GBA GROUP
MedTech Solutions

GBA Group MedTech Solutions With you from Concept to Care!

Turning ideas into real-world medical solutions requires more than design — it demands strategic engineering, regulatory insight, and an integrated path to market.

At GBA MedTech Solutions, we turn complexity into clarity — with end-to-end support across development, testing, regulatory strategy, and training.

As a pan-European network of experts, we help our clients navigate global requirements and launch safe, compliant and effective medical devices.

From first concept to market readiness and beyond, we are your trusted partner — combining scientific depth, regulatory intelligence and operational excellence.

Concepts & Education - From Vision to Strategy

Success in MedTech demands more than technical innovation — it requires regulatory understanding, strategic market planning, and continuous organisational learning.

We support you with tailored concepts and modular training programs that build internal expertise and align your product strategy with global compliance and business goals.

What it takes to start strong

Regulatory & Strategic Planning
- Alignment of device classification, regulatory pathways and target markets
- Definition of product roadmap, market strategy and lifecycle planning
- Risk based planning integrated with development and compliance goals
- Support in developing funding concepts and identifying financial support schemes (e.g. public grants, early-phase investment alignment)

Training & Education
- Comprehensive programs from regulatory fundamentals to advanced topics (CE marking, PMS, funding strategies)
- Modular, multilingual formats: on site, virtual, hybrid
- Coaching and competency development for teams and leadership
- Long term enablement, workshops and project specific training

Cross-Functional Enablement
- Support for Quality Management (incl. ISO 13485 & Lean QMS
- Integration of regulatory insights into business planning and technical documentation
- Tailored concepts that match your internal processes and project needs

Why this matters
- A structured approach reduces risk, cost and time
- Your teams are empowered to act with clarity and confidence
- Strategic insight built into your product lifecycle from day one

Design & Development

Great product ideas need more than theory — they need expert execution.

We design and develop medical devices that are not only functional, but ready for the realities of clinical use, manufacturability, and global compliance. As an ISO 13485 certified and FDA registered developer, we deliver market-ready engineering solutions through an integrated approach — combining deep technical expertise with regulatory insight and hands-on collaboration.

What it takes to make innovation real

Integrated Product Development
- Mechanical, electronic, software & usability engineering
- Full development services from concept to market launch
- Human factors integration and risk mitigation throughout

Compliance-Ready Documentation & QA
- Design history file (DHF), technical documentation
- Aligned with MDR/IVDR, FDA 21 CFR Part 820
- Established Notified Body interaction processes

Industrialisation & Transfer to Manufacturing
- Design for manufacturability and scale-up
- Supplier qualification and production support
- Interface with testing and validation labs to ensure product robustness

Why this matters
- Shortens time from prototype to product
- Ensures alignment between design, compliance, and market needs
- Builds the foundation for global launch and long-term viability

Verification & Validation

Smart testing goes beyond data

We combine accredited laboratory services with deep regulatory and scientific insight to support you throughout the medical device lifecycle. From cleanliness, reprocessing and packaging validation to biocompatibility testing, we help you generate evidence that meets global expectations.

Our unique edge: We offer more than testing – strategic consulting for ISO 10993 compliance across the entire product lifecycle. With experts in toxicology and regulatory affairs, we guide your Biological Evaluation Plan (BEP) and deliver customized Biological Evaluation Reports (BER) that strengthen your submission dossier.

What it takes to qualify your device

Verification & Validation Services
- Product cleanliness and residue analysis, incl. bioburden, endotoxin, cytotoxicity, chemical and particulate testing (ISO 19227, DIN/TS 5343)
- Sterilization validation (ISO 14937), packaging testing (ISO 11607)
- Re-use and re-processing validation (ISO 17664-1/2, AAMI TIR12, ANSI AAMI ST98)
- Accelerated ageing, shelf-life and stability studies
- Comparative testing and sampling strategies for evaluating product or process changes

Testing & Analytical Expertise
- Biological testing acc. ISO 10993 series: cytotoxicity, sensitization, irritation, systemic toxicity, genotoxicity and hemocompatibility
- Electrochemical corrosion testing (ISO 10993-15)
- Chemical characterization (ISO 10993-18) and Toxicological Risk Assessment (TRA, ISO 10993-17)
- Testing under ISO 17025 accreditation and GLP certification

Why this matters
- Strengthens your technical documentation
- Combines lab data with regulatory relevance
- Builds trust with Notified Bodies and global regulators

Device Approval - From Submission to Certification

Clear, compliant documentation for CE marking, FDA clearance and global approvals.

Turning complex data into compliant submissions: we help you align technical, clinical, and design files with global expectations — including MDR, FDA, and other major regulatory systems. With risk-based planning and integrated expertise, we make your product approval process clear and controlled.

What it takes to get approved

- Technical documentation and regulatory strategy for CE, FDA and global approvals
- Clinical evaluation reports (CER), clinical development plans and justifications
- Audit and inspection readiness (gap analysis, QMS alignment)
- Cross-functional collaboration with quality, design, and testing teams

Why this matters

- Ensures submission success through regulatory precision
- Supports faster, more confident approvals
- Bridges compliance and innovation from the inside out

Post-Market Surveillance - Compliance That Never Stops

Maintain regulatory confidence and patient safety after launch.

We help you keep your products safe and compliant after market entry. With proactive monitoring, smart digital tools, and scientific insight, we support your PMS and vigilance efforts - aligned with international standards and tailored to your needs.

What it takes - and how we support it

- PMS planning and reporting aligned to major global regulations
- Vigilance: complaints, signal detection, literature reviews
- Updates: risk files, clinical evidence, PSURs
- Regulatory intelligence and digital monitoring tools
- Testing support for product or process changes

Why this matters

- Protects patients and brand reputation
- Meets evolving global requirements
- Strengthens readiness for audits and inspections

GBA GROUP
MedTech Solutions

Let's bring your innovation to market. Together.

We believe that innovation thrives on collaboration. Whether you're looking for a development partner, strategic guidance or accredited testing – our multidisciplinary teams are here to help.

Reach out today and let's explore how we can support your success.

Denmark Copenhagen · **Germany** Gilching, Rossdorf · **Italy** Bologna, Imola, Lainate, Pavia, San Martino Siccomario, Tortona · **Sweden** Gothenburg, Lund, Stockholm · **Netherlands** Hengelo · **Switzerland** Viganello, Winterthur

"Our mission is to be your trusted partner across the entire medical device lifecycle, turning complexity into clarity through personalized guidance, expertise and seamless performance by ensuring safe products for the global market."

gba-group-medtech.com

medtech-solutions@gba-group.com

GBA Group – MedTech Solutions