TRINZO

What Will It Take to Innovate and Scale with Confidence?

A directional industry snapshot across Quality, Regulatory, Clinical Strategy, and Governed AI.

DATA SOURCE

Global Access Pulse Survey
21-22 October 2026



EXECUTIVE SUMMARY

Signals of Change

MedTech is being asked to do more at once. Innovate faster. Navigate changing regulatory expectations. Generate stronger evidence. Improve Quality performance. Adopt new technologies. Reduce unnecessary cost and complexity. And do all of it without compromising patient safety or trust.

At Global Access 2026, Trinzo asked MedTech professionals where they see the biggest opportunities, and the hardest challenges, across Quality, Regulatory, Clinical Evidence, remediation, digital health and AI. The individual answers varied, but a consistent pattern emerged.

The opportunity is increasingly less about adding another process, system or requirement. It is about creating the organisational capability to make better decisions, reuse knowledge, manage change and execute with confidence.

When delegates were asked what one thing would most improve MedTech's ability to innovate and scale with confidence, responses repeatedly returned to collaboration, predictability, shared learning, education, trust, regulatory reliance, resilience, and continuous assessment.

This report looks beyond the percentages to ask a more useful question: What do these signals mean for MedTech organisations, and what should leaders be doing about them?

Liam Turley, CEO, Trinzo

FIVE CORE SIGNALS

1. **Quality:** Evolving from a compliance gatekeeper into a proactive decision-making engine.
2. **Regulatory Reliance:** Designing evidence architectures to travel across multiple markets.
3. **Remediation:** Focusing on sustainable execution and systemic change rather than closure alone.
4. **Clinical Evidence:** Moving clinical strategy upstream before design freezes lock in risk.
5. **Digital Trust & AI:** Anchoring AI in data integrity, workflow redesign, and human accountability.

Quality Creates Value at Multiple Points Simultaneously

What the Pulse Told Us

UNTAPPED OPPORTUNITIES FOR QUALITY



Key Finding: The relatively even distribution demonstrates that Quality creates value at multiple points simultaneously: preventing failures, steering development early, and managing operational risks.

THE TRINZO PERSPECTIVE

The next evolution for Quality is not simply to become "more strategic". It is to become more deeply connected to how the organisation makes decisions and performs.

When Quality intelligence sits primarily inside the Quality function, organisations can still find themselves reacting late: investigating problems after they occur, escalating risk after decisions have been made or identifying systemic issues only when performance deteriorates.

The genuine commercial opportunity is to make Quality signals part of everyday operational decision-making. Connecting them directly with Operations, Engineering, Regulatory, Clinical, Supply Chain, and executive leadership so emerging risks can shape proactive choices and influence decisions earlier.

What Organisations Should Consider

STRATEGIC IMPERATIVES FOR LEADERSHIP

• **Commercial Alignment:** Link Quality metrics directly to business and operational performance indicators rather than treating them solely as compliance logs.

• **Systemic Synthesis:** Connect recurring signals across CAPA, customer complaints, supplier quality audits, and shop-floor production lines.

• **Early Escalation Triggers:** Define clear operational triggers that allow clinical and technical risks to influence decisions before design commitments lock.

• **Upstream Participation:** Embed Quality leads in product, process, and change control forums before critical project paths narrow.

• **Financial Visibility:** Make the true cost of poor Quality (COPQ) and operational disruption visible to executive and financial leadership.

WHAT TO WATCH FOR

• Volumes of compliance metrics with very little actionable operational insight.

• Repeated quality anomalies appearing in separate QMS subsystems without cross-functional correlation.

• Quality involvement restricted to post-mortem audits after fundamental product decisions have passed.

Quality Reflections

EXPERT LENS

"Quality becomes significantly more valuable when it helps the organisation make better decisions before a problem becomes a failure."

Experienced leaders must distinguish between isolated operational hiccups and emerging systemic vulnerabilities. Boards do not need more dashboards; they need clear line-of-sight to the signals that threaten delivery, margins, and patient trust.

Quality should be championed as an economic enabler rather than an unavoidable compliance overhead.

Carl Dover · Systemic Quality & Governance Specialist

SELF-PULSE DIAGNOSTIC: SCORE 1 TO 5

1 = Ad hoc · 5 = Embedded

How decision-ready is your Quality system?

1. Can leadership quickly identify the Quality risks most likely to affect performance, patients, or product delivery?

2. Do Quality signals actively influence engineering decisions before an issue manifests as an expensive failure?

3. Are recurring deviations analysed across interconnected systems rather than resolved in piecemeal isolation?

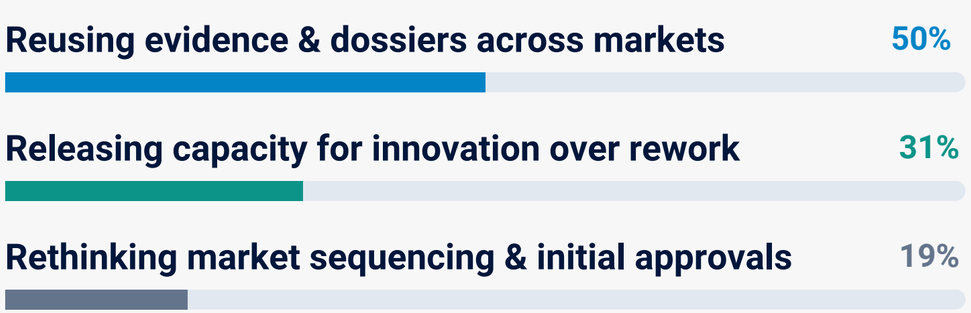
4. Can Quality demonstrate verified business value through reduced scrap, less rework, or faster commercial approvals?

Use this diagnostic to benchmark functional maturity across executive reviews.

Regulatory Reliance is not Simply a Regulator-Efficiency Issue

What the Pulse Told Us

GREATEST OPPORTUNITIES AS RELIANCE EXPANDS



Key Finding: Regulatory reliance is no longer just a regulator-efficiency story. It is a commercial roadmap question: is evidence architected for global reuse or bespoke repetition?

THE TRINZO PERSPECTIVE

As international health authorities build formal reliance mechanisms, manufacturers must ask: *How reusable is the evidence we are generating today?*

Historically, the CE Mark was the unquestioned global passport into secondary markets. Under the EU MDR, timelines have lengthened while FDA clearance pathways have become increasingly predictable.

Clinical evidence, technical documentation, risk decisions and regulatory rationales are often generated for a particular submission. But the strategic opportunity is to develop evidence architectures that can support multiple regulatory pathways and markets wherever requirements allow. That does not remove local requirements, but it does mean moving away from treating each submission as an entirely independent exercise.

What Organisations Should Consider

STRATEGIC IMPERATIVES FOR GLOBAL ACCESS

• **Early Global Mapping:** Map regulatory, clinical, and quality evidence requirements across tier-1 and tier-2 target markets before clinical protocols harden.

• **Systematic Data Reuse:** Establish clear protocols identifying where bench testing, biocompatibility, and clinical evaluations can travel across dossiers.

• **Challenge Inherited Paths:** Actively interrogate traditional "CE first" launch assumptions when US 510(k) or De Novo routes offer faster, leverageable approvals.

• **Portable Regulatory Rationales:** Document regulatory logic and substantial equivalence justifications in structured repositories accessible to local country affiliates.

• **Upstream Commercial Integration:** Unify market prioritisation, clinical evidence generation, and regulatory affairs in a single governance conversation.

WHAT TO WATCH FOR

• Duplicative literature reviews repeated from scratch for identical device families across regions.

• Fragmented country-level submissions written in total isolation by regional distribution teams.

• Crucial regulatory rationales and predicate justifications trapped in personal inboxes or local spreadsheets.

Regulatory Reflections

EXPERT LENS

"The regulatory question is increasingly not only 'where can we obtain approval first?' but 'which pathway gives us the strongest platform for the markets that matter next?'"

Australia's TGA is a prime role model: they accept comparable overseas approvals from the US, Europe, Canada, and Japan. If a manufacturer obtains FDA clearance early, that approval can unlock secondary jurisdictions 18–24 months ahead of a delayed CE Mark.

Regulatory reliance transforms market access from a linear queue into a flexible global network. Design evidence to travel better.

Colm O'Rourke · Regulatory Strategy & Market Access Specialist

SELF-PULSE DIAGNOSTIC: SCORE 1 TO 5

1 = Ad hoc · 5 = Embedded

Is your evidence strategically designed for global reuse?

1. Do cross-functional product teams understand priority international markets before clinical evidence protocols are frozen?

2. Can your teams easily retrieve and reuse existing clinical and technical evidence before commissioning new laboratory work?

3. Are regulatory decisions and benefit-risk rationales documented so that another regional market team can defend them?

4. Does your leadership actively challenge historical approval sequences when regulatory reliance policies evolve?

A low score may indicate significant budget waste in redundant testing and regional dossier drafting.

Closure is Not the Same as Effectiveness

What the Pulse Told Us

THE HARDEST CHALLENGES IN MAJOR REMEDIATION



Key Finding: Identifying non-conformances is difficult, but ensuring the fix endures once the audit spotlight fades is significantly harder.

THE TRINZO PERSPECTIVE

Remediation programmes launched in the wake of 483s, warning letters, or major audits naturally prioritise rapid closure. But closure is not effectiveness.

A resilient remediation programme must definitively answer three questions: *1) Did we isolate the real systemic root cause?*
2) Did we execute the corrective action effectively?
3) Has the organisation changed enough to prevent recurrence?

The third question moves remediation beyond documentation and directly into operational leadership, capacity management, governance and corporate culture.

What Organisations Should Consider

CORE RECOMMENDATIONS FOR ENDURING RECOVERY

- **Effectiveness Over Closure:** Define programme success by post-market stability and verified non-recurrence, never by CAPA milestone closure rates alone.
- **Systemic Scoping:** Structure programme governance around enterprise risk and root-cause analysis rather than tracking an overwhelming list of disparate actions.
- **Pre-Handover Ownership:** Appoint and empower permanent business owners before the programme team dissolves or external advisors depart.
- **Measure Behaviour Change:** Track whether frontline operating behaviours and documentation quality actually change on the shop floor after SOP updates.
- **Institutionalise Capability:** Embed technical mastery into the permanent organisation rather than letting domain expertise leave with the remediation taskforce.

WHAT TO WATCH FOR

- Massive CAPA backlogs and action dates repeatedly extended due to operational exhaustion.
- Remediation accountability immediately dumped back onto Quality as soon as the external project team leaves.
- The same systemic finding reappearing in slightly different language during subsequent Notified Body audits.

Remediation Reflections

EXPERT LENS

"Are we fixing the right system?"

Remediation is rarely just a QA issue. Sustainable remediation requires the engineering, manufacturing, and executive teams who own the process to change their daily operating disciplines.

Carl Dover · Systemic Quality & Governance Specialist

"Will the organisation sustain the fix?"

Programmes often hit delivery milestones, yet promised operating value evaporates. Leaders must take legacy work off specialists' plates and create capacity to make change sustainable.

Kathryn Cullen - Head of Client Delivery & Operations

“Do leaders have better visibility of risk?”

The real test of successful remediation is whether leaders have better visibility of risk, whether ownership is clear, and whether the business can demonstrate sustained control once the remediation team has gone.

Liam Turley, Trinzo CEO

SELF-PULSE DIAGNOSTIC: SCORE 1 TO 5

1 = Ad hoc · 5 = Embedded

Will your remediation survive programme closure?

1. Could leadership explain the systemic root cause of the breakdown in a single clear statement?

2. Are corrective actions permanently altering the operational workflows that created the non-conformance?

3. Is there a named operational line owner held accountable long after the remediation programme closes?

4. Do empirical effectiveness checks confirm that recurrence risk has genuinely reduced over time?

5. Would your newly established procedures continue without disruption if the project team vanished tomorrow?

Ultimately, change readiness is an organisation's ability to maintain control under regulatory scrutiny.

Evidence as a Strategic Enabler

What the Pulse Told Us

BIGGEST OPPORTUNITIES IN CLINICAL EVIDENCE



Key Finding: The single strongest response in the entire survey sits right at the start: defining intended purpose, clinical benefits, and claims with surgical precision.

THE TRINZO PERSPECTIVE

Clinical evidence cannot be relegated to a late-stage compliance hurdle, to satisfy the next regulatory milestone after engineering freezes the device design.

The intended purpose, target population, claims, clinical benefits, endpoints, regulatory strategy and commercial ambitions all influence the evidence that will ultimately be required. Misalignment between them can lead to additional studies, delayed submissions or evidence that supports approval but does not adequately support adoption or market access.

The earlier those questions are connected, the more useful the evidence becomes. When clinical evidence is designed upstream, it does not merely document the finished device. It actively shapes the engineering concept, refines endpoints, and optimises commercial adoption.

What Organisations Should Consider

STRATEGIC IMPERATIVES FOR CLINICAL ALIGNMENT

• **Precision in Purpose:** Define intended indications, target patient populations, use environments, and clinical comparators before locking verification protocols.

• **Cross-Functional Integration:** Unify Clinical, Regulatory, Risk Management, and Commercial teams early so that risk analyses do not overlook clinical harms.

• **Reusable State-of-the-Art:** Audit existing clinical data and accumulated literature across similar device families before commissioning costly new investigations.

• **Dual Approval & Adoption Endpoints:** Design clinical trials to satisfy both Notified Body safety/performance criteria and payer reimbursement requirements.

• **Lifecycle Evidence Continuity:** Ensure post-market clinical follow-up (PMCF) actively tests the baseline assumptions established during initial CE or FDA review.

WHAT TO WATCH FOR

• Intended purpose statements being narrowed late in submission reviews under Notified Body pressure.

• Month-to-month certification delays translating into significant commercial revenue losses.

• Regulatory clearance achieved, but commercial adoption stalled due to missing health economic outcomes.

Evidence Reflections

EXPERT LENS

"Clinical evidence is most powerful when it is treated as a strategic enabler rather than a downstream regulatory deliverable."

Leadership teams must answer three fundamental questions early:
1) What clinical story must we tell?
2) What evidence is capable of defending it?
3) Are Clinical, Regulatory, and Commercial aligned before we commit?

Regulatory trust is built when organisations openly demonstrate clear understanding, not when they attempt to conceal evidence gaps.

Dr. Amie Smirthwaite · Senior Clinical & Regulatory Strategist

SELF-PULSE DIAGNOSTIC: SCORE 1 TO 5

1 = Ad hoc · 5 = Embedded

Is your clinical evidence strategy early and robust enough?

1. Is your device's intended purpose sufficiently granular to determine exact endpoints and comparators?

2. Do Clinical, Regulatory, and Risk management specialists agree on what constitutes clinical benefit?

3. Have procurement and payer reimbursement requirements been incorporated into study designs?

4. Do development teams map existing literature and clinical evidence before designing novel trials?

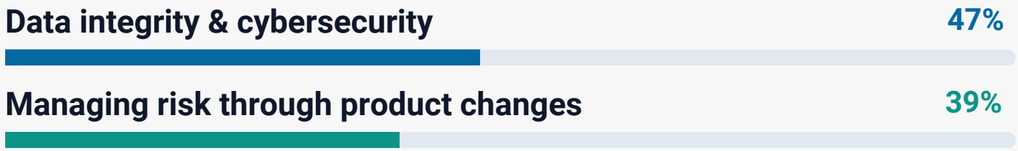
5. Can your organisation articulate a coherent narrative connecting intended purpose directly to patient benefit?

A low score may be the primary predictor of Notified Body technical file clock-stops.

Evidence as a Strategic Enabler

What the Pulse Told Us

BUILDING TRUST AS DIGITAL & AI DEVICES EVOLVE



BUILDING CONFIDENCE IN AI IN Q&R OPERATIONS



Trust will not be created by technology alone; it is created by the systems around it.

THE TRINZO PERSPECTIVE

The AI conversation is maturing from "Can we use AI here?" to a far more critical test: *"Where does it add defensible value? and can we defend how we use it?"*

Deploying AI in life sciences requires eight interconnected foundations: defined intended use, reliable training data, proportionate risk controls, formal validation, human accountability, clear process ownership, workforce training, and post-market drift monitoring.

AI cannot live as a detached IT initiative; it must seamlessly integrate into your QMS and everyday regulatory practices.

What Organisations Should Consider

SIX MOVES FOR CONTROLLED AI ADOPTION

- **Start with the Problem:** Define the measurable Quality, Regulatory, or Clinical friction point before procuring or evaluating software tools.
- **Understand & Simplify:** Streamline and eliminate manual waste from workflows prior to introducing automation.
- **Classify Intended Use:** Apply risk-proportionate validation controls under ISO 13485 rather than treating every AI model identically.
- **Control the Data:** Rigorously audit the provenance, context, and bias of underlying training datasets and prompt inputs.
- **Explicit Human Accountability:** Mandate named expert oversight and sign-off wherever AI draft outputs support regulated decisions.
- **Measure Net Business Value:** Track reductions in cycle times, rework, and audit friction — not merely software adoption metrics.

WHAT TO WATCH FOR

- Unregulated "Shadow AI" spreadsheets and drafting tools being used informally without SOP controls.
- Tool-led enthusiasm automating broken, unnecessarily complex manual processes.
- Human verification devolving into rubber-stamping without verifiable technical review criteria.

Digital Trust Reflections

EXPERT LENS

Digital Governance & Operational Excellence

"Knowledge is the foundation of trust. Understanding data limitations and model constraints is what allows teams to manage risk compliantly."

Liam Turley, Trinzo CEO

"Moving from pilots to trusted capability requires making AI use visible and governed: defining decisions supported and where human oversight sits."

Conor Flynn, Head of Innovation

"Lean before AI. Never automate waste. Simplify the workflow first, then deploy technology where it creates undeniable performance lift."

Jack Cunningham, Margin Improvement Consultant

SELF-PULSE DIAGNOSTIC: SCORE 1 TO 5

1 = Ad hoc · 5 = Embedded

Is AI becoming a trusted capability in your business?

1. Do you know precisely where AI tools are being used across your regulated processes?

2. Does every material AI use case have a documented intended purpose and named owner?

3. Do technical teams verify the provenance, quality, and bias of underlying training data?

4. Is qualified human accountability legally and procedurally explicit for all AI drafts?

5. Have underlying workflows been streamlined using Lean principles before automating them?

6. Can you demonstrate that the AI-assisted process outperforms the legacy baseline?

STRATEGIC DIRECTIONS

What Connects the Findings? The Power of Organisational Confidence



Evidence Architecture

Build portable data assets designed to travel across international reliance routes without duplicated clinical testing.



Upstream Expertise

Unify Clinical, Regulatory, Risk, and Commercial functions early to shape the device concept and avoid costly redesigns.



Disciplined Execution

Embed operational line ownership and clear governance that survives long after the remediation taskforce departs.

The findings are not five separate problems. They represent a single capability challenge. The organisations best positioned to innovate and scale will not necessarily be those that move fastest. They may be those that can learn, decide and adapt with the greatest confidence.

EXECUTIVE DIAGNOSTIC

Six Questions for MedTech Leadership Teams

Dimension	Critical Leadership Question	Score
01 · Quality Systems	Do our Quality systems help us make better decisions or mainly tell us what has already happened?	**1 – 5**
02 · Evidence Reuse	Are we creating evidence once and using it intelligently, or repeatedly recreating knowledge from scratch?	**1 – 5**
03 · Remediation	When we remediate a finding, can we demonstrate that the underlying operating system actually changed?	**1 – 5**
04 · Clinical Strategy	Are Clinical Evidence decisions being made early enough to actively influence product and market strategy?	**1 – 5**
05 · AI Governance	Do we understand exactly where AI is deployed and what human controls make that use trustworthy?	**1 – 5**
06 · Connected Systems	Are specialist functions operating as one connected system when major regulatory or design changes occur?	**1 – 5**

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Innovate and Scale with Confidence

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Thank you to all who contributed to the Global Access Pulse and helped raise funds for HopeSpace.

HopeSpace
Children's grief support service

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