IQVIA MEDTECH

END-TO-END LIFECYCLE SOLUTIONS

Integrated MedTech Solutions

Expert strategy and evidence across the product lifecycle—built to help innovative devices thrive in market



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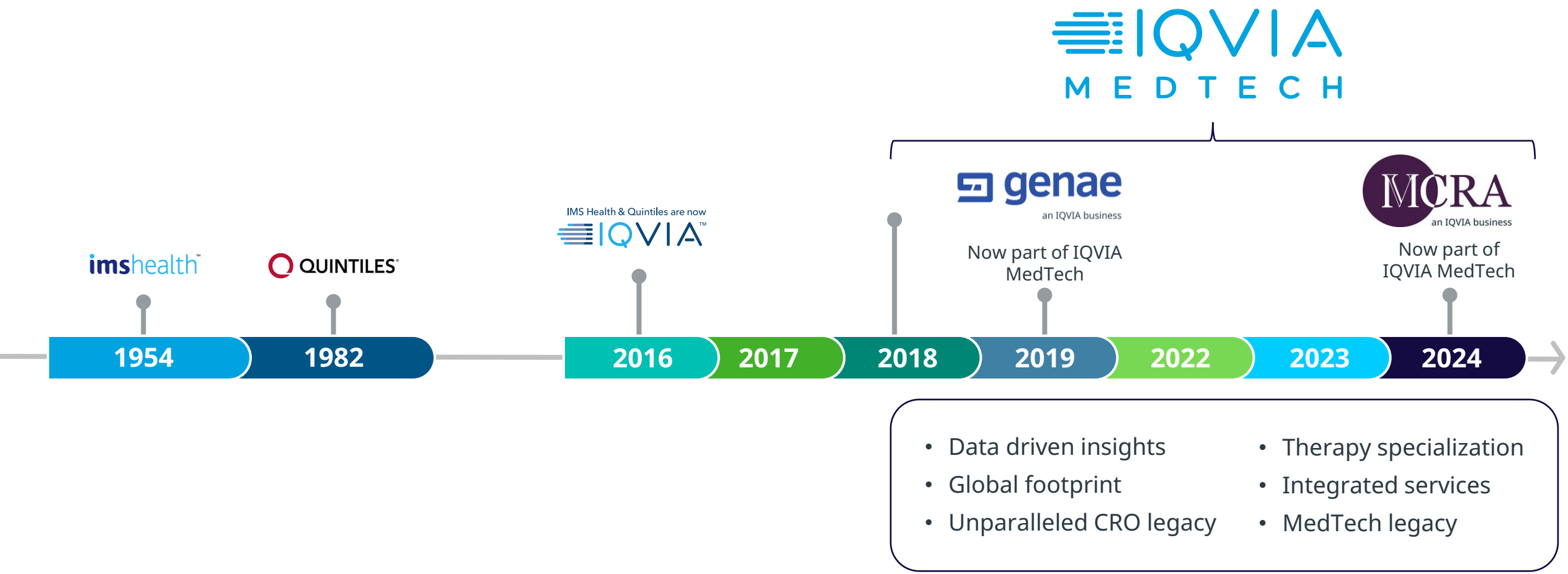
IQVIA MEDTECH

MCRA is now part of IQVIA MedTech.

Together, we deliver integrated solutions across the medical device lifecycle by uniting specialized expertise with proven capabilities.

Our combined team helps clients of every size and footprint move faster and smarter to accelerate regulatory pathways, optimize clinical development, and support evidence-driven market access.

Evolution of a MedTech dedicated organization



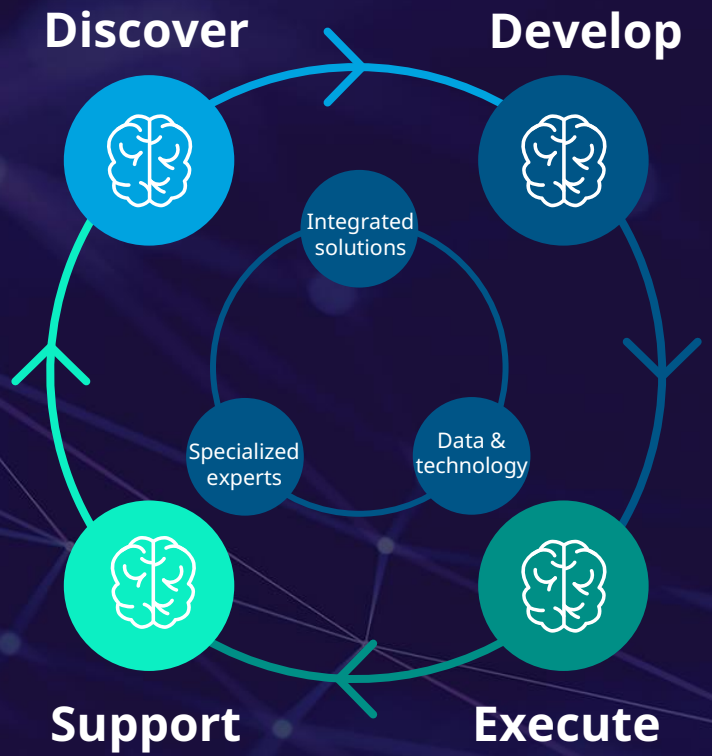
Built to help you thrive in market.

We support you at every step.

The only MedTech partner with therapeutic specialized expertise, advanced data and technology capabilities, and integrated solutions—delivering the focus, strategies, and staying power to help you thrive in market.

Our integrated solutions are tailored to your goals. From early strategy to global expansion, we simplify complexity, remove barriers, and help your innovation reach more patients.

Specialization matters, and our approach is built to deliver exactly what your innovation requires to succeed.



"Progress isn't about checking boxes—it's about knowing which ones matter most. We bring regulatory insight, therapeutic area specialization, and industry know-how to fuel smarter, more confident decisions, together."

Kelley Kennedy
Vice President
IQVIA MedTech



IQVIA MEDTECH

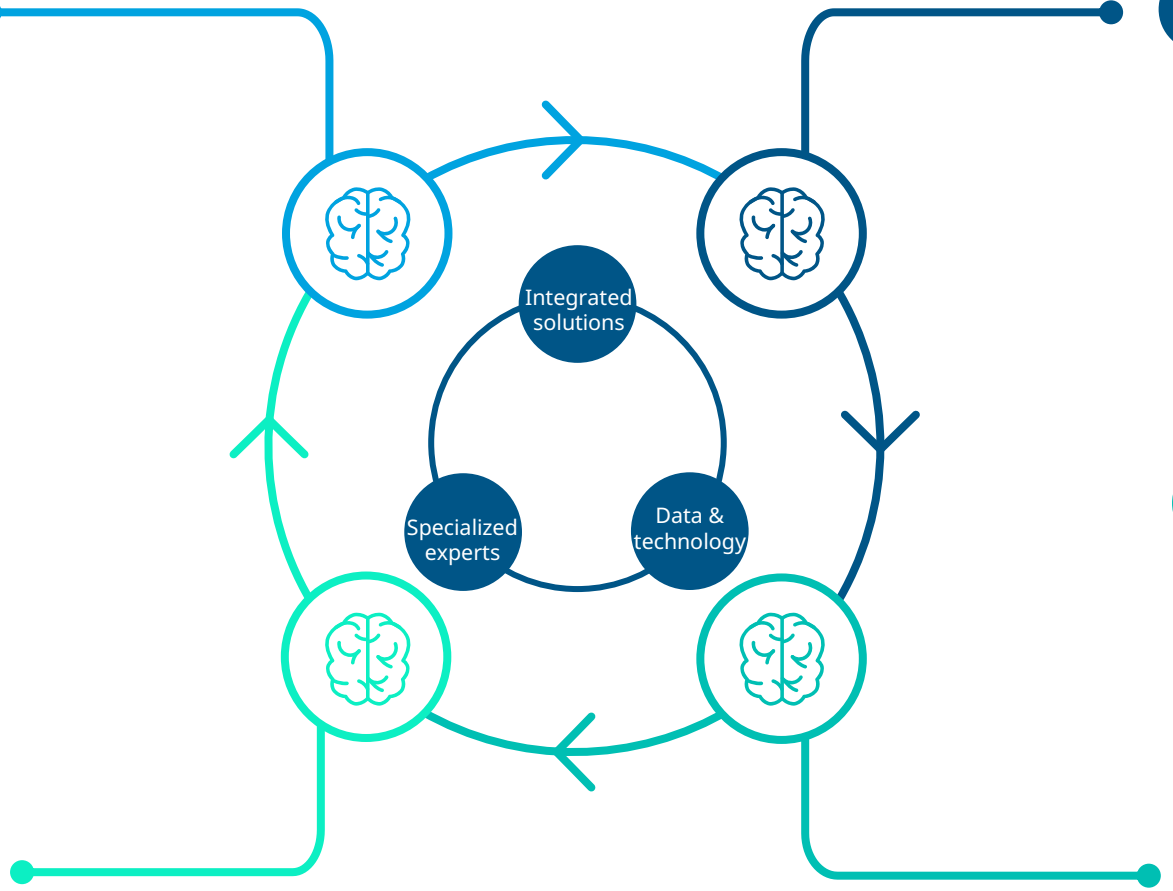
Your challenges are unique. So is our approach.

1. Discover

We start by evaluating your product concept, target markets, and regulatory landscape to build a clear picture of the environment. This step identifies risks and opportunities, defines clinical evidence needs, maps payer expectations, and benchmarks competitor strategies to create a strong foundation for success.

2. Develop

We then develop an integrated regulatory, clinical, and reimbursement plan that aligns with payer and regulatory requirements. This roadmap supports compliance, accelerates timelines, and positions your product for global market access.



3. Execute

Once the strategy is defined, we move into seamless execution. This includes preparing and submitting regulatory filings, managing clinical trial operations, monitoring data integrity, coordinating health economics and outcomes research, and engaging with payers to secure coverage and reimbursement. Throughout this phase, we maintain cross-functional alignment to deliver on time and on target.

4. Support

Finally, we provide continued support as your product enters the market and beyond. This includes navigating post-market surveillance, managing regulatory updates and renewals, monitoring safety and performance, and adapting to evolving market and regulatory needs. Our goal is long-term success and sustained market presence.

IQVIA MEDTECH

Guiding innovation from strategy through commercialization

Integrated solutions to optimize your product journey and support you every step of the way.



Global regulatory

- Market entry roadmap (landscape assessment, submission planning, reimbursement alignment)
- US FDA, EU/UK, APAC Consulting & submissions
- Biocompatibility
- Cybersecurity
- Regulatory technology (QMS, RIM, AI-driven)

Clinical research

- Study planning & design (protocol, feasibility)
- Clinical operations (start-up, site management, patient recruitment)
- Data management & biostatistics
- Real World Evidence
- Safety services (medical monitoring, DSMB)

Quality assurance

- QMS development & optimization
- Audit readiness & inspection support
- Training & technology (SmartSolve eQMS)

Reimbursement

- Coding, coverage & payment strategy
- Payer engagement & patient access programs
- Evidence generation

Commercialization

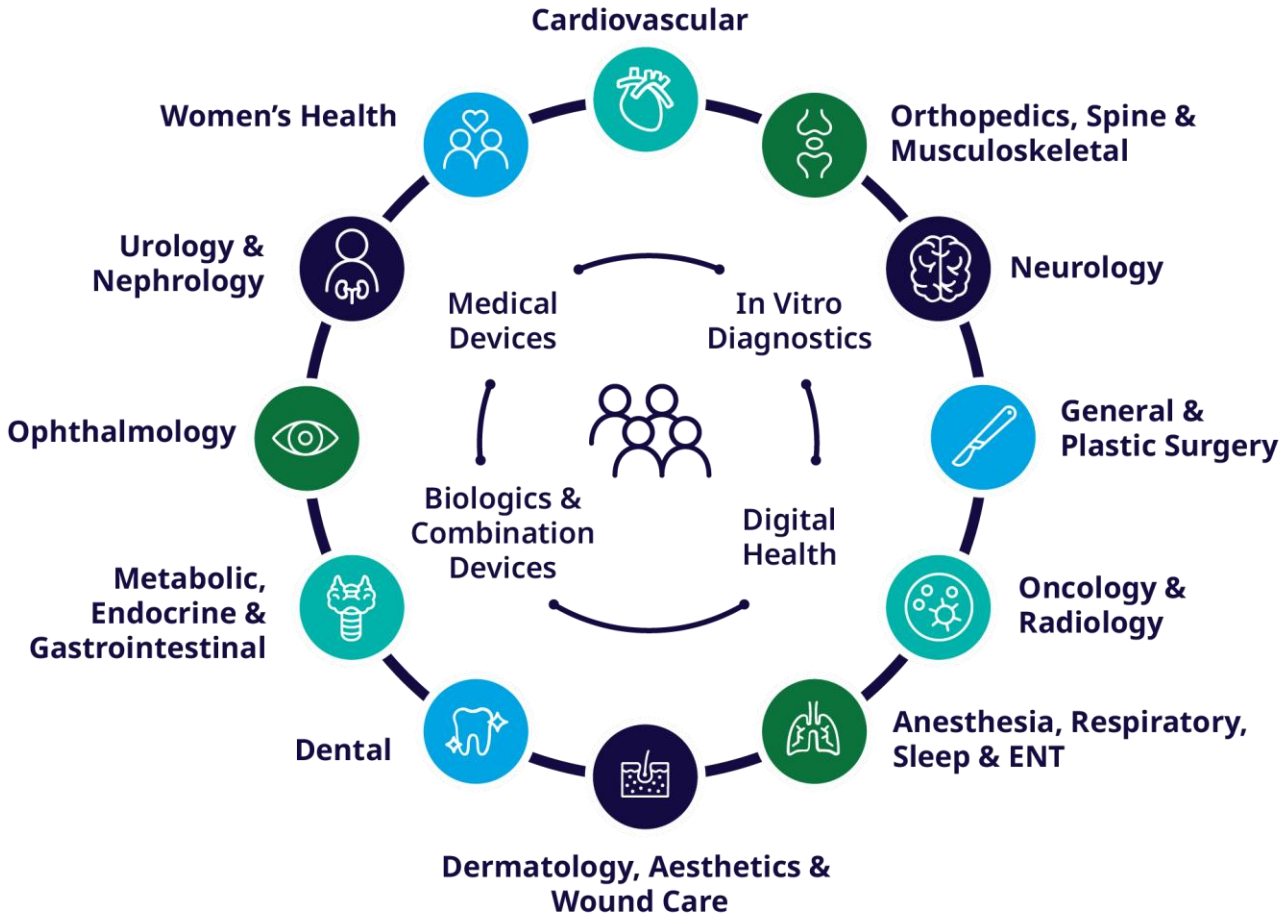
- Brand strategy & launch planning
- Stakeholder engagement
- Data & analytics
- Commercial compliance & field solutions
- Lifecycle management

IQVIA MEDTECH

Stronger alignment delivers stronger impact

Device and therapeutic area specialization

- Specialization across 15+ therapeutic areas
- Integrated evidence strategies and domain experts inform smarter protocols, site selection, patient engagement, and regulatory strategies
- From early pilot studies to global pivotal trials, therapy-aligned clinical and regulatory teams deliver across all phases of development
- Deep understanding of patient populations and disease interconnections helps avoid delays and optimize enrollment



Better data. Bolder strategy.

Data and technology for your medical device innovation

As a MedTech innovator, we know you need more than surface-level insights. You need connected data and technology to move faster, see further, and act with confidence.

From smarter trials to stronger launches, we connect every stage of development and commercialization, giving you the insights to thrive.

Our configurable technology ecosystem integrates with your business to drive efficient, informed decision making.

Connected intelligence platform integrates 800K+ data feeds, 10M+ HCPs, and 725K+ organizations.



Industry-leading platforms and data power faster, efficient decision-making across development and commercialization.

Advanced site selection and recruitment data improve enrollment speed and trial outcomes.

Real-world evidence and AI-driven insights inform regulatory submissions, payer strategies, and commercial growth.

IQVIA MEDTECH

Powered by talent. Proven in market.

40+ years of experience accelerating innovation in MedTech



GLOBAL REGULATORY SOLUTIONS

Global reach, locally informed.

Accelerate global approvals with medical device regulatory consulting tailored to local markets



IQVIA MEDTECH

US Regulatory

We help clients engage with the FDA, build strong dossiers, and navigate feedback to accelerate compliant U.S. market access.

70 Successful PMA's

125+ Breakthrough designations

25 Former FDA & Notified Body Reviewers

1,350+ Regulatory clients

15 Successful De Novos granted

- Regulatory strategy & gap assessment
- FDA consulting and submissions

  - ✓ 510(k)
  - ✓ De Novo
  - ✓ Pre Market Approval (PMA)
  - ✓ Breakthrough
  - ✓ Investigational Device Submission (IDE)

- Biocompatibility

  - ✓ Biological Evaluation Plans
  - ✓ Toxicological Risk and Test Justification
  - ✓ Submission-ready documentation

- Cybersecurity

"Our FDA authorization for ProSense® Cryoablation System was a defining moment for our company and for patients seeking innovative, less invasive breast cancer treatment options. IQVIA MedTech was an exceptional partner throughout this complex regulatory journey. Their expertise, strategic guidance and integrated support were instrumental in helping us reach this milestone. Together, we have demonstrated what is possible when visionary companies and trusted partners unite to advance patient care."

Eyal Shamir
CEO of IceCure Medical



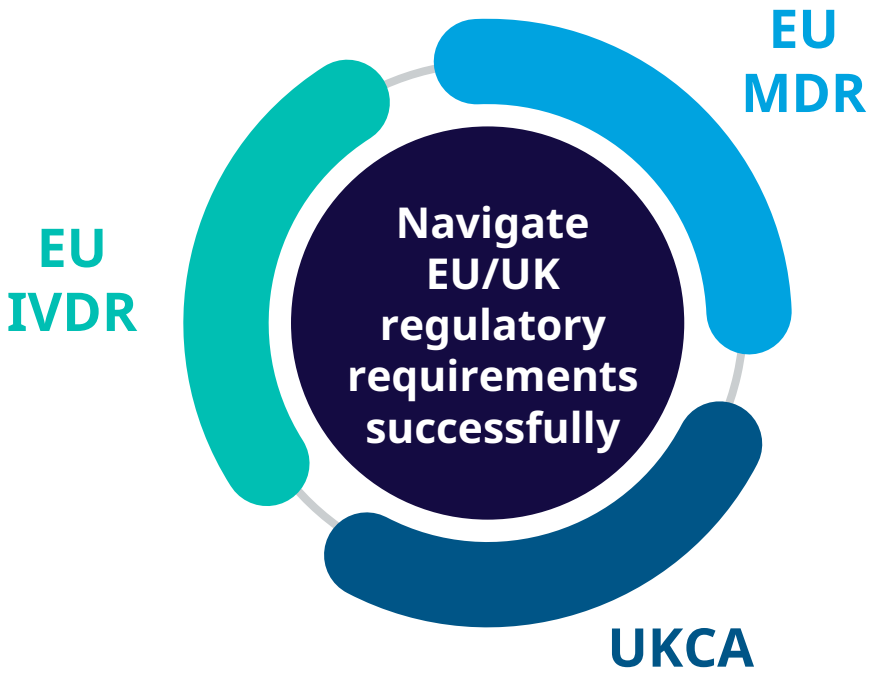
IQVIA MEDTECH

Meet the largest team of former FDA experts in the industry

							
Name	**Glenn Stiegman, MS**	**Natasha Griffin, Ph.D.**	**Rob Kazmierski, Ph.D.**	**James Mullally, Ph.D**	**Tim Marjenin**	**Todd Courtney, M.S.**	**Carolyn Yong, Ph.D**
FDA position	Former FDA Branch Chief Orthopedic Devices	Former FDA Team Lead, Division of Microbiology Device	Former FDA Team Lead and Assistant Director, Hemodynamic and Heart Failure Diagnostics	Former FDA Assistant Director Chemistry Toxicology Devices	Former FDA Branch Chief, Neurostimulation Devices	Former FDA Assistant Director/Branch Chief Anesthesia Devices	Former FDA Chief of Policy & Special Projects, Office of Therapeutic Products (CBER)
Expertise	Orthopedics	IVD	Cardiovascular	IVD	Neurology	Anesthesia	Regenerative Medicine
							
Name	**Kayla Scott, Ph.D.**	**Alex Cadotte, Ph.D**	**John Doucet, Ph.D**	**Dave McGurl**	**Hollace Rhodes**	**Eric Kong, Ph.D.**	**Nima Akhlaghi, Ph.D**
FDA position	Former FDA Team Lead, Division of Peripheral Interventional Devices	Former FDA Team Lead, Mammography, Ultrasound & Imaging Software	Former FDA Policy Lead, Breakthrough Devices & Lead Reviewer, Neurostimulation Devices	Former FDA Senior Lead Reviewer, Orthopedic & Joint Devices	Former FDA Lead Reviewer, Orthopedic & Joint Devices	Former FDA Team Lead, Bacterial Respiratory and Medical Countermeasure (CDRH)	Former FDA Lead Reviewer, Radiological Health
Expertise	Cardiovascular	Radiological Health	Neurology	Orthopedics	Orthopedics	IVD	Radiological Health

								
Name	**Robert Hermann, Ph.D**	**Rob Allen, Ph.D**	**Mehdi Kazemzadeh-Narbat, Ph.D**	**Veronica Downen, M.S.**	**Eric Sussman, Ph.D**	**Ethan Naylor**	**Alvin Cutler Van Orden, M.S.**	**Chava Zibman, Ph.D**
FDA position	Former FDA Team Lead Reviewer, Neurointerventional Devices	Former FDA Lead Reviewer and Biocompatibility Reviewer, Cardiovascular Devices	Former FDA Biomedical Engineer & Scientific Lead Reviewer, Dental & Orthopedic Devices	Former FDA Reviewer, Joints & Fracture Fixation	Former FDA Biomedical Engineer & Regulatory Reviewer	Former FDA Lead Reviewer, Spine Devices	Former FDA Mathematical Statistician	Former FDA Mathematical Statistician
Expertise	Neurointerventional	Biocompatibility	Dental	Orthopedics	Biocompatibility	Spine	Biostatistics	Biostatistics

Europe



Having worked within a Notified Body, I understand the complexity many teams face navigating EU MDR. Now, supporting clients at IQVIA MedTech, the value of what we do is clear—helping teams prioritize, align to expectations early, and ultimately move confidently toward approval.

Hamidreza Alidousti
Director, Regulatory Affairs - Europe

Why it matters

Europe's regulatory landscape has become significantly more stringent under MDR and IVDR. IQVIA MedTech provides specialized expertise to help you navigate increased documentation expectations, reduced NB capacity, and heightened clinical evidence requirements—so you can reach approval and maintain compliance

Empowered by expert guidance

- Former Notified Body reviewers embedded within IQVIA MedTech
- Expertise across high-risk and novel device categories
- Strategic interpretation of NB feedback to accelerate readiness

Achieve your goals faster with integrated services

- Strategic regulatory planning aligned to commercial timelines
- End-to-end gap analysis to identify and remediate risk areas
- Technical documentation development and remediation support
- Notified body engagement and submission preparation

IQVIA MEDTECH

APAC & Japan Region

Thriving across APAC markets

10+ years supporting manufacturers entering and scaling in Asia-Pacific regions

Local, bilingual teams across key APAC hubs

Cultural and language fluency for clearer communication, faster execution

Tailored strategies for each country

Customized regulatory pathways & submission support across Japan, China, Korea, Singapore, Australia, and more

Japan: our flagship market

- Best-in-industry Shonin approval track record
- 60+ Shonin approvals and 50+ lifetime DMAH programs
- Full regulatory pathway guidance: PMDA consultations, strategy, dossier development, post-market control
- DMAH services for companies without a Japan entity (representation, quality, GVP/GMP compliance)

Why it matters

Japan is the world's #3 medical device market, forecast to grow by $15.56B between 2024–2028. IQVIA MedTech removes regulatory, operational, and cultural barriers so global innovators can enter Japan and APAC efficiently and confidently.

Entering the Japanese market comes with many challenges, including regulatory complexities, market entry barriers and cultural nuances. With a bilingual staff and a culturally informed perspective, we combine extensive knowledge of the APAC regulatory process with the power of IQVIA MedTech's global reach.

- Hitoshi Torii, Director APAC

CLINICAL RESEARCH SOLUTIONS

Evidence generation aligned to the MedTech lifecycle

Clinical development solutions to help you generate the evidence MedTech regulators and markets require



IQVIA MEDTECH

Complete clinical pathway support for MedTech

From full service to functional service provider

Study phases and designs



Healthy volunteer / human factors

Confirm baseline safety and usability of your device



Feasibility / pilot trials

Early first-in-human pre-market pilot trials



Pivotal trials

Pre-market trials to obtain regulatory approval



Controlled post-market trials

Regulated studies as conditions of device or diagnostic approval



Real world evidence / observational registries

Data collection as part of the regular standard of care to proactively collect long-term clinical evidence

Research & Development Services

- Study Planning & Design (Protocol, Feasibility)
- Clinical Operations (Start-up, Site Management, Patient Recruitment)
- Data Management & Biostatistics
- Real World Evidence
- Safety Services (Medical Monitoring, DSMB)

IQVIA MEDTECH

Evidence-driven clinical delivery across the device lifecycle



585+
Medtech studies supported

We are pleased to have a long-standing partnership with IQVIA MedTech to guide our strategy as we scale and expand our product into new indications and new markets.

- CEO, Emerging MedTech Company

9,800+
Sites activated

IQVIA MedTech worked with our site across initiation, enrollment, and closeout, providing responsive support and exceptional FDA inspection preparation.

- Ariel Aponte, ACRP-PM, CCRC, Sr. Clinical Research Coordinator, Department of Orthopedic Surgery, NYU Grossman School of Medicine

745k+
Patients enrolled

Enrollment is often a pain point, but IQVIA MedTech helped us identify risks early, keep sites motivated, and maintain a steady pipeline of eligible patients. They turned a potential bottleneck into one of our biggest strengths.

- VP, R&D, MedTech Company

IQVIA MEDTECH

REIMBURSEMENT SOLUTIONS

Because approval alone isn’t enough

Planning for coverage, coding, and payment early supports a clearer path from approval to adoption.



IQVIA MEDTECH

Reimbursement strategy built in from the start

Reimbursement & market access strategy

Reimbursement decisions shape whether approved devices reach patients. IQVIA MedTech helps innovators plan for coverage early by aligning reimbursement strategy with regulatory and clinical insight—reducing downstream risk and supporting sustainable market access.

Why it matters

When regulatory, clinical, and reimbursement teams work together from the beginning, you can anticipate challenges, reduce rework, and move forward with greater confidence.

Our support includes:

- Market opportunity and reimbursement landscape assessments
- Coding, coverage, and payment pathway evaluations
- Early identification of reimbursement risk and mitigation strategies
- Life sciences expert advisory panels to validate assumptions and pressure-test strategy

Turning reimbursement planning into access and adoption

Reimbursement strategy activation

Once the reimbursement strategy is defined, IQVIA MedTech supports execution across the activities that turn planning into market access. Our teams help operationalize reimbursement pathways, engage stakeholders, and move strategies forward with clarity and momentum.

Integrated advantage

Because reimbursement strategy is connected to regulatory, clinical, and commercial realities, our teams stay aligned across functions—enabling efficient implementation while keeping strategies grounded in market conditions that support approval and adoption.

Activation support includes:

- Payer engagement to gather feedback and align evidence with expectations
- Coding and payment application support with submission-ready documentation
- Health economics and outcomes research (HEOR)
- Real-world evidence to demonstrate performance in clinical practice
- Patient access programs that generate insights while facilitating early access where appropriate



Powering MedTech breakthroughs, together

LEARN MORE AT IQVIAMEDTECH.COM