

# Layer 6

## Essential Principles

Layer 6 Essential Principles is your trusted partner in Medical Device Consulting, specializing in the six essential principles of market access. Our team of experienced industry professionals works closely with each client, providing comprehensive support throughout the entire product lifecycle.



### Quality Assurance

In the highly regulated medical device industry, having a **suitable, effective, and compliant Quality Management System (QMS)** is not just a regulatory requirement—it's essential for sustainable growth and market success. Layer 6 - Essential Principles focuses on creating robust quality management systems that cover every aspect of your product lifecycle, from design to production. Ensuring compliance with FDA, ISO 13485, EU MDR, and other global regulatory standards can be complex, but our expertise in **Quality Assurance (QA) consulting services** can help you navigate these challenges with confidence.

We provide tailored solutions to establish, optimize, and maintain an effective QMS that aligns with your company's size, product portfolio, and market goals. Our services include:

- **QMS Development & Implementation** – Design standard processes built for efficiency and compliance.
- **Regulatory Compliance & Audits** – Ensuring readiness for FDA, ISO 13485, MDR, and other global regulations.
- **Process Validation & Risk Management** – Establishing robust systems to ensure product quality and patient safety.
- **CAPA & Nonconformance Management** – Proactive and corrective actions to drive continuous improvement.
- **Change Control Management** – Implementing structured processes to assess, document, and control changes to products, processes, and documentation while maintaining compliance.
- **Supplier & Manufacturing Quality** – Strengthening quality control across the supply chain.
- **Post-Market Surveillance & Complaint Handling** – Implementing systems for adverse event monitoring, reporting, and trend analysis to maintain compliance and product safety.



With our expertise, you can focus on **innovation and product development** while we help you build a **quality-driven culture** that ensures compliance, enhances efficiency, and accelerates market access.

Let's work together to position your medical device company for long-term success with a strong and compliant Quality Management System.



At Layer 6 - Essential Principles, we offer responsive and innovative consulting services focused on achieving client goals. If you have any questions or need further information, please don't hesitate to contact us. Our team is here to assist you every step of the way.