AKRA TEAM

Consultancy Services for Regulatory, Quality and Clinical Affairs

We are a highly specialized consultancy supporting various stakeholders in bringing medical device, in-vitro diagnostic and combination device products to market in a timely manner and in line with complex legal obligations.

Consulting | Writing | Auditing | Training

AKRA TEAM

PROFESSIONAL | PREDICTABLE | PATIENT-ORIENTED

CONSULTING

Professional and Strategic

Our leading team of experts at AKRA TEAM offers support with all major global jurisdictions including EU, US, UK, Switzerland and other global markets. AKRA TEAM is a full-service consultancy providing a wide range of services including:

- **Clinical Strategy**
- **Regulatory Strategy**
- **Post-Market Strategy**
- **Market Authorisation**
- **Remediation Support**
- **Compliance Support**
- **Ad-hoc Consultancy Support**

MONTHLY FEES – FULL YEAR BENEFITS

SUBSCRIPTION-BASED CONSULTING: YOUR MEDICAL DEVICE SOLUTIONS ON-DEMAND

Access Expert Guidance When You Need It Most

In the fast-paced world of medical device and diagnostic manufacturing, challenges don't arrive on a schedule. Our innovative subscription model gives you dedicated consulting hours at your fingertips – ready when you need them, without the stress of unexpected costs.

"Pay monthly, benefit annually" – predictable expenses with maximum flexibility.

CHOOSE YOUR PERFECT FIT:

Essential	Advanced	Premium
Perfect for emerging companies or specific project needs:	Our most popular option for growing manufacturers:	Comprehensive support for established operations:
Benefits: • Dedicated consulting hours to use at your own pace • Full access to our expertise when you need it • Predictable monthly investment	**Benefits:** • Increased yearly hour allocation • Priority scheduling with our consultants • Quarterly strategy check-ins	**Benefits:** • Maximum flexibility with our highest hour allocation • Guaranteed 48-hour response time • Dedicated senior consultant • Annual strategic planning session • Quarterly strategy check-ins

Incentives:
• Access to monthly
  • Compliance Café live online sessions
  • Regulatory Check-in recorded sessions
• Access to VOD training library
• Discounted subscription renewal fee
	Incentives:
	Same as in the Essential package, plus:
	• Discounted access to our Trainings & Events
		Incentives:
		Same as in the Essential package, plus:
		• Complimentary access to 3 Trainings per year, to select from our Training Portfolio or Accelerator Programs
		• Discounted access to
		  • TOM's Mentorship
		  • Tailored Training Solutions

Hours per year: 60h	**Hours per year:** 120h	**Hours per year:** 240h

The number of hours can be customised to address specific needs and expectations.

WHY SUBSCRIBE?

- **Budget Certainty:** Transform variable consulting costs into predictable monthly expenses
- **Immediate Access:** No lengthy procurement processes when urgent needs arise
- **Relationship Continuity:** Work with consultants who understand your products and processes
- **Flexible Application:** Apply your hours to any service in our portfolio as needs change
- **Simplified Administration:** One agreement, one invoice, unlimited possibilities

HOW IT WORKS

1. Select the subscription tier that fits your anticipated needs
2. Your dedicated hours become available immediately
3. Request support whenever challenges arise
4. Adjust your subscription level as your requirements evolve

Ready to bring predictability to your medical device consulting needs? Contact us today for a personalized consultation and discover how our subscription model can transform your approach to expert support. Learn more about our dedicated services: **www.akrateam.com/service**

TRAINING

Tailor made and interactive

At AKRA TEAM, we design custom training programs that address your medical device and diagnostic company's specific knowledge needs across the entire product lifecycle.

Our specialized programs cover regulatory compliance, clinical affairs, quality systems, technical documentation, post-market surveillance, risk management, and more – precisely tailored to your team's requirements.

More Than Training – A Partnership for Success

When you entrust your team's development to us, you're not just booking a training session – you're gaining a committed partner invested in your success. We take time to understand your specific challenges, knowledge gaps, and strategic objectives before crafting learning experiences that deliver measurable impact.

CUSTOM-BUILT FOR YOU

Each program addresses your specific challenges and objectives

INDUSTRY EXPERT INSTRUCTORS

Learn from seasoned medtech professionals

INTERACTIVE & PRACTICAL

Application-focused learning that transforms knowledge into actionable skills

FLEXIBLE DELIVERY OPTIONS

In-person, virtual, or hybrid formats

We don't just deliver information – we ensure your people gain the knowledge and skills to excel in today's complex medtech landscape.

Ready to elevate your team's capabilities? Contact us to discuss your training needs.

Scan here or follow the link to learn more about our upcoming Trainings and Webinars

www.akrateam.com/training/

THE TOM MENTORSHIP

TRAINING | ONBOARDING | MAINTAINING

Meet TOM – Your Partner in Medical Device & Diagnostic Excellence

Starting in regulatory, quality, or clinical roles can be overwhelming. Complex regulations, specialized terminology, and high-stakes responsibilities await. That's why we created TOM – not just another corporate initiative, but a trusted companion who walks beside your junior staff from day one.

WHY TOM MATTERS

Junior professionals in medical devices and diagnostics face unique challenges:

- Navigating complex regulatory frameworks
- Understanding quality systems that ensure patient safety
- Building confidence in high-stakes decision-making

TOM transforms overwhelmed newcomers into confident contributors through personalized support exactly when they need it.

HOW TOM HELPS

TRAINING

Targeted knowledge transfer tailored to your specific products and regulatory environment.

ONBOARDING

Accelerated integration into your team with guided immersion in critical systems and processes.

MAINTAINING

Ongoing mentorship and development that continues long after the initial training period.

THE BENEFITS

FOR COMPANIES

- Reduces time-to-productivity
- Decreases early turnover of promising talent
- Ensures regulatory compliance through consistent knowledge transfer

FOR JUNIOR STAFF

- Never navigate complex regulations alone
- Build confidence through structured support
- Develop specialized skills that accelerate career growth

INVEST IN TOMORROW'S LEADERS TODAY

TOM isn't just a mentorship initiative – it's your insurance policy for regulatory excellence and talent retention. Contact us today to bring TOM to your organization.

WRITING

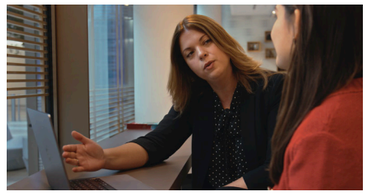
Predictable and Compliant

AKRA TEAM offers the development and writing of clinical, regulatory and quality documentation for EU and/or US strategy:

- Clinical (Performance) Evaluation Documentation, including execution of the literature searches in key databases.
- Drafting and regular update of various reports including but not limited to CEP, PEP, CER, PER, PSUR, SS(C)P, etc.
- Analysis of all relevant data and development of compliant PMS Plan including PMC(P)F Plan.
- Writing of the Technical Documentation and support in the planning of pre-clinical testing.
- FDA: Drafting of 510(k)s, PMAs, Q-Sub, 513(g) requests, including relevant documentation.
- Study Protocol and Report for pre- or post-market Clinical Investigation (Performance Study).

AUDITING

Internal and Supplier Audits



AKRA TEAM offers a variety of audit and assessment services to ensure readiness of clinical, quality and regulatory documentation, including but not limited to:

- Internal Audits of the QMS against various standards and regulations (e.g., ISO 13485, MDR, IVDR, ISO 14155, MDSAP, etc.)
- External Audits of critical suppliers and processes
- Readiness Checks against new requirements such as MDR and/or IVDR provisions to prepare for audits and inspections
- Technical Documentation and Clinical Evaluation Assessment

From our specialized team covering all regulatory, clinical and quality topics, to our track record of success, we will be happy to support customer requests.

WHY AKRA TEAM

SPECIALISED EXPERTISE

Special matter experts in Regulatory, Clinical and Quality who worked for manufactuers and notified bodies with cumulated experience of +250 years.

INVOLVEMENT IN REGULATIONS IMPLEMENTATION

Contribution in implementation of medical device regulation in Europe, drafting European guidance documents and International Standards.

MEMBERSHIPS IN BOARDS

Various memberships in advisory boards and planning committees.

Our diverse and deep experience, expertise and activities seize our influence, involvement and contribution to current legislation and hence exceptional knowledge about current requirements and upcoming changes.

Our activities in supporting various stakeholders to achieve their targets in the healthcare industry ensure continuity of the healthcare system in the interest of patient populations.

150+
CUSTOMERS WOLRDWIDE

250+
YEARS OF EXPERIENCE

1,000+
COMPLETED PROJECTS

3,000+
LINKEDIN FOLLOWER

Your Experts for Regulatory, Quality and Clinical Affairs

We offer a wide range of service to support various stakeholders on their pathway towards compliance.

AKRA TEAM is a consultancy on a mission to make a difference for stakeholders in the highly regulated medical device, IVD and combination device spaces. With 250+ years of combined and proven expertise in regulatory, clinical, quality and more, the Team supports manufacturers, notified bodies and regulators with timely management and successful execution of complex projects, all while providing high level training programs.

Dr. Bassil Akra, CEO

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EU MDR & IVDR Insider!

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