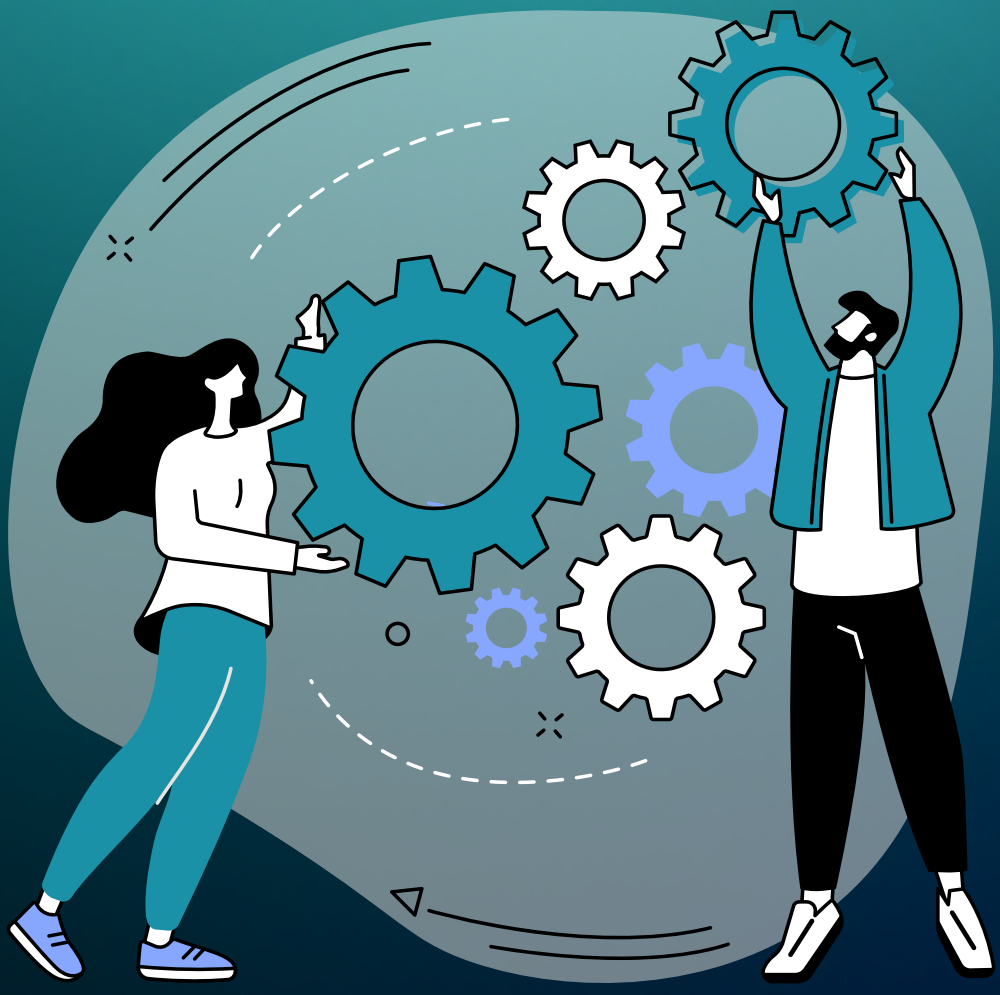
Survey

AI + Digital Maturity in Contract Development and Manufacturing

Global survey of CDMOs reveals critical implementation barriers and opportunities in 2025-2026

MasterControl™

Pharma Source



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Executive Summary

Global Survey of CDMOs Reveals Critical Implementation Barriers

The digital divide is opening: **60%** of Contract Development and Manufacturing Organizations (CDMOs) operate at preliminary maturity levels even as **92%** report sponsors are now raising digital requirements in negotiations.

The results of PharmaSource's survey of 50+ global CDMOs, in partnership with MasterControl, exposes the brutal economics of digital transformation in regulated manufacturing. Contract manufacturing organizations recognize digital value but face resource constraints, legacy infrastructure, and the unique complexity of digitizing environments where compliance failures carry existential risks.

The challenge is *how quickly* can CDMOs overcome barriers to implementation?

The timeline is compressing. While 92% of CDMOs report sponsors discussing digital requirements, these conversations haven't yet reached deal-breaking status. That window is closing. Digital readiness is shifting from competitive advantage to market requirement.

We surveyed organizations across the spectrum—revenue sizes from under $1 million to over $1 billion, facilities spanning Europe, North America, and Asia. The findings reveal a sector in transition: ambitious about AI's potential yet realistic about implementation timelines, eager to satisfy sponsor demands yet constrained by fundamental operational challenges.

The data reveals sharp contrasts. Laggards grapple with century-old facilities, limited resources, and cost-prohibitive transformation requirements. Leaders achieve enterprise-level integration through strategic system connectivity and measured AI deployment.

Between these extremes lies the majority—CDMOs running pilots, exploring possibilities, and working to bridge the gap between digital aspiration and manufacturing reality.

Strategic Imperatives for Digitization Success

Five priorities emerge for CDMO leaders:

1. Build the foundation before chasing AI

Only 27% of CDMOs have integrated electronic batch records; just 25% use manufacturing execution systems.

Organizations pursuing AI without core digital systems and data infrastructure in place are more likely to fail. Foundation first, innovation second.

2. Target implementation gaps with proven ROI

Supply chain forecasting and predictive maintenance show the widest disparity between perceived value and deployment—making them prime candidates for near-term investment with demonstrable returns.

3. Fix processes before digitizing them

Leading CDMOs follow the principle: "Don't digitalize the chaos." Process optimization must precede technological implementation.

Digital tools amplify existing processes—broken or functional.

4. Solve the sponsor integration problem

Zero CDMOs report full digital integration with sponsors, yet 92% hear these requirements in negotiations.

Early movers who crack sponsor connectivity will capture outsized value as expectations crystallize into contract terms.

5. Deploy resources with surgical precision.

Resource constraints remain the primary transformation barrier. Digitally mature competitors succeed through "start small, pilot, scale" methodology.

Broad investments diffuse impact; focused deployments generate momentum and ROI that fund expansion.

CDMO Digitization Priorities

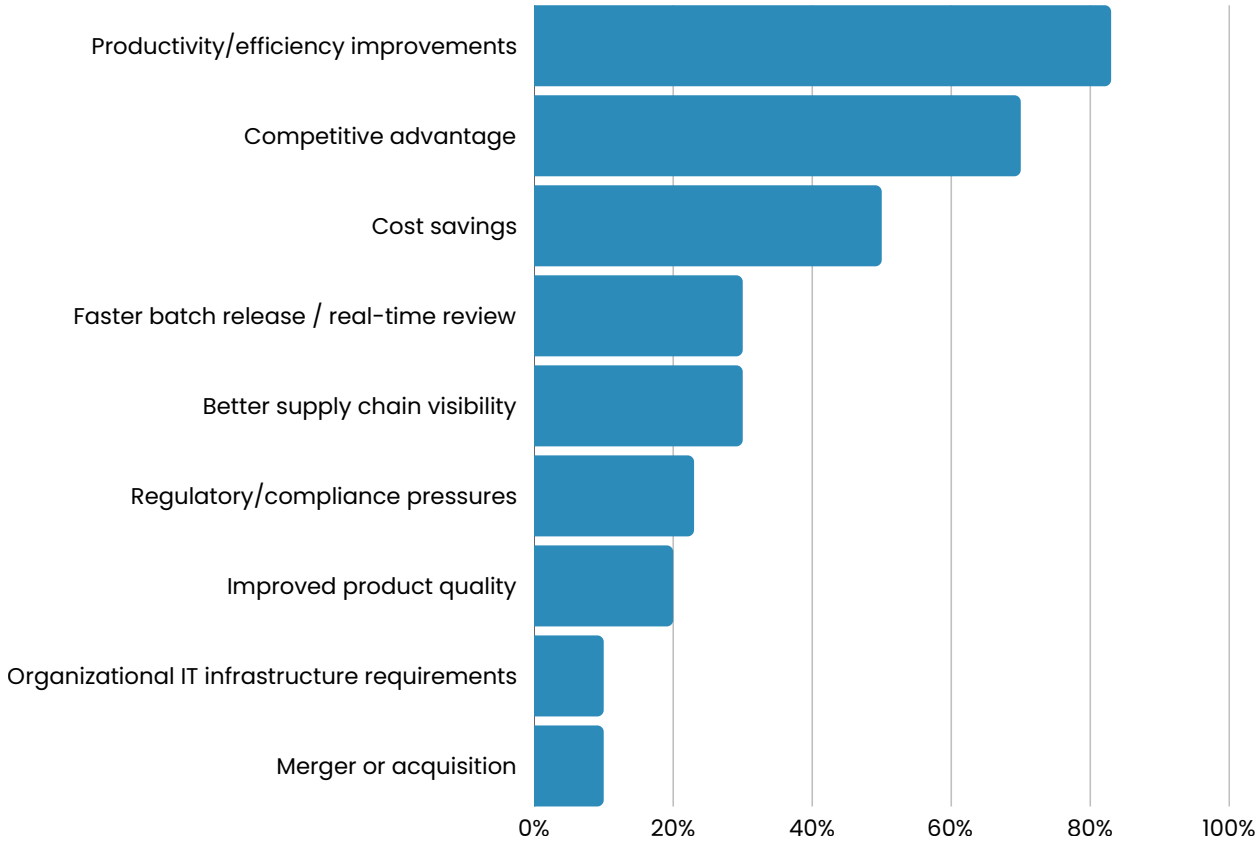
Why Is AI + Digitization Important for CDMOs?

When asked "**What are the top drivers pushing your company to implement digitization and AI in manufacturing?**", the survey reveals that CDMOs are primarily motivated by operational excellence and strategic positioning rather than cost reduction or regulatory pressure.

Productivity and efficiency improvements emerge as the priority, driving 83% of CDMO digitization initiatives. This focus reflects the industry's imperative to optimize manufacturing processes, reduce manual interventions, and maximize throughput in an increasingly competitive market.

Competitive advantage ranks as the second major driver at 70%, indicating that CDMOs view digital capabilities not just as operational improvements but as strategic differentiators in winning and retaining client business.

Cost savings, while important at 50%, ranks third among priorities, suggesting that while financial benefits matter, CDMOs are primarily motivated by performance enhancement and market positioning rather than pure cost reduction.

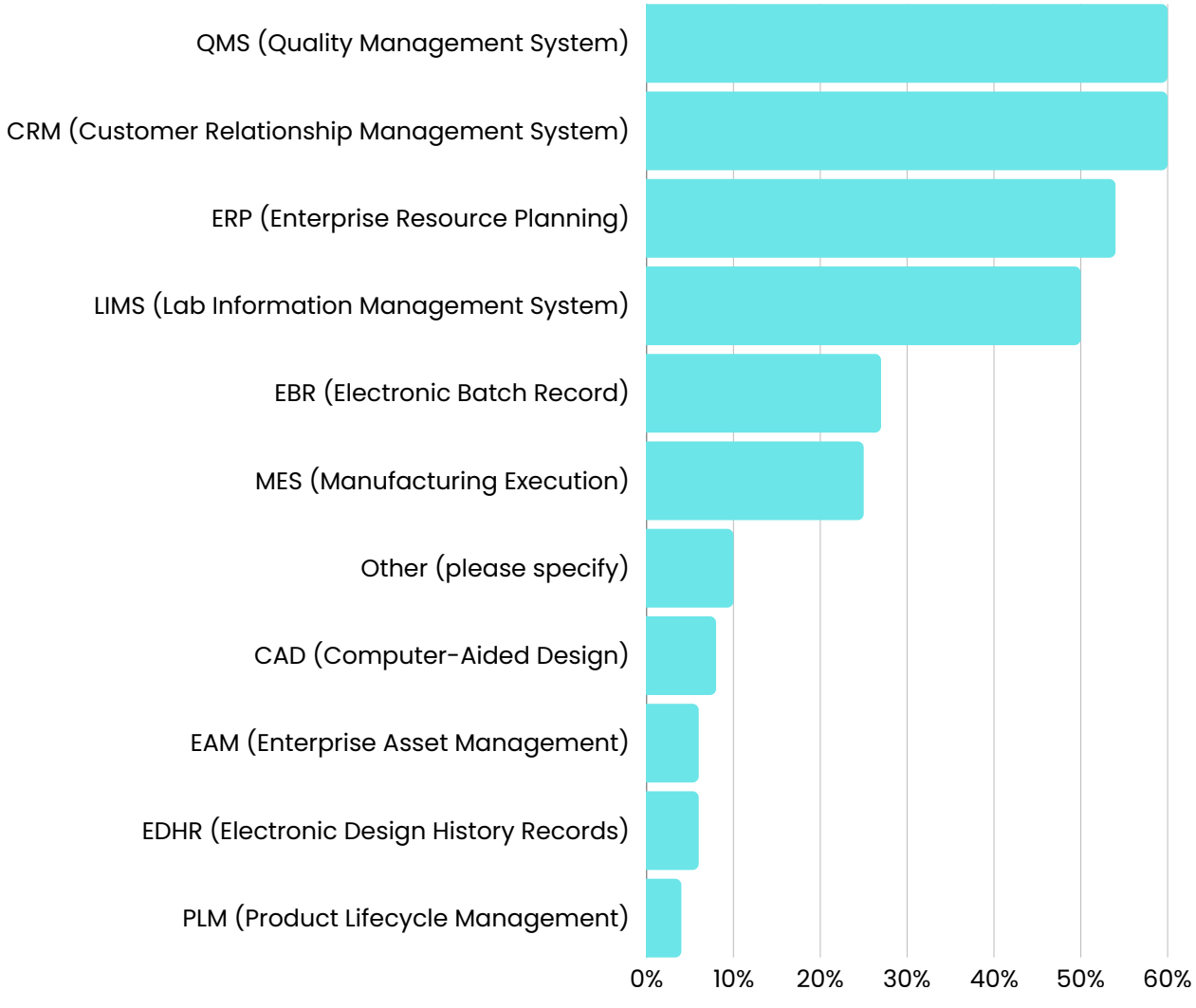


Which Systems Are Currently Integrated With Manufacturing Operations?

The survey reveals significant variation in digital system adoption across CDMO operations, with quality management and customer management systems leading the way.

Meanwhile just one quarter of respondents have electronic batch records (EBR) and/or manufacturing execution systems (MES) in place in their facilities.

Quality management systems (QMS) and customer relationship management (CRM) systems both achieve **60%** adoption rates, representing the highest integration levels across all categories. This dual leadership underscores the industry's focus on regulatory compliance and client relationship management as operational priorities.



Core Business Infrastructure Shows Strong Penetration

Enterprise resource planning (ERP) systems demonstrate solid adoption at 54%, indicating most CDMOs have established foundational business management capabilities.

Laboratory information management systems (LIMS) follow closely at 50%, reflecting the critical importance of data integrity and regulatory compliance in pharmaceutical manufacturing environments.

Manufacturing Systems Reveal Significant Implementation Gap

Despite their operational importance, production-specific technologies show concerning adoption gaps. EBR systems reach only 27% implementation, while MES achieve just 25% penetration.

This represents substantial untapped potential for operational digitization in core manufacturing processes.

Specialized Technologies Remain Largely Untapped

Advanced manufacturing and design systems show minimal industry penetration. The remaining systems all fall below 11% adoption:
Computer-aided design systems (8%), enterprise asset management (6%), electronic design history records (6%), and product lifecycle management (4%).

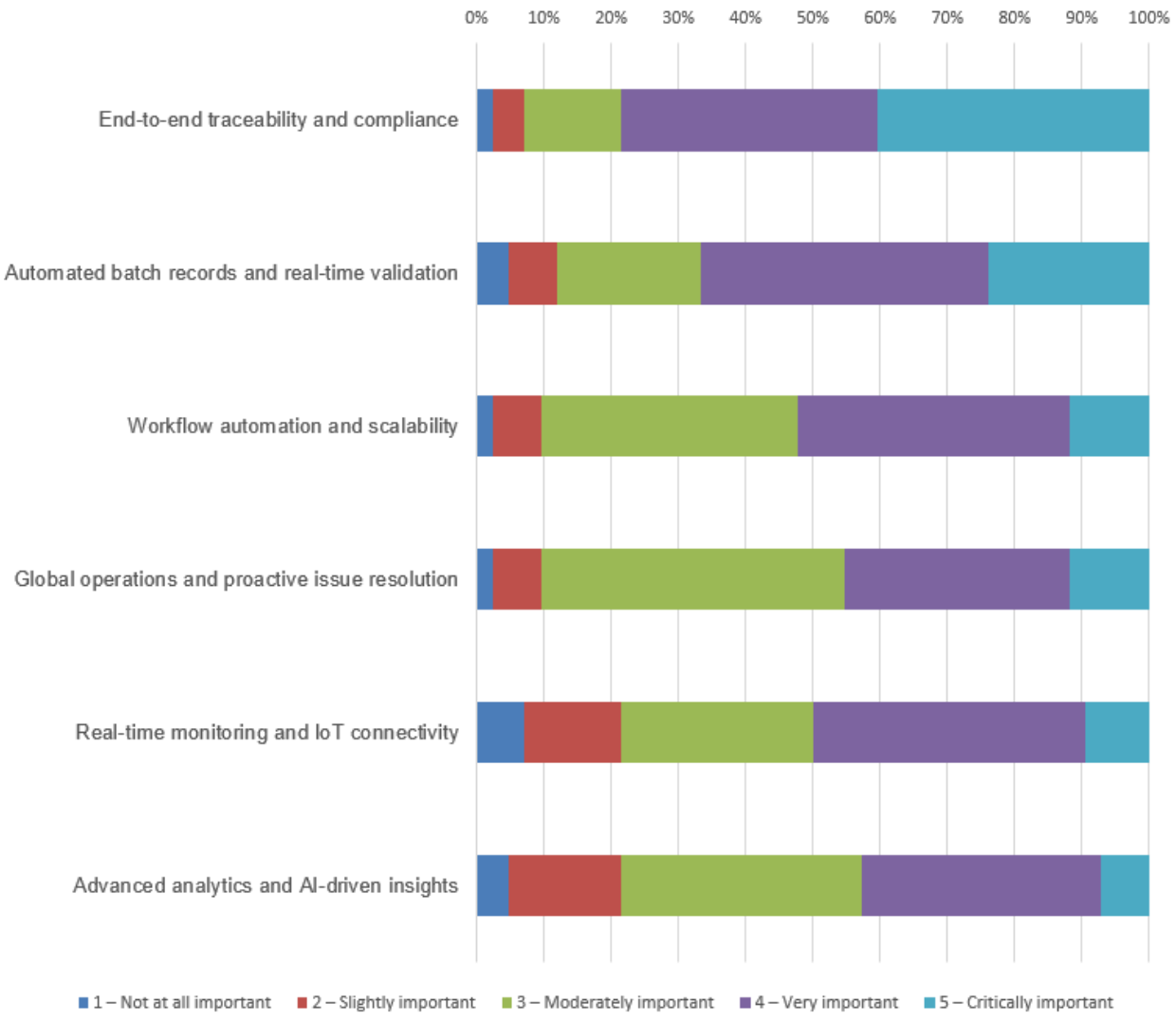
CDMO Digital Priority Areas

When asked to **rank digital capabilities by importance,** CDMO responses reveal a clear hierarchy that prioritizes foundational technologies such as regulatory compliance and core manufacturing functions.

Critical Priority - Compliance Focus
End-to-end traceability and compliance dominates as the top priority, with 79% rating it very/critically important. This reflects the heavily regulated pharmaceutical manufacturing environment where compliance is non-negotiable.

High Priority - Operational Excellence
These focus on core manufacturing efficiency and quality assurance:
Automated batch records and real-time validation - 67% rate very/critically important
Workflow automation and scalability - 52% rate very/critically important

Moderate Priority - Advanced Technologies
Global operations and proactive issue resolution - 45%
Real-time monitoring and IoT connectivity - 50%
Advanced analytics and AI-driven insights - 43%

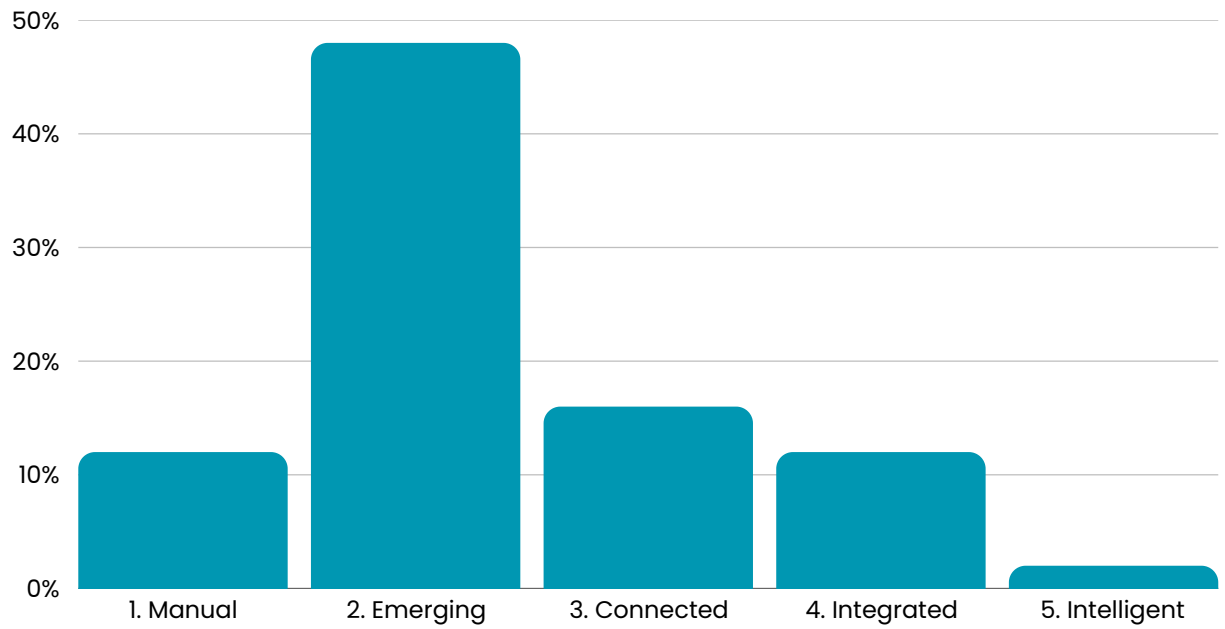


Digital Maturity Index

The survey reveals a CDMO sector in digital transition, with 60% of organizations still in early phases of digital adoption (48% "Emerging" and 12% "Manual").

The remaining organizations show more advanced capabilities: 16% "Connected," 12% "Integrated," and only 2% achieving "Intelligent" real-time digital operations.

How would you rate your organization's current level of digital maturity?



Laggards: Resource-Constrained and Legacy-Burdened

Organizations at the Manual and Emerging stages face fundamental challenges that keep them anchored in traditional, paper-based operations.

Resource Constraints Drive Delayed Adoption
Limited financial and human resources are the primary barriers preventing digital advancement. As one Manual-stage respondent stated: "We have limited resources," while another noted that digital initiatives are "cost prohibitive."

This resource scarcity forces organizations to move cautiously, with one noting: "We do not have the capital that PE-backed firms have so we tend to move very carefully."

Legacy Infrastructure Creates Inertia
Many CDMOs operate facilities with decades-old infrastructure that presents significant digitalization challenges. One respondent explained: "Our facility is somewhat 100 years old, so we are in the process of updating and digitalizing our operations." This legacy burden requires substantial investment to overcome.

Organizational Priorities and Awareness Gaps
Some organizations haven't prioritized digital transformation, with one Manual-stage company stating that "digitalization & AI has not been a priority." This suggests that leadership awareness remains a critical success factor.

Early-Stage Progress Indicators Despite Challenges
Emerging organizations show promising progress. Many are actively exploring solutions, with responses like "We are in discussion with various players to procure the software." Several have implemented foundational systems such as electronic quality management systems (eQMS) and ERP platforms, representing crucial first steps toward comprehensive digital integration.

Leaders: Strategic Integration and Value-Focused (40%)

Organizations at higher maturity stages demonstrate strategic approaches to digital transformation while acknowledging ongoing challenges.

Strategic System Integration
Connected and Integrated organizations focus on creating unified digital ecosystems. One Connected organization described using "a variety of specialized software that communicate with one another across business functions." Integrated companies have achieved deeper connectivity, with one noting: "LIMS, SAP ERP, Power BI all connected."

Continuous Improvement Mindset
Advanced organizations recognize digital maturity as an ongoing journey. An Integrated-stage respondent reflected: "I think that we are committed to keep improving our digitalization and AI implementation but as this world is continuously changing and evolving there are always new ways of working to catch up on."

Business Value Realization
Leaders clearly articulate the business benefits of their digital investments. One Integrated organization explained their motivation: "To simplify all decision processes, to have immediate information, to take a decision reducing timing and effort." This focus on operational efficiency distinguishes advanced organizations from their less mature counterparts.

Emerging AI Capabilities
While still limited, AI adoption is beginning among Connected and higher-maturity organizations. One Connected company noted that "Basic AI tools are occasionally used by some functions (R&D, Business Development)," while another is "moving towards AI driven tools."

Remaining Challenges for Leaders
Even advanced CDMOs face resource constraints in reaching full digital maturity, with one Connected organization noting they are a "small company exploring needs in integrated digital systems."

Lessons From the Digital Leaders

CDMOs with digital transformation experience offer valuable lessons learned, organized around key strategic themes:

Foundation First - Process Before Technology

The most emphatic advice centers on getting fundamentals right before implementing digital solutions:

- "Don't digitalize the chaos but fix the process first - ensure all SOPs, quality flows and have clean and consistent data to start"
- "Address the process and don't think a system will fix an underlying issue"
- "Get your data and clearly understand your business processes. Don't spend money on consultants until you do the above"

Strategic Planning and Alignment

Experienced organizations stress the importance of thoughtful preparation:

- "Start with clear alignment between business goals and digital initiatives"
- "It's better to plan the implementation from the beginning and not to modify or adapt systems well established"
- "Design your needs first and then go for one thing that will have a high impact at low implementation time and cost"

Implementation Approach - Start Small and Scale

Practical advice emphasizes measured, pilot-driven approaches:

- "Start with pilot project(s) to demonstrate value and educate workforce"
- "Define tangible objectives and thoroughly check the quality of outcomes - not all that shines turns out to be gold (AI hype wastes a lot of time)"
- "Spend the time and effort to do things properly the first time, it will pay dividends in the long run"

Change Management and Human Factors

Organizations highlight the critical importance of people in digital transformation:

- "It's all about people and process. Not the tool"
- "Bring everyone onboard at the start"
- "We need to implement AI considering the human value, considering the good relationship between people and machine"

Realistic Expectations and Risk Management

Veterans warn about common pitfalls and timeline expectations:

- "It will take far longer than you expect"
- "Make sure you check the raw data on AI responses as they still hallucinate. AI is not a magic bullet - it is a very powerful tool"
- "Industry does not always speak about the same things when discussing AI - make sure you and your counterpart are actually discussing the same things"

The overarching message is clear: successful digital transformation requires disciplined process improvement, strategic thinking, and patient change management rather than rushing toward flashy technology solutions.

CDMO and Sponsor Digitization

Current State of Sponsor/CDMO Digital Integration

The survey results reveal that the CDMO industry is primarily operating at basic integration levels, with the majority of organizations still dependent on manual processes for external partner communication and data sharing.

No respondents reported having fully integrated systems with sponsors that enable real-time data sharing and joint dashboards.

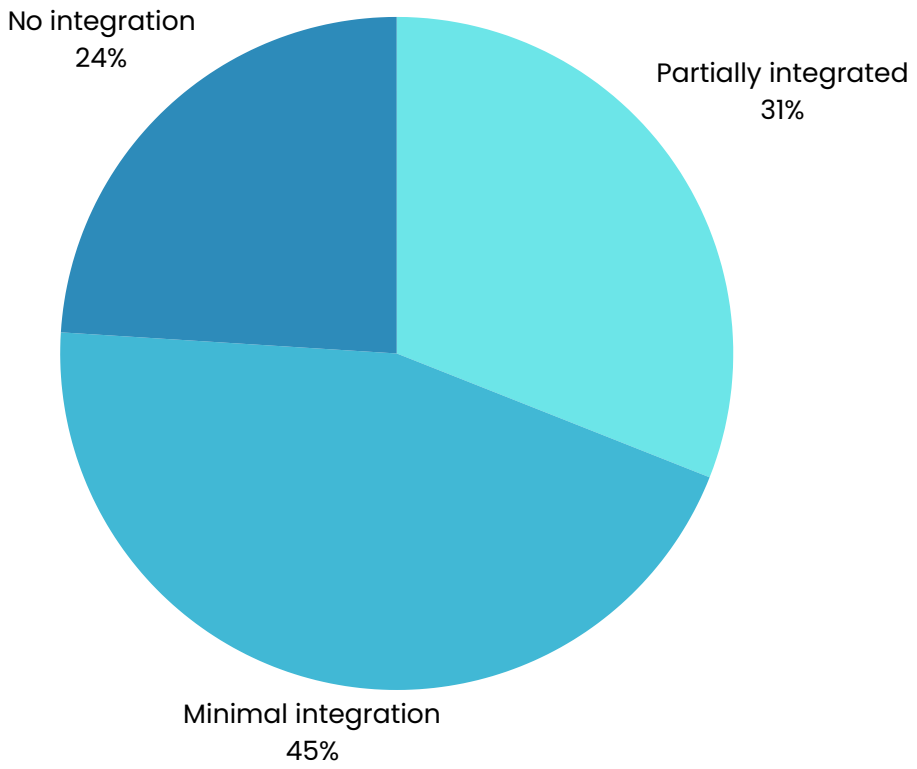
Integration Maturity Levels

Nearly half of CDMOs (45%) operate with minimal integration, relying primarily on manual data transfer or batch reports only. This represents the most common approach among surveyed organizations.

Just under one-third (31%) have achieved partial integration through some automated data transfer or shared portals.

Limited Digital Connectivity

Almost a quarter of CDMOs (24%) report no current integration with external partners. Combined with those operating at minimal integration levels, nearly 70% of CDMOs are functioning with limited or no automated data sharing capabilities with their external partners.



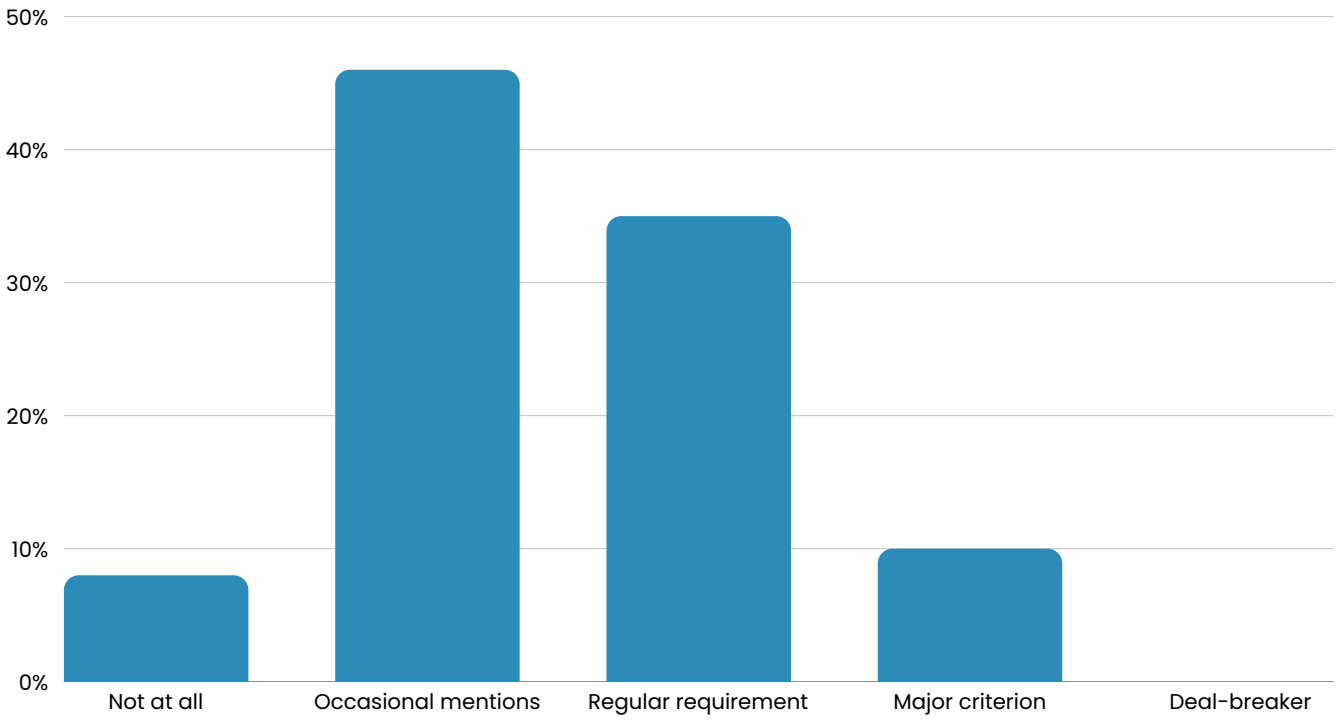
Demand for Digital Capabilities

The survey reveals that digital capabilities are still in a **transitional phase** within the CDMO selection process, and have not yet reached universal critical status.

Sponsors often talk about demanding digital capabilities from their CDMO partners, the survey suggests that while it is part of partner evaluations, it is not yet a blocker for deal completion.

The majority of CDMOs report that partners are actively discussing digital requirements, with over **92% of respondents** indicating that digital capabilities are mentioned occasionally or more frequently in partner interactions.

- Nearly half of CDMOs (46%) report that digital capabilities are occasionally mentioned by partners during discussions.
- More than one-third (35%) indicate that digital capabilities have become a regular requirement in Request for Proposals, suggesting these capabilities are moving from optional discussions to formal evaluation criteria.
- Just over 10% of CDMOs report that digital capabilities serve as a major selection criterion for partners, while none indicated that lack of digital capabilities would be a deal-breaker.



Sponsor Digital Requests Are "Foundational"

Sponsor requests reveal foundational rather than sophisticated digital expectations, clustered around regulatory compliance and basic visibility:

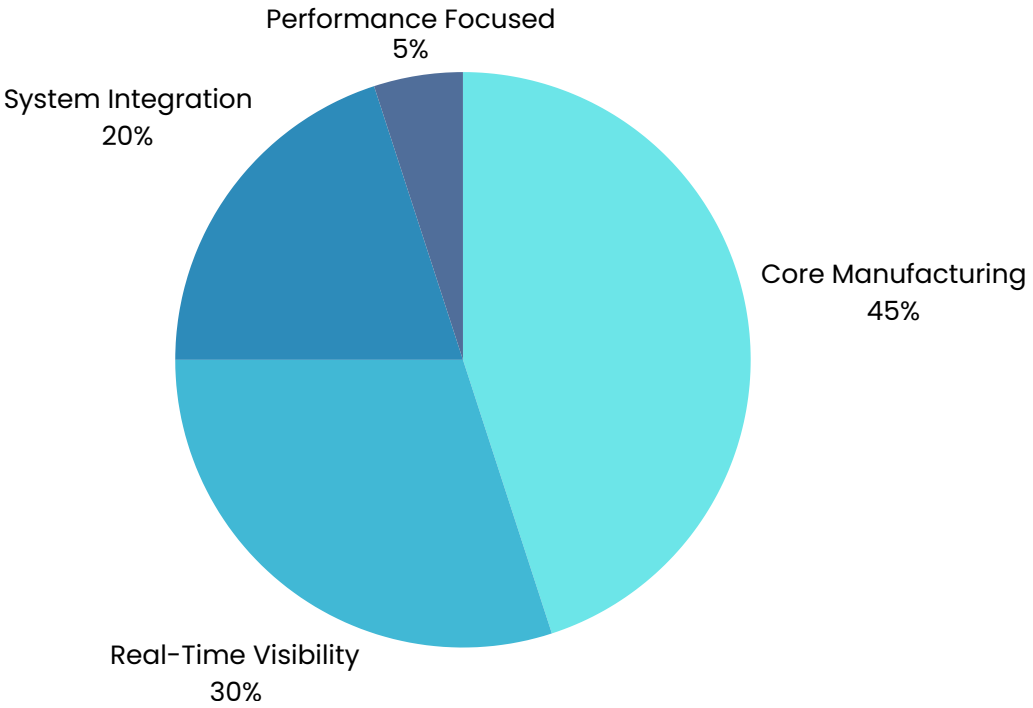
Core Operational Systems (45%)
Partners consistently demand QMS and LIMS as basics, with frequent requests for digital batch records alongside ERP systems.

Real-Time Visibility (30%)
Growing demands for operational transparency through "real-time data sharing" and "live visibility to shop floor data." Dashboard requests are common, though remain basic rather than sophisticated analytics.

System Integration (20%)
More advanced partners seek comprehensive connectivity: "System integration for manufacturing, quality, warehouse, procurement" and "MES, LIMS as basics. ERP integration. Cloud-based sharing platforms."

Performance-Focused (5%)
A small segment requests outcome-driven capabilities "that increase execution speed, reliability of outcome and real-time visibility."

Which digital capabilities do sponsors typically request?



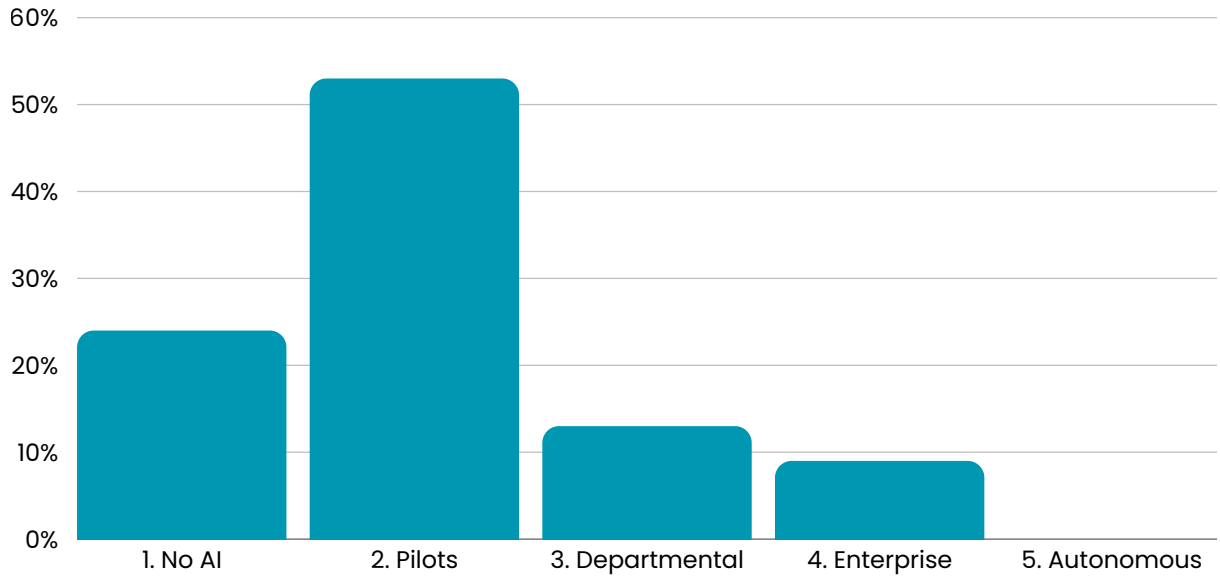
AI in Contract Manufacturing

CDMO AI Maturity Index

CDMOs are at an early-stage of AI adoption. Nearly 80% of CDMOs remain in preliminary phases with 24% having no AI implementation and 54% conducting pilot projects.

Only 22% have achieved operational deployment: 13% at departmental level and 9% at enterprise level. Zero respondents have reached autonomous AI operations, highlighting the significant journey ahead.

How would you rate your organization's current level of AI maturity?



AI Laggards: No Implementation and Early Pilots (77%)

Organizations at 'No Implementation' stage cite fundamental barriers: AI is "not a priority" with "not enough maturity." Resource constraints dominate through "high cost" and "limited resources."

Digital readiness gaps emerge: "not fully digital in other areas and no focus at all on AI" - highlighting AI's dependency on existing infrastructure. Many admit "no plan" for AI adoption.

Pilot Projects (53%)

Organizations at 'Pilot Projects' stage demonstrate exploratory approaches, driven by desires to understand possibilities: "exploring possibilities with existing systems" and recognizing they're "at the beginning of the new era."

While resource limitations persist ("smaller firm, with limited resources"), these organizations show greater awareness that "AI adoption requires cross-functional support which is still fragmented."

Pilot-stage organizations display sophisticated AI strategies spanning multiple functions:

- Business Development: "AI lead generation" and using AI to "identify and qualify adequate new business targets" with goals to "increase Salesforce effectiveness"
- Operational Integration: "Scale AI from pilot to production - Integrate AI with MES and QMS - Digitalize batch records" and implement "planning tools, monitoring tools and data control within manufacturing"
- Quality and Efficiency: Target AI for QMS improvements and "implement AI to remove routine tasks" to "bring efficiency and smartly implement AI where it brings most value at least cost"
- Change Management: Prioritize "ensuring AI and digitization is seen as a positive change across the business"

AI Adopters: Departmental and Enterprise Integration (22%)

Organizations deploying AI within a specific department have achieved success through focused, practical approaches. For example, a respondent explained their use of "in-house LLM for basic tasks".

Strategic priorities include:

- Data Architecture: "Design and implementation of correct underlying data architecture to support digitization"
- Knowledge Management: "Vectorising proprietary information to respond to RFI's more quickly"
- Measured Growth: Strategic consolidation rather than aggressive expansion

Enterprise AI Integration (8%)

The sector's most advanced organizations focus on comprehensive transformation, including:

- Customer-Centric Automation: "Leveraging AI to automate content creation and personalization, enabling faster and more targeted communication with emerging and small pharma clients"
- Integrated Business Functions: Prioritizing "sales & planning" integration across multiple business functions

The absence of **autonomous AI operations** (0% of respondents) indicates even the most advanced CDMOs remain several maturity steps away from fully AI-driven manufacturing, representing significant future competitive differentiation opportunities.

AI Timeline to Value

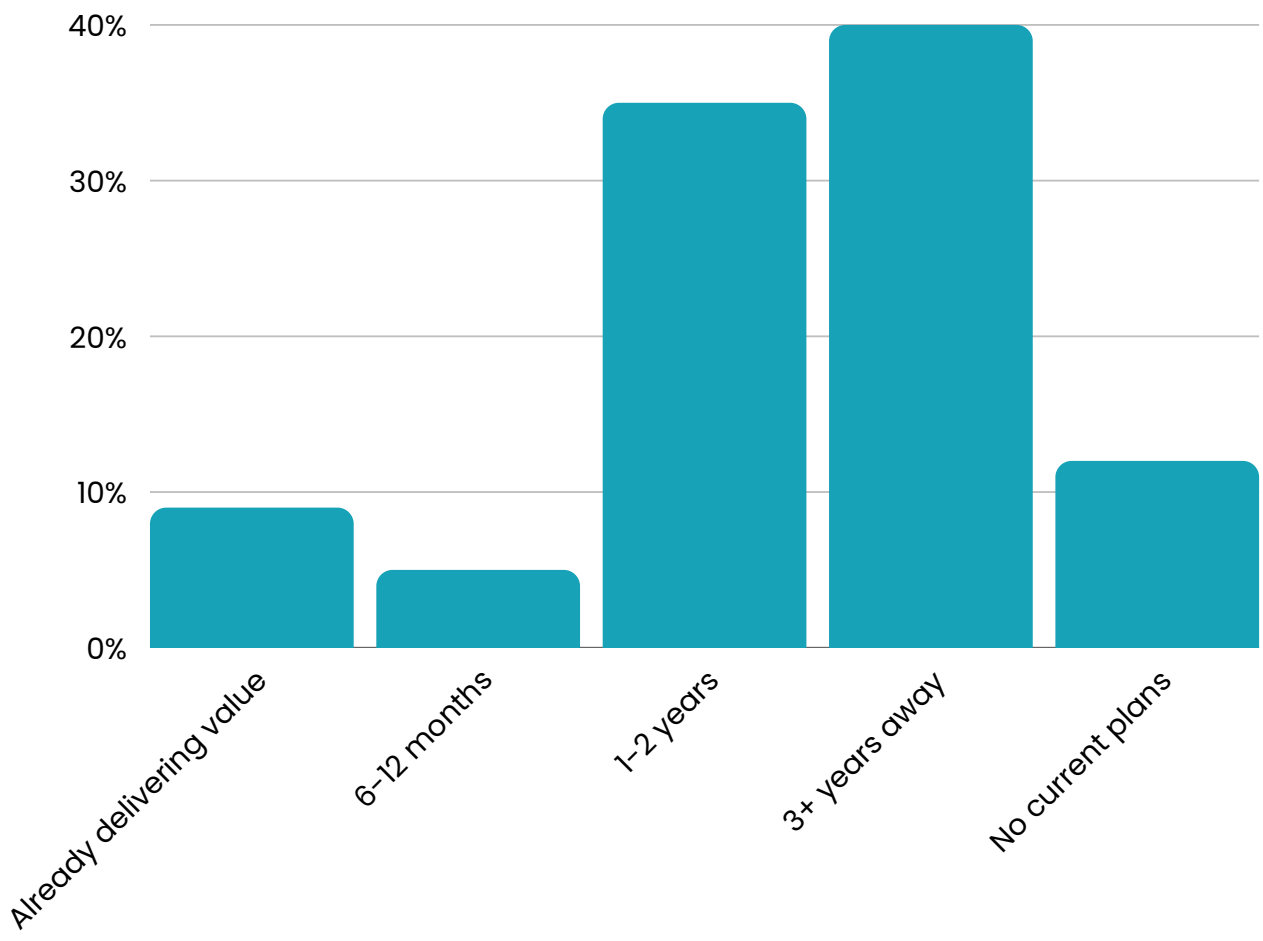
This survey reveals a measured outlook for AI's time to value in their organization. This aligns with the sector's current reality suggesting CDMOs recognize the substantial implementation journey ahead.

75% of CDMOs expect AI value within 1-3 years, with 40% placing it 3+ years away and 35% within 1-2 years.

The modest 9% already claiming they are already realizing value corresponds closely with the 8% achieving enterprise-level AI integration asked previously.

Meanwhile, 12% have no current AI plans, potentially risking competitive disadvantage as sponsor digital expectations increase.

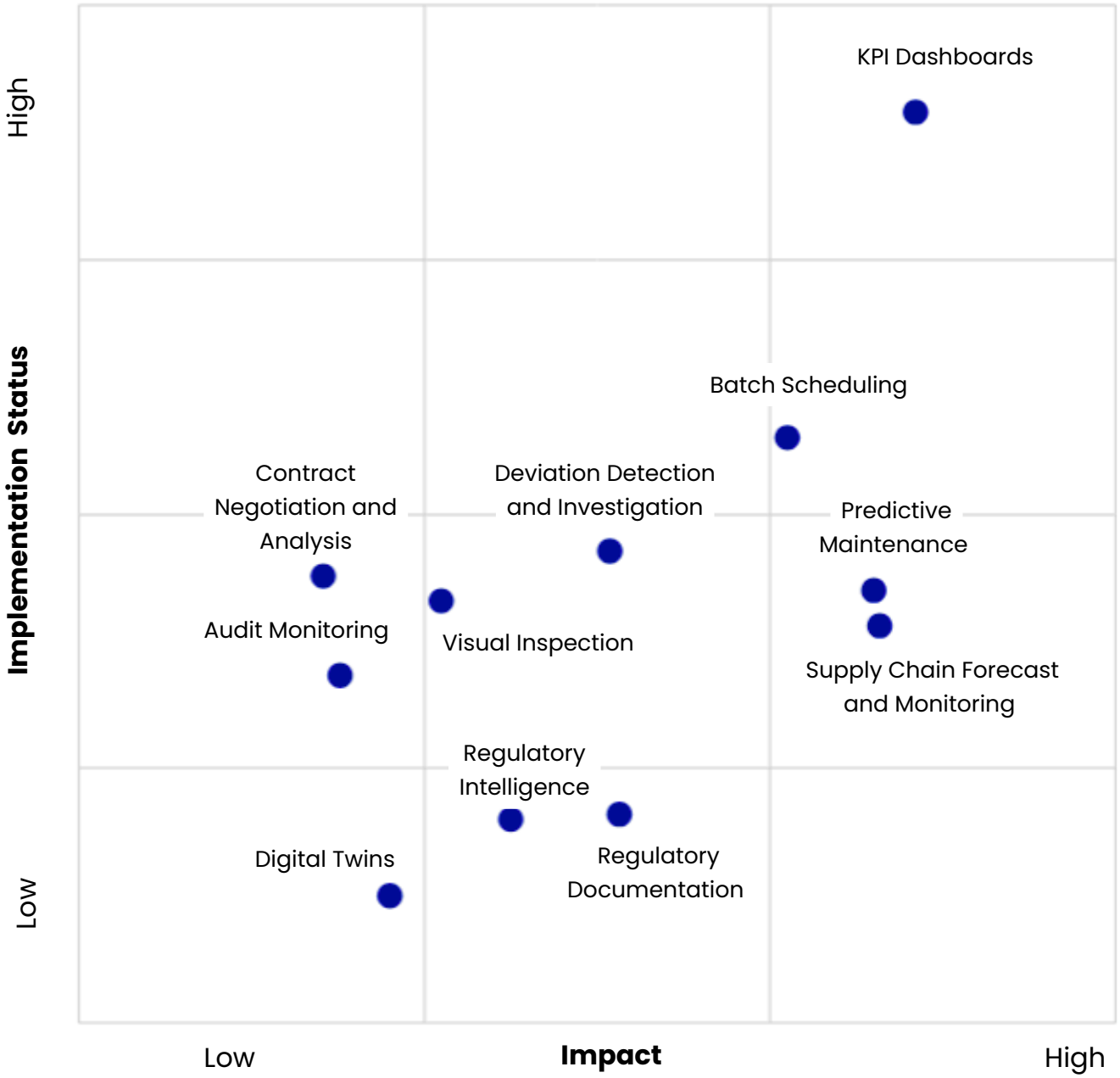
When do you expect AI to achieve significant value to your manufacturing operations?



CDMO AI Applications: Impact Vs. Implementation

This survey of reveals a clear divide between high-impact AI opportunities and current deployment realities.

When asked to **rank applications by impact and implementation status**, it was clear that KPI dashboards are today leading in both metrics while areas such as supply chain and predictive maintenance applications show the greatest untapped potential.



High Impact, High Implementation (Upper Right Quadrant)

- **KPI Dashboards** is the clear leader, positioned in the upper right with high impact (7.4) and the strongest implementation status (5.8). This represents proven technology that CDMOs have successfully deployed and see significant value from.

High Impact, Lower Implementation (Lower Right Quadrant)

These technologies are prime candidates for investment, offering substantial business value but requiring implementation focus.

- **Supply Chain Forecasts and Monitoring** and **Predictive Maintenance** both show high impact (7.3 each) but lower implementation status (4.8 and 4.9 respectively).

- **Deviation Detection & Investigation** (6.5 impact, 4.9 status) also falls here, showing quality applications have strong potential despite deployment challenges.

TAKEAWAY: CDMOs should focus investment on these applications that promise high impact but need implementation support.

Lower Impact, High Implementation (Upper Left Quadrant)

- **Batch Scheduling** sits in this quadrant with moderate-high impact (7.1) but strong implementation (5.2), suggesting it's operationally mature but perhaps not as transformative as other applications.

Lower Impact, Lower Implementation (Lower Left Quadrant)

- **Digital Twins** occupies the bottom-left position (5.9 impact, 4.3 status), indicating both limited perceived value and significant implementation barriers.

- **Regulatory Intelligence** and **Regulatory Documentation** cluster in the lower-left area, suggesting documentation-focused AI applications face both value and deployment challenges.

- **Contract Negotiation/Analysis, Audit Monitoring**, and **Visual Inspection** complete this lower-priority group.

Implementation Barriers + Priorities

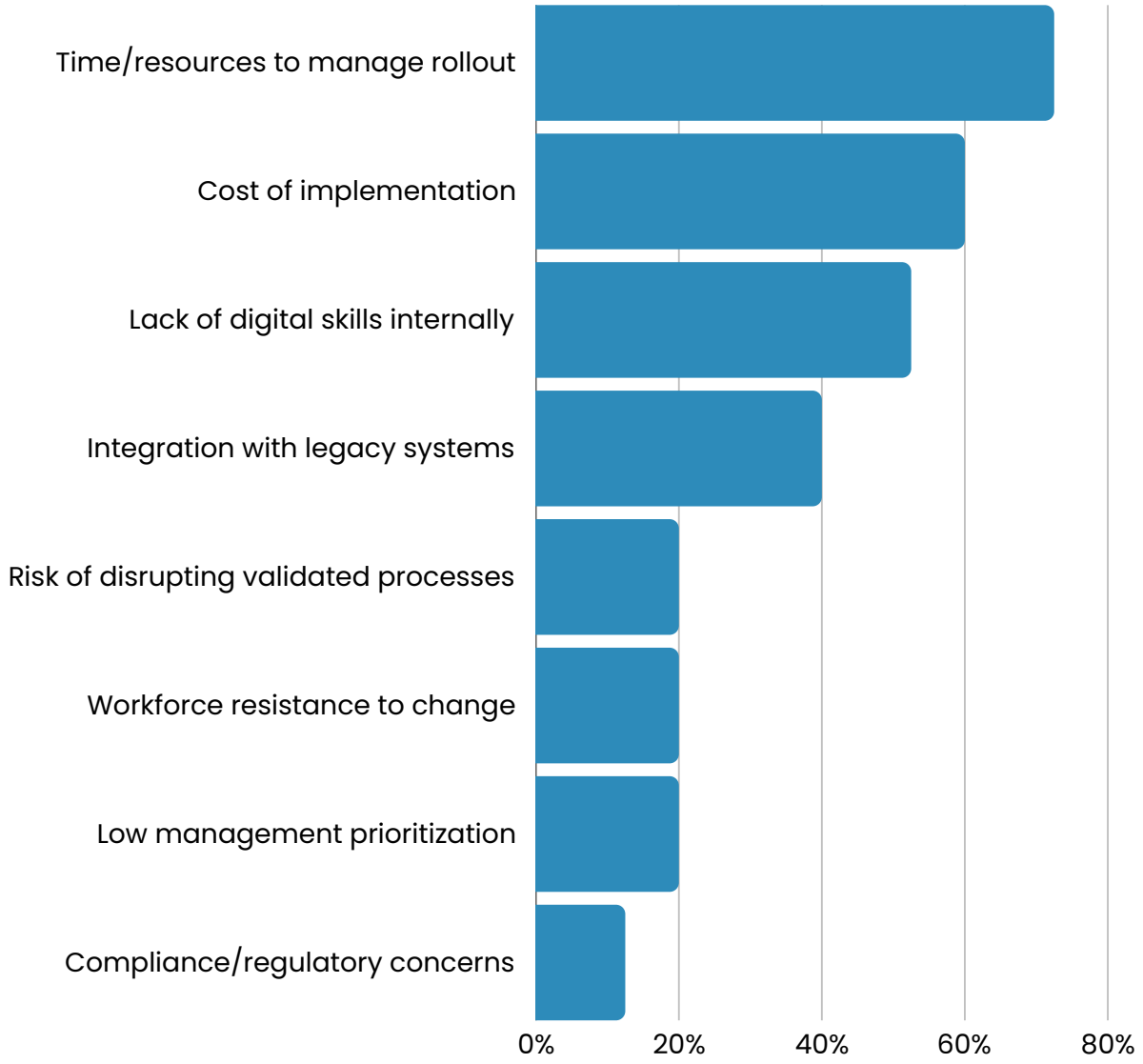
Greatest Barriers to Implementing AI +Digitization

CDMOs face a hierarchy of challenges in their digital transformation journey, with practical implementation barriers significantly outweighing cultural and strategic resistance.

Nearly three-quarters of CDMOs struggle with time and resource management, while traditional change management concerns (workforce resistance, management buy-in) affect only one in five organizations.

This suggests that CDMOs recognize the value of digital transformation but face significant operational hurdles in execution.

What are the greatest barriers to advancing your AI and digital maturity?



Top 3 AI Priorities for 2025-6

CDMO AI priorities and opportunities often closely mirror those for overall digitization-focusing on their foundational infrastructure, core processes, and change management to ensure meaningful value from adoption.

The sector moving from exploratory phases toward concrete implementation, though with varying levels of ambition and clarity.

Operational Integration and Manufacturing Systems (30%)

The most sophisticated responses focus on systematic operational integration. Leading organizations prioritize "Scale AI from pilot to production - Integrate AI with MES and QMS - Digitalize batch records" and "Planning tools, monitoring tool and data control within manufacturing."

Others emphasize foundational work: "Design and implementation of the correct underlying data architecture to support digitization" and "Complete implementation of e-BPR and e-lab notebooks, DCS, LIMS."

This systematic approach reflects understanding that AI requires robust digital foundations.

Business Process Automation and Customer Engagement (25%)

Commercial applications feature prominently, with organizations targeting "AI lead generation" and seeking to "leverage AI to automate content creation and personalization, enabling faster and more targeted communication with emerging and small pharma clients."

Knowledge management emerges as a practical quick win: "Vectorising our proprietary information so we can respond to RFI's more quickly" and "increase Sales Force Effectiveness by fast and streamlined processes."

Strategic Planning and Exploration (30%)

Many CDMOs acknowledge they're still developing strategies. Responses include "Get familiar and start making plans for implementation" and "Explore and understand what options do we have in the market."

One pragmatic voice captures the sector's challenge: "sorting real opportunities from appealing blah blah blah," whilst another emphasizes measured progress: “Start small. Show validation and value-add.. Keep the big picture in mind."

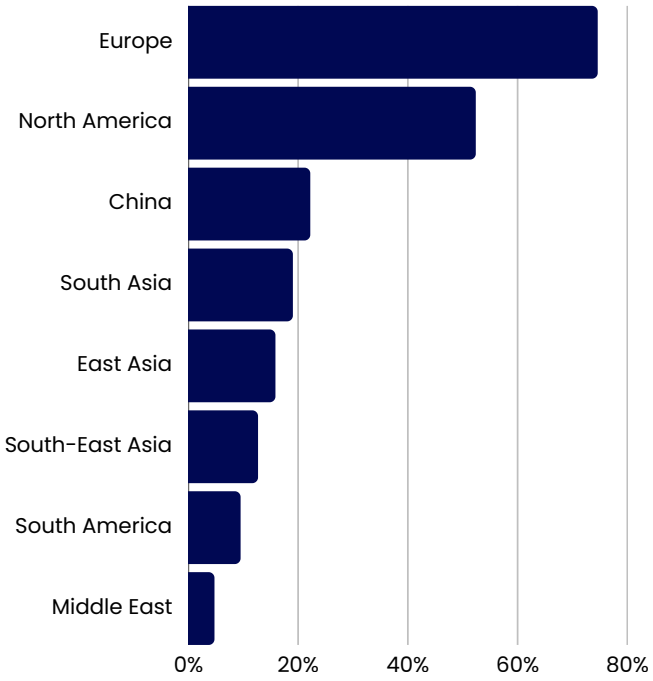
Respondent Profiles

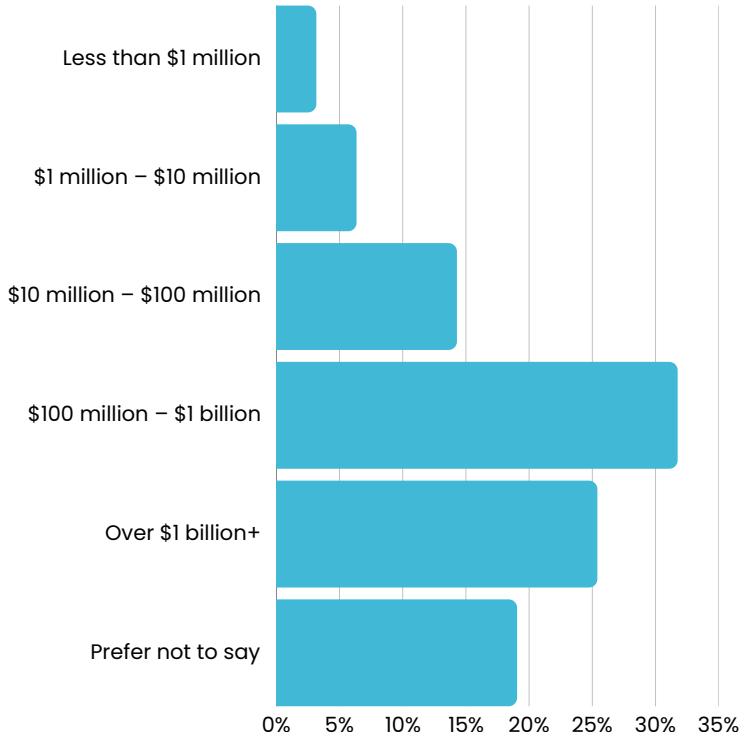
Survey respondents were from across the CDMO sector, with companies of varying sizes and facility locations:

Facility Locations

CDMOs with European facilities dominate survey participation at 75%, followed by North America at 52%, reflecting strong engagement from established Western pharmaceutical manufacturing markets.

Asian participation is from key manufacturing markets with China leading at 22%, followed by South Asia (19%) and East Asia (16%).





Revenue Distribution

The survey captures a well-balanced mix of company sizes, with the $100 million to $1 billion segment leading at 32%, followed by companies under $1 million at 32%.

Large-scale CDMO operations over $1 billion represent 25% of respondents, while mid-tier companies ($10-100 million) account for 14%.

The smallest revenue segment ($1-10 million) comprises 6% of participants.

Adapt to Evolving Life Sciences Manufacturing Regulations With MasterControl

Adapting to an evolving regulatory landscape demands more than makeshift adjustments. Life sciences manufacturers need a strategic approach to managing quality and manufacturing processes that can evolve alongside changing regulatory frameworks.

Rather than viewing compliance as merely another challenge, industry leaders are leveraging this opportunity to transform their quality management and operational processes through intelligent digital platforms.

Successfully navigating regulatory changes requires true quality transformation. **MasterControl's Quality Excellence (Qx)** solution provides a fully integrated, cloud-based platform specifically designed to help life sciences manufacturers adapt to the evolving regulatory landscape while driving operational excellence through:

- **Adaptive document control**

Automatically manage documentation requirements across various regulations and standards, eliminating duplication of effort, reducing document lifecycle times by 30%-50%, and ensuring alignment with the latest regulatory requirements.

- **Risk-based training management**

Drive competency, not just compliance, through intelligent training that automatically adapts to regulatory changes, tracks comprehension, and ensures all personnel understand new requirements across quality system touchpoints.

- **Integrated audit readiness**

Transform audits from frenetic periodic events to continuous states of readiness through real-time compliance monitoring, automated gap analysis against standards, and predictive insights that identify potential issues before they become audit findings.

- **Holistic risk management**

Move beyond siloed risk assessments to implement the comprehensive risk-based approach demanded by both FDA and ISO frameworks, connecting risk data across the product lifecycle and quality ecosystem.

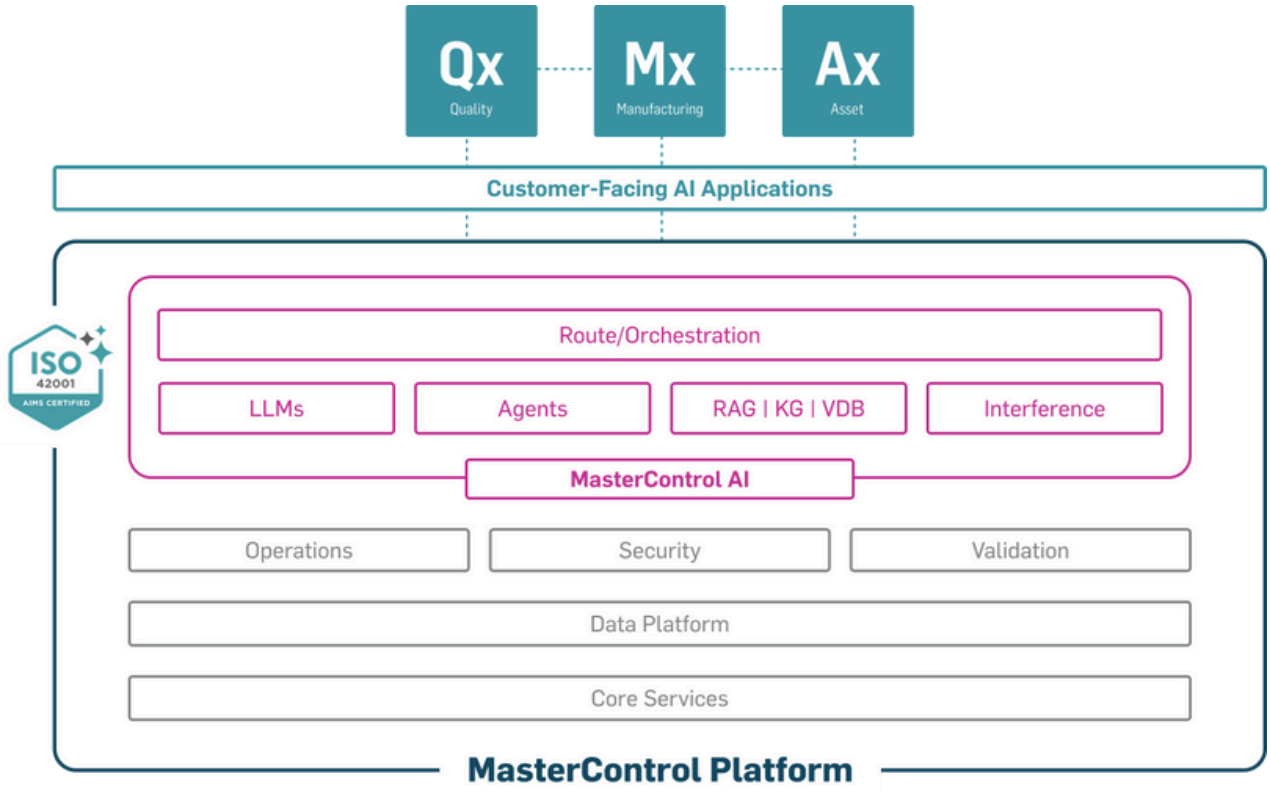
- **No-code quality event workflows**

Respond to regulatory evolution by rapidly configuring quality processes that align with regulatory requirements without IT dependency, enabling quality teams to implement changes within hours rather than months.

Achieve Manufacturing Excellence Within an Established Regulatory Framework

MasterControl's **Manufacturing Excellence (Mx)** solution operates on the same intelligent platform as Quality Excellence, creating a single source of truth that embeds quality directly into production processes.

This connected approach is uniquely suited to help organizations meet regulatory requirements while accelerating production and market access.



By uniting quality and manufacturing processes within a single platform, life sciences companies can benefit from:

- **Unified digital production records**
Eliminate paper-based processes that create compliance gaps between quality and manufacturing with fully digitized production records that enforce regulatory requirements at every step.

- **Intelligent electronic batch records (EBRs)**
Automatically adapt manufacturing documentation to evolving regulatory requirements, ensuring production processes remain compliant with both FDA and ISO standards without manufacturing disruption.

• **AI-powered error prevention**
Deploy intelligent in-line checks that enforce regulatory requirements during production, reducing deviations by up to 90% while capturing the data needed to demonstrate compliance under both regulatory frameworks.

• **Real-time document control at the production line**
Ensure manufacturing always executes against the current approved procedures that align with regulatory standards, eliminating the risk of using outdated work instructions.

• **Data-driven manufacturing intelligence**
Transform production data into actionable insights through advanced analytics that support continuous improvement while maintaining the evidence needed for regulatory submissions across markets.

• **Closed-loop quality and manufacturing processes**
Connect quality events directly to production activities, enabling immediate corrective actions and preventive measures that satisfy both FDA and ISO requirements while maintaining production continuity.

By adopting MasterControl's connected platform approach, manufacturers can transform regulatory compliance from a challenge to a strategic advantage—reducing time to market, improving product quality, and creating sustainable compliance that adapts as regulatory requirements continue to evolve.