IQVIA TECHNOLOGIES

White Paper

The Value of Commercially Focused QARA Solutions in Global MedTech

How MedTech leaders go to market, grow in market, and stay in market

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Executive summary

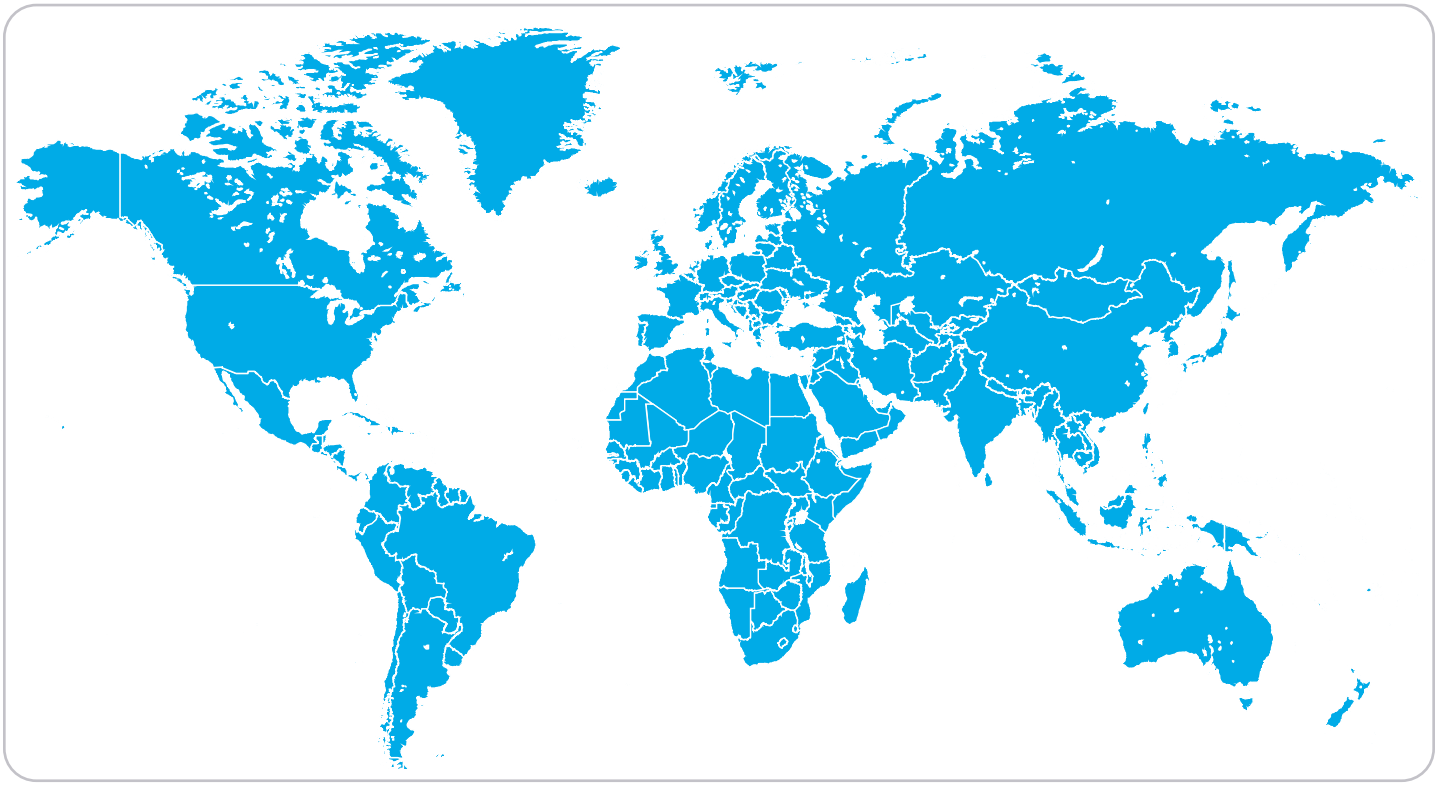
There has never been a time when the innovation and commercialization of global MedTech solutions have been more dynamic, more demanding and more complex. Accelerated innovation from new materials and technologies, the advance and divergence of global regulations and standards, and commercial pressures to deliver shareholder value collide with heightened public awareness of what constitutes a high quality, safe and effective device. A key differentiator for companies that successfully navigate this environment of complex drivers is the maturity and agility of their Quality Assurance and Regulatory Affairs (QARA) professional function. Their ability to achieve right-first-time execution across design and development, product submission and registration, manufacturing and supplier quality, and post-market surveillance positions QARA as a true market access enabler.

This paper, created from a live presentation during IQVIA's October 2025 Fusion Conference in Florida, presents a pragmatic, commercially focused blueprint with key points for consideration when digitizing and harmonizing QARA solutions to accelerate patient access, improve commercial performance, and enhance product quality. It outlines the primary challenges in the existing environment (i.e. country regulatory divergence, product-specific standards, and elongated global registration timelines), shows how to convert QARA excellence into a value driver for top-line growth, and details roadmap principles for AI-enabled workflows that can be deployed in a range of QMS and RIM processes.

The approach aligns commercial, quality, regulatory, clinical, and supply chain around a shared set of outcomes and KPIs, ensuring organizations not only go to market with improved speed and predictability but also maintain market access through ensuring continued compliance to an ever evolving global landscape. Ultimately this pulls through into how QARA solutions enable an organization to deliver a dual focus on patient safety and commercial performance.

Driving harmonized, digitized QARA processes and systems

Unlock potential through optimisation of professional activities, while driving global compliance



THE PROBLEM STATEMENT:

MedTech, including IVD, strives for global market access frameworks that are:

1. Aligned to commercial and strategic objectives
2. Efficient, timely, and repeatable
3. Effective in adapting to global compliance process variations

Market context and imperatives

Global Medtech markets are progressively challenging

Optimizing innovation pipeline, commercial activities and operational efficiencies are critical

The global environment that QARA teams need to navigate to provide MedTech solutions to global markets continues to evolve across a four key fronts:

- **Innovation velocity**: Adoption of software as a Medical Device (SaMD), Software-in-a-Medical Device (SiMD), new Artificial Intelligence (AI) and Machine Learning (ML) capabilities, and the advancements of material science are accelerating product innovation. Commercialization of such solutions must keep pace without compromising safety or compliance and QARA play a key role in ensuring the development of such solutions is both safe and effective
- **Global market access and commercial performance**: Evidence-led HCP adoption is critical to accelerate patient access and sustain growth. Data generated during the design and development phase of MedTech innovation can play a critical role, not only in product registration activities, but in customs and importation and reimbursement activities that are necessary in a range of countries
- **Regulatory complexity**: Divergence in regulations and standards continues to evolve. Requirements in healthcare 'vertical' regulations need to interplay with broader 'horizontal' regulations For example, in Europe alone the requirements of the EU MDR and IVDR verticals can interplay with the horizontals of the EU AI Act, EU GDPR and environmental regulations such as the EU WEEE, REACH, RoHS and Waste Packaging acts are some of many. Globally, requirements are broader than those in the U.S. and EU with countries such as China and Russia in many cases requiring local technical, toxicological and clinical studies,

audits of manufacturing sites and in country legal representatives who are held accountable for the placement of safe and effective products in their markets. Global regulatory strategies are needed for global product launches

- **Operational efficiency**: Clinical, pre-market, post-market, production quality, supply chain, and field service must operate as a controlled, cost-effective end-to-end system. Where companies have historically grown through mergers and acquisitions to increase either the product portfolio and/ or the target markets, that has often come with the adoption of additional technological infrastructure and divergent internal processes executing the same client facing outputs. Companies are now looking to harmonize, with a focus on optimizing data capture and maintenance, process execution and technological ecosystems. QARA are under the same pressures as they review their global QMS and RIM solutions and end to end organizational activities

Implication: QARA maturity is no longer a "cost of doing business" — it is a **growth lever** that provides key strategic insights to a range of activities that **accelerate global market** access of company products.

The three structural challenges

Effectively communicating the complexity of the environment that companies need to navigate if often a key factor that determines the success of QARA in conveying the value of their insights. Through supporting broader business teams in recognizing how QARA can help the organization navigate complexity, companies can accelerate global market access of safe and effective product solutions. The below sections outline three critical components that need consideration in this ever-changing landscape.

Country specific requirements

Challenge 1: Country specific requirements

Objective: Maintain oversight of global country regulatory change, variation and complexity

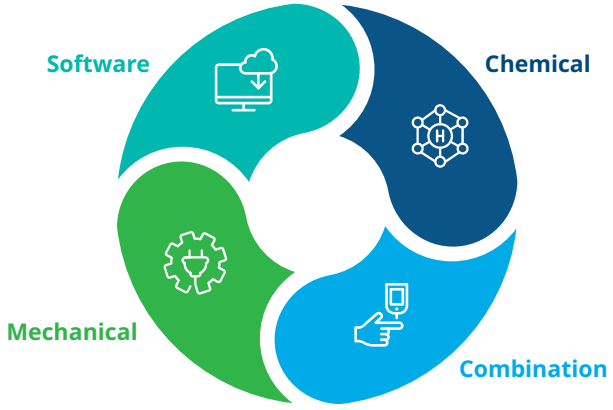
1. U.S. and EU approvals are not universally accepted globally
2. Many countries have additional documentation reviews and require supplementary documents
3. Some countries require additional technical, toxicological and clinical activities performed in country

- **U.S./EU are not universally accepted**. Many countries require additional technical, toxicological and clinical data in addition to what has been gathered for the U.S. and EU markets. In many cases, the 'start' of the local country process occurs near the 'end' of the U.S. and/ or EU approval route when the product design has been frozen
- **Local representation matters**. Many markets require an in-country legal entity to act as a local authorized/ responsible person for product registration and post market surveillance activities irrespective of what may already be in place for the U.S. and EU. Local importers need to work closely with organizations for the successful importation of products and that is where the role of QARA can, in many companies, extend into supporting customs and excise activities
- **Continuous change**. Where local regulations and standards change, having processes and systems in place that catch that change early gives organizations the best chance of executing impact assessment and change management activities to ensure continued compliance and sustained market access of their clinical solutions. Additionally, where a company change has taken place, such as a product design, manufacturing location and/ or change to a key supplier, ensuring that the impact on a local registration is consciously known is also key to sustaining market access. What may be a 'non-significant' change in the U.S. and/ or EU can be very significant elsewhere globally

Product-specific standards

Challenge 2: Product specific requirements

Objective: Identifying product specific requirements for effective global launches



Non-invasive, invasive, surgically invasive, active, implantable, IVD

1. Different product types are subject to different global and local standards
2. Local standards can vary with globally accepted standards
3. A Medical Device isn't always a Medical Device (sometimes it is a Non Medical Device or a Pharma product)

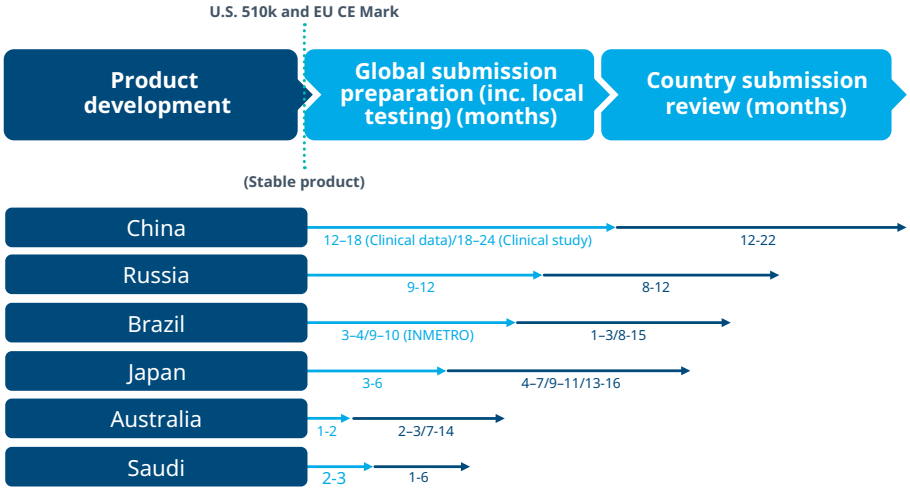
- **Heterogeneity across device categories**. Non-invasive, invasive, implantable, IVD, active devices, and combinations (software/mechanical/chemical) follow different standards that are specific to their product type. Additionally, the way in which data is captured demonstrates the safety and efficacy of specific products can vary across a range of MedTech products that have over 500,000 industry device types

- **Local vs. global divergence**. There are areas in global regulations where difference in definitions and country practices drives significant complexity in execution of key QARA activities. A device classified as an Medical Device in one market may be treated as non-medical device or pharmaceutical in another depending on the nature of the product or the country submission pathway. For example, a U.S. 510k submission can take a path where items, such as material, software and hardware that 3D prints/mills the material based on software designs, is grouped in one submission. In other regions, these different products may need their own registration pathway and in some cases the hardware in the solution is considered a non-medical device

Global registration timelines

Challenge 3: Global registration approval timelines

Objective: Incorporate market access requirements early in strategic planning



1. U.S. and EU approvals are not universally accepted globally
2. Route to market matters — some countries require local legal entities to act as importer/registration holder
3. Lengthy timelines in countries that require additional toxicological, technical and clinical testing

- **Lengthy or staged approvals.** As previously mentioned, some global markets require additional toxicological, technical, and clinical testing (sometimes in-country). The 'end' of the approval process for the U.S. and EU can often be the 'start' of the process of approval in other countries as a design freeze is needed so that local testing activities can begin and/or the source product documentation is available for the start of the local country submission activities
- **Strategic planning is decisive.** Incorporating key market access requirements into the design phase that can account for more than just the U.S. and EU markets can be critical in accelerating global market access. QARA teams play a key role in strategic planning so that companies can begin with the end in mind and ensure the highest possible success of global launches being ready for importation into global markets

Takeaway: Treat **regulatory strategy as product strategy** — embed country and product specificity from concept through lifecycle to ensure a global product launch has the highest possible chance of success.

Why commercially focused QARA wins

Communicating the value of QARA in commercial terms…

…supports investment towards global market access activities

Top line growth	Operational effectiveness	Process efficiency	Global compliance
Drive performance through acceleration of patient access	Improved 'right first time' activities	Reduce manual activities and increase resource utilization	Optimized controls from concept to patient

QARA teams live in a world of high complexity and variation that can change based on country requirements, product type and therapeutic areas of MedTech solutions. Effectively communicating the value of QARA and the need for organizational change and/ or support is often a key success factor for high performing teams. QARA leaders that can interface the technical to the commercial, and translate value into commercial terms, often express the benefits of digitized, harmonized QARA processes in four terms:

1. **Top-line growth**: Digitized, enterprise wide QARA solutions accelerate market access, support the navigation of complexity, and ultimately ensure companies have transparency of global launches and change activities. This drives top line growth
2. **Operational effectiveness**: Standardized workflows and data reduce handoffs and manual effort, thereby reducing enterprise risk and improving resource utilization through automating manual activities. This improves operational cost
3. **Process efficiency**: Digital systems drive right-first-time activities such as the creation of design dossiers, execution of global product registrations, and the execution of change plans. This lowers rework, accelerates performance and reduces audit findings thereby improving operational cost
4. **Global compliance**: Proactive surveillance and consistent controls ensure that companies stay compliant with global enterprise activities. This ensures the protection of company image, brand equity and ultimately drives the provision of globally available, safe and effective MedTech solutions

Case for change: Public awareness and risk

Publicly known, high-profile device quality issues (e.g. PIP breast implants, metal-on-metal hips) demonstrate that **proactive post-market surveillance** activities that leverage data from a wide variety of sources, and thereafter drive updated Risk Management and Clinical review are essential to protect patients, brands, and commercial growth. Effective QARA solutions enable faster detection, triage, and action with a **digitized QARA ecosystem** supporting the efficient and effective execution of critical activities.

A Target operating model for digitized QARA

Objective: Both QARA teams and commercial organizations have the same vision — transforming global healthcare through the provision of safe and effective product solutions. A globally consistent, yet locally adaptive, QARA capability that ties directly to commercial targets can be achieved through the delivery of QMS, RIM and Regulatory Intelligence solutions that have a multi-point focus on patient safety, product quality and commercial growth.

Core capabilities

The following are some of the key capabilities of a digitized QARA solution:

- **Regulatory intelligence and strategy**: Country/region rule mapping, in-country testing guidance, local holder requirements, and registration playbooks
- **Design controls and technical documentation**: Structured requirements management for technical/toxicological/clinical, labeling and packaging, product registration and importation, and global UDI
- **Post-Market Surveillance (PMS)**: Complaint intake and reporting requirements, coding of adverse event reports, investigations, PMCF/PMPF/PSUR, integration into CAPA/Risk/Change control, field action requirements, and trend analytics
- **Quality Management System (QMS)**: A modular and scalable ecosystem of connected solutions reduces the risk of manual connectivity and improves resource utilization. Core modules can include document control, training, non-conformance, CAPA, audit/inspection readiness, change control and supplier quality
- **Commercial alignment**: Data connectivity and management oversight allows organizations to drive transparent and measurable activity, and pivot from reactive quality management into a proactive approach that links QARA to commercial outputs

Data and architecture principles

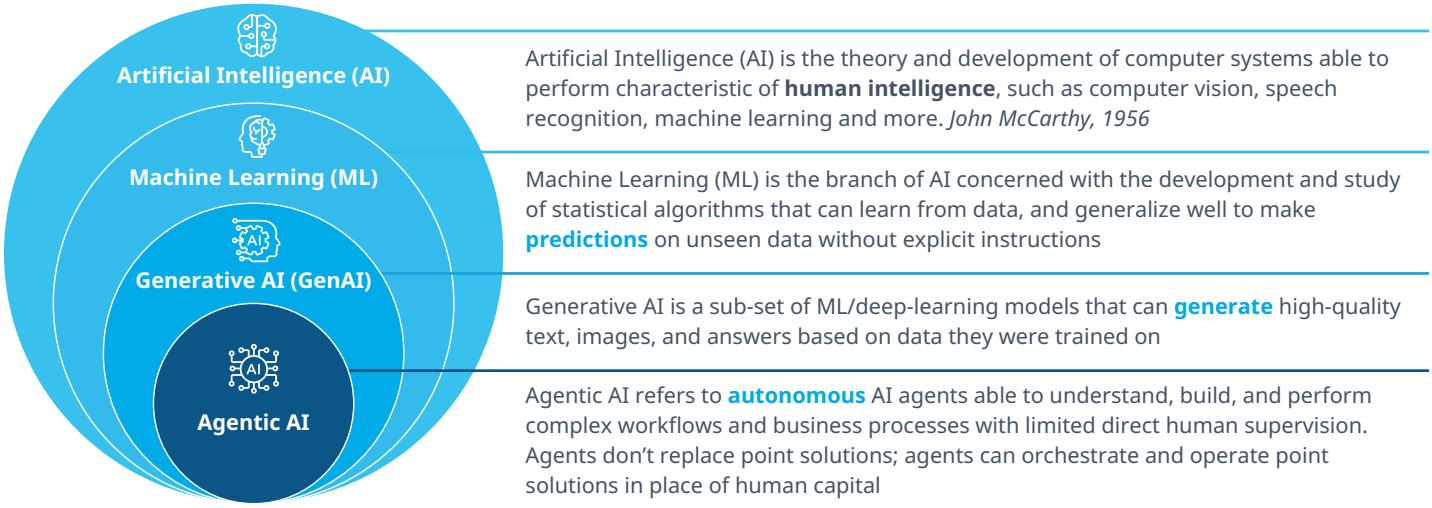
The following provide key points of consideration when looking at the deployment of digitized QARA solutions, in particular QMS, RIM and Regulatory Intelligence capabilities:

- **Single source of truth**: A harmonized data model supports the connectivity of related QMS/RIM modules and supports the execution of data driven insights and intelligently automated workflows
- **Interoperability**: APIs with PLM, LIMS, ERP, CRM, and safety systems ensures that benefits in operational efficiency can be realized and that data driven insights can be obtained
- **Traceability and auditability**: End-to-end connectivity from requirement → design → verification/validation →submission → PMS signals ensure full chain of custody of connected quality records and closes the loop from PMS activity back into design and development/risk
- **Privacy and security by design**: Role-based access, PHI controls, telemetry, and robust logging are mandatory for company critical QMS/RIM solutions

Pragmatic AI: Where it works now

Optimizing a company's digital QARA footprint, with considerations into data and process management, forms part of a key foundation to the successful uptake of AI enabled solutions. However, AI itself is not a monolith and different AI solutions have different benefits and can be used against a range of use cases. The diagram below illustrates some of the many possibilities that are available today.

Artificial Intelligence (AI) is a broad set of complementary methods



High value use cases

The key driver for QARA and commercial organizations alike is to provide safe and effective global product solutions. In this context, AI and digitized QMS/RIM solutions are the enabler to — not the product of — this vision. Clearly defining the use case at hand is critical in ensuring the right AI solution, if any, is chosen as part of the solution design. The below sections provide some examples of where a specific AI solution has been chosen to support a specific use case.

A. DATA SEARCH AND EXTRACTION (SAFETY LANDSCAPE)

AI/NLP to effectively surface medical device safety

Use case: Data search

Situation

- Large global medical device wanted to understand safety landscape around reprocessing procedures, contamination issues and clinical outcomes for medical inspection instruments
- Data buried in unstructured text within medical literature and medical device reports
- Large manual effort needed to gain insights

Solution

- AI/NLP was used to process over 1.5M relevant records from FDA's MAUDE, customer reports, and full text literature to find key information on 30+ variables such as:
  - » Instrument name and model, contamination type, microbe if applicable, cleaning and processing method, disinfection process, clinical outcome, patient disease, residue, patient harm

Results

- Clean structured data fed into central database with visualisations
- Enabled brand and product teams to understand safety issues for their brand vs. competitor brands

Class1	Relation	Class2	#Docs	Doc	#Hits	Hit
Endoscopic Procedure	control	Communicable Diseases	4	35035585	1	Since then, international recommendations from professional societies on ir
Laparoscopy	complicate	Postoperative Complications	2	32808863	1	Conclusions: Although serious postoperative complications in laparoscopic c aware of their possible occurrence.
Colonoscopy	detect	Adenoma	3	34156591	1	Relative to screening colonoscopies, there were higher odds of adenoma de CI 1.30-1.55) and even higher odds among surveillance colonoscopies for a
Endoscopic Mucosal Resection	induce	Ulcer	2	32782549	1	The aim of the present retrospective study was to evaluate the effectiveness technique for wounded microvessels in promoting the healing of endoscopic
Arthroscopy	complicate	Hemorrhage	1	35123721	1	TXA may also reduce bleeding complications in arthroscopic surgery, and th need for knee joint aspiration and reduced knee swelling.
Endoscopic Retrograde Cholangiopancreatography	predictive	Cholelithiasis	1	32682482	1	Our findings support a conservative strategy in patients with predicted sever cholestasis.
Thoracic Surgery, Video-Assisted	nodulate	Multiple Pulmonary Nodules	3	34955000	1	Methods: From April 2020 to April 2021, a total of 66 patients were selected thoracoscopic surgery (VATS) guided by the 3D-printed emulation localizatio
Videothoracoscopy	nodulate	Multiple Pulmonary Nodules	3	34494526	2	Objective To investigate the application value of indocyanine green(ICG)in t
Gastrointestinal Endoscopy	control	Communicable	2	34540547	1	Therefore, we have developed a new shielding device called STEP for infec

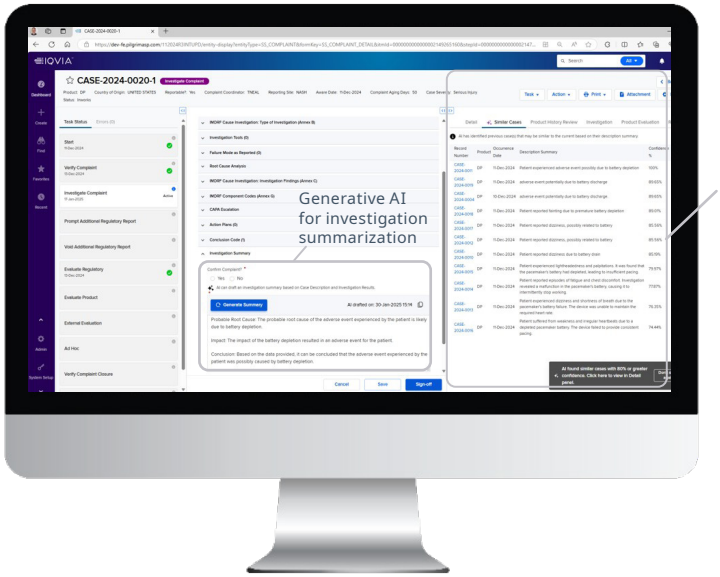
In this example:

- The use case needs the solution to process unstructured sources (e.g., literature, device reports, internal records) to surface contamination types, microbes, processing methods, outcomes, and competitive benchmarks
- The required use case output: Clean, structured datasets with visualizations for brand/product teams

B. COMPLAINT HANDLING — SUMMARIES AND SIMILAR RECORDS

Complaint handling — Generative AI and NLP usage

Improve team efficiency and understanding of complaint handling activities



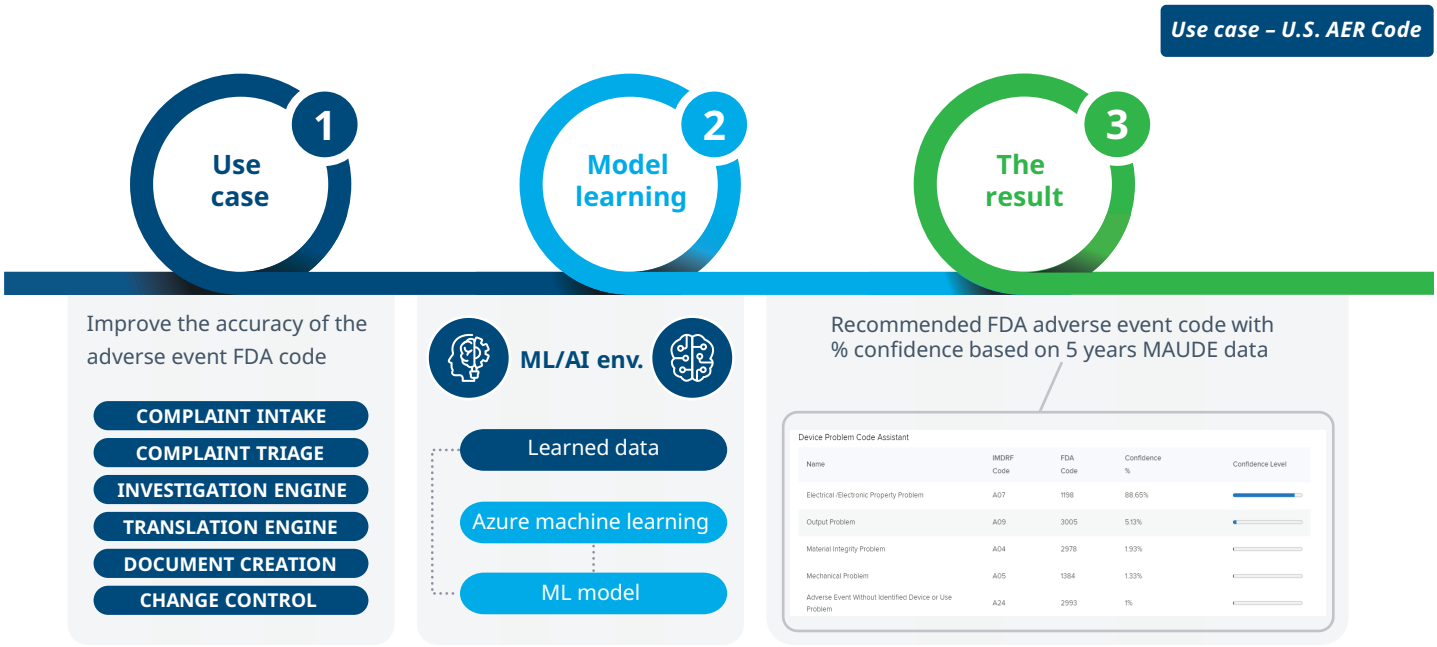
In this example:

- GenAI produces investigation summaries; NLP clusters similar cases for faster triage, consistent coding and the review of previous content to support consistency in organizational response
- The use case impact: Reduced complaint processing cycle time, improved complaint investigation consistency and lower variability across teams/sites

C. REGULATORY CODE RECOMMENDATIONS

Complaint handling — FDA code recommendation

FDA code recommendation — improving efficiency and accuracy using artificial intelligence



In this example:

- The use case requires support in consistently choosing the right IMDRF AER code for U.S. reports. AI models trained on U.S. MAUDE data suggest adverse event codes (e.g., FDA-style taxonomies) with confidence levels trained on historical data, improving speed and consistency
- The use case impact: Improved FDA relationships through a company driving consistency in how different individuals code and report US AERs

What to potentially expect with the use of targeted AI solutions: 20–40% reduction in manual draft time for literature/scientific content, 15–30% faster complaint triage, and measurable uplift in coding consistency — subject to data quality, governance, and change adoption.

Regulatory and governance considerations for AI

The delivery of high value AI-enabled solutions relies on a company clearly defining the use case at hand. This allows the appropriate data inputs, data outputs and process steps to be identified from the range of vertical and horizontal regulations and standards that can vary based on country, product type and therapeutic area of the company's operations. When the defined problem statement contextualized, a range of potential solutions can be explored along with the associated costs to deliver and maintain them.

Navigate complexity by solutioning out from targeted use cases

Be specific and focused — a default fallback is legacy solutions and/or personal herculean effort

Relevant

- What is my **QARA use case(s)**?
- What **process steps** are outputs are defined by regulations and standards?

Controlled

- What healthcare **verification and validation** requirements are required? (e.g. U.S. 21 CFR)
- What other **regulations** apply? (e.g. EU AI Act, EU GDRP, Cyber security,...)

Cost effective

- What **solutions** are available, inclusive of AI?
- What is the **risk benefit/ value** of each?
- What is the **cost** to implement and maintain?

Five key points of consideration when solutioning for AI-enabled QARA activities:

- **Risk classification**: What is the organizational risk for the use case and potential deployment of the AI solution? Is this decision support or autonomous decision making?
- **Human in the loop**: How does the organization maintain a qualified professional review for high-impact outputs (investigations, submissions, labeling)?
- **Validation and monitoring**: How is the solution to be validated and what governance structure should be in place? How does the organization define performance acceptance criteria, bias checks, drift monitoring, and periodic re-validation?
- **Records and traceability**: What type of audit trail is recorded in the solution? To what extent does this preserve prompts, model versions, training data lineage (where possible), and decision rationales?
- **Data protection**: How does the solution segregate PHI/PII and apply global data protection and cyber security requirements?

Change management and risk mitigation

QARA leaders often sit at the interface between the technical and the commercial. Being able to effectively communicate the commercial value of investing in AI-enabled digital QMS/RIM solutions is critical for QARA teams. A modest investment in cost of quality can drive a significant reduction in the cost of non-quality and, through communicating value, measuring success and continuously reinforcing the commercial benefits of investing in QARA, companies can drive a dual focus on patient safety and commercial performance. Leaders that can create partnerships and advocates from all areas of an organization have the greatest chance of securing the necessary investment needed to support their organization with digitized QMS, RIM, and Regulatory Intelligence solutions.

Communicate value effectively to gain organisational champions

Commercial teams and QARA professionals can align on the same outcomes

The following points offer insights into improving QARA leadership's influence with organizational leaders:

- **Stakeholder engagement**: QARA teams that co-designing solutions with other business leaders establish shared vision and risk transparency which may help drive uptake in ownership of the desired solution
- **Communication cadence**: FAQ and response guides tailored for executives, managers and field teams help different audiences see the 'why' for change and the value that the solution will bring to their daily activities
- **Training**: Role-based curricula for different individuals helps them navigate the transition from the 'old' state to the 'new' state whilst providing the opportunity to learn, question and grow individually
- **Controls**: Segregated environments (dev/test/prod), SOP updates, and periodic audits of AI-assisted decisions support the end-to-end governance model and provide critical information needed to monitor, measure and communicate a project's progress

Conclusion

The value of commercially focused, digital, QARA solutions

Patient outcomes | **Product quality** | **Commercial performance**

For organizations to successfully drive commercial performance through the provision of safe and effective global solutions, investment in accelerating the **discipline and digitization of QARA** is a critical differentiator. By aligning quality and regulatory outcomes with commercial objectives and empowering teams with digitized QMS, RIM and Regulatory Intelligence solutions, embedded with AI that augments the human in the loop QARA professional, organizations can compress approval timelines, elevate product quality, reduce cost of non-quality and in parallel improve trust with global regulators, clinicians, and patients. The leaders will be those who **standardize the fundamentals, govern responsibly, and execute relentlessly** recognizing that the delivery of AI enabled QMS/RIM solutions needs to operate in a heavily regulated market and drive the global provision of safe and effective product solutions in commercially beneficial ways. Effective investment in QARA solutions can **drive commercial growth** and **differentiate company performance, brand awareness, and patient outcomes**.

About the author

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Mike King is the Senior Director of Product and Strategy at IQVIA, where he leads global teams across quality assurance and regulatory affairs. With over 20 years of experience in life sciences and enterprise software, Mike drives innovation for IQVIA's SmartSolve® solution including SmartSolve® eQMS, SmartSolve® RIM, and SmartSolve® Fundamentals, helping organizations streamline compliance and accelerate digital transformation. A recognized expert in AI for regulatory and quality functions, he is passionate about improving patient outcomes and empowering professionals to enhance safety and performance across healthcare systems.

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