2026 TRENDS

Quality + Compliance

clarkston CONSULTING

TREND 1

Regulatory Harmonization and Reliance for Market Expansion

TREND 2

Quality as a Driver of Trust and Loyalty

TREND 3

Responsible AI Compliance in a Digital-First World

TREND 4

Compliance as a Competitive Advantage to Support Growth

Quality and Compliance (Q+C) departments work together to ensure high-quality products are manufactured with consistent efficacy and safe consumption, while ensuring adherence to regulations. In both the life sciences and consumer products industries, the approach of these functions is shifting from reactive to proactive, and collaboration with various regulatory agencies is growing.

In this report, we will explore a few Q+C trends for 2026, including regulatory harmonization and reliance on market expansion, the importance of quality in consumer experience, how to use Artificial Intelligence (AI) within quality responsibly, and investing in Q+C for successful organizational growth.

TREND 1

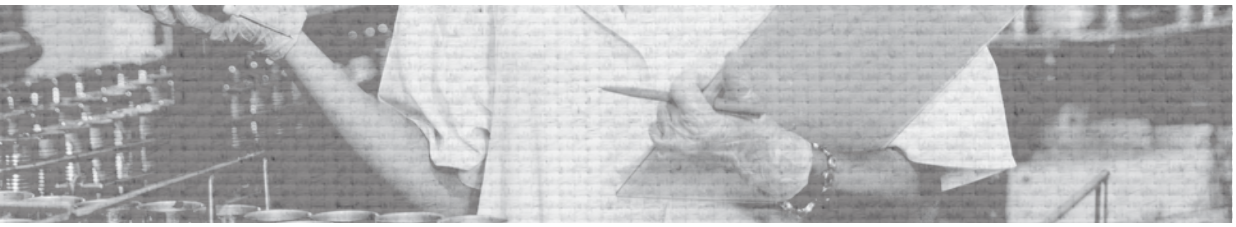
Regulatory Harmonization and Reliance for Market Expansion

Medical Technology (MedTech) and pharmaceutical companies are increasingly adopting regulatory harmonization and regulatory reliance to accelerate global market expansion and streamline product launches. Harmonization aligns technical requirements across countries, reducing discrepancies in the approval processes, and enabling regulators to accept shared data submissions, audit results, and surveillance findings.

A notable example is the U.S. Food and Drug Administration's (FDA's) upcoming Quality Management System (QMS) rule, effective February 2, 2026, which aligns U.S. standards with International Organization for Standardization (ISO), reinforcing global consistency in compliance frameworks.

Regulatory reliance complements harmonization by allowing one country's regulatory authority to leverage assessments and decisions from another, significantly shortening approval timelines. Programs like the World Health Organization's (WHO's) Collaborative Registration Procedure (CRP) enable National Regulatory Authorities (NRAs) to issue decisions within 90 days by relying on documentation from Stringent Regulatory Authorities (SRAs) such as the FDA and European Medicines Agency (EMA). This approach transforms global expansion from fragmented, country-by-country efforts into a strategic, planned sequence of approvals.

Together, these mechanisms offer companies a competitive advantage when integrated into a compliance-first global strategy. By systemically leveraging harmonization and reliance, organizations can reduce regulatory complexity, accelerate product launches, and position themselves for success in diverse markets worldwide. As we move into 2026, this is evolving from a policy discussion to an important business variable for product approval and market expansion.

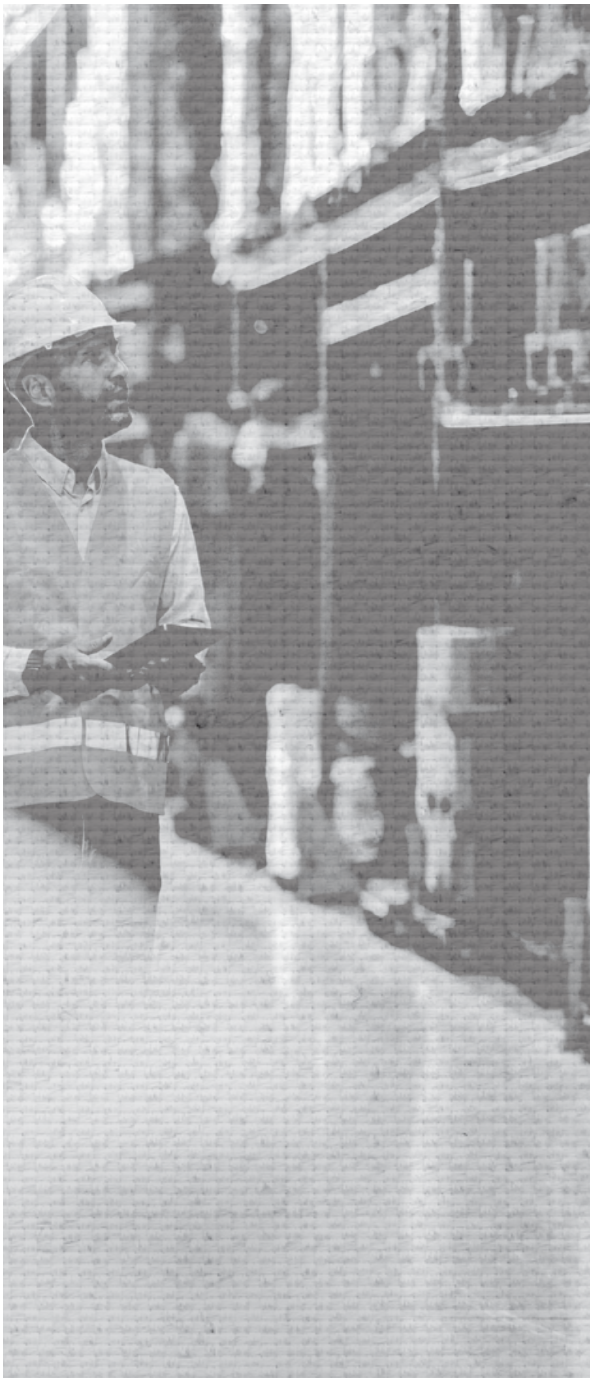


TREND 2

Quality as a Driver of Trust and Loyalty

With consumers today becoming more educated and directive about their health, Q+C organizations must evolve from a defensive, audit-focused function into a proactive driver of trust, patient experience, and customer loyalty.

As consumers and patients increasingly interact with companies through digital tools, wearables, patient services, and real-world data platforms, compliance failures now surface first as customer failures (delays, system outages, or poor communication/confusion) long before regulators are involved. Quality is no longer behind the scenes; it has become a visible part of the patient's experience, shaping perceptions of reliability, transparency, integrity and trust.



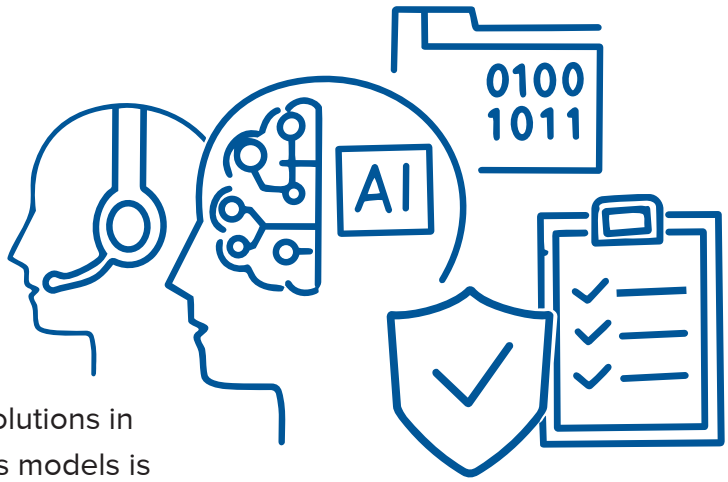
There are four principles upon which Q+C organizations can base their approach to increase patient trust:

1. recognizing the patient as the ultimate beneficiary of quality decisions,
2. treating patient experience as a core quality attribute,
3. using transparency to build loyalty during quality events, and
4. fostering a culture throughout the organization where quality is understood as caring for patients rather than avoiding failure.

By reframing quality activities around human impact and trust, not just regulatory sufficiency, Q+C professionals can position themselves as strategic partners who reduce risk, improve experiences, and help organizations compete on reliability and trust in an increasingly crowded market.

TREND 3

Responsible AI Compliance in a Digital-First World



As life sciences organizations continue to implement AI solutions in 2026, incorporating responsible AI practices into business models is essential to maintaining regulatory compliance. Traditional Q+C frameworks that were originally built without adaptive learning algorithms are no longer sufficient for today's AI solutions.

The U.S. Food and Drug Administration (FDA) requires extensive traceability, especially for organizations relying on electronic records. As AI becomes more integrated into life sciences operations, it is critical to ensure the same level of traceability is maintained throughout AI-driven processes. This includes maintaining detailed records for data inputs and outputs, system versions, and decision-making processes. Traceability must be a core element of any AI strategy.

There will continue to be various use cases for AI in Q+C operations. For example, as regulatory bodies such as the FDA continue to advocate for Computer Software Assurance (CSA) to support risk-based approaches for system validation, life sciences organizations adopting responsible AI compliance can use AI for automated test case generation; accelerating validation processes by reducing manual effort and minimizing human error. However, without human oversight, AI use would be detrimental.

Studies show AI creates inaccuracies, known as "hallucinations," up to 94% of the time, depending on which AI model is used. These staggering percentages highlight the importance of using human oversight for responsible AI compliance while performing not only traceability and validation tasks, but all tasks involving AI.

To remain in compliance while using AI, companies need to embed human oversight at all key decision points, such as reviewing AI automatically generated test cases. Ultimately, final approval of all AI-generated content should require human oversight to ensure compliance with regulatory standards.

TREND 4

Compliance as a Competitive Advantage to Support Growth

Many organizations still view Q+C as an overhead cost, but in today's market it represents a significant value driver. Traditional Quality Management (QM) processes are often manual and cumbersome, making them difficult to manage under increasing supply chain pressures and regulatory scrutiny. Simply adding more staff or extending work hours is not a sustainable solution; instead, companies need to equip quality teams with modern compliance infrastructure tools to enhance efficiency and effectiveness.

To meet growing demands, organizations should invest and prioritize digitization and standardization of quality operations. Implementing systems such as Laboratory Information Management Systems (LIMS) and Quality Management Systems (QMS) - including modules for CAPAs, deviations, change controls, document management (eDMS), and learning management (eLM) enables automation, streamlined workflows, and improved reporting.

These tools also ensure critical compliance elements like data integrity and audit trails are maintained. Standardizing processes and tools across the enterprise creates a "single source of truth," which supports better analytics, faster regulatory approvals, and smoother integration during acquisitions or partnerships.

Although implementing these solutions can require significant investment, the cost of poor quality, such as product failures, recalls, and negative audit findings, can be far greater. Advanced compliance tools deliver efficiency gains through automation, real-time tracking, and analytics, helping organizations reduce risk and improve responsiveness. In 2026 and beyond, it's crucial for organizations to make these investments to support organizational growth and have a competitive advantage.

Looking Ahead

The landscape of Q+C is shifting to a proactive, patient/consumer-centric approach to improve operations by leveraging other regulatory bodies for decision-making, better patient/consumer interactions, responsible use of AI, and investing in compliance for expansion. All of these work together to create a reliable, repeatable product with efficiency gains and will be key toward enhancing quality in 2026 and beyond.

ABOUT CLARKSTON CONSULTING

Businesses across the life sciences, consumer products, and retail industries partner with Clarkston Consulting to enhance strategic decision-making, improve operational efficiencies, implement new technologies, and promote business growth and market diversification. Leveraging deep functional and industry expertise, our people discover, design, and deliver solutions that fit your business, your goals, and your future. At Clarkston, your purpose is our purpose.

For more information about how we can help your company, please contact us.