Your Trusted Partner

for Medical Device Quality and Regulatory Compliance

MANSOURCONSULTING

At Mansour Consulting LLC, we offer a comprehensive suite of services tailored to meet all your medical device quality and regulatory compliance needs. Whether you are a small startup or a Fortune 500 company, we provide personalized, high-quality solutions that span across the U.S., Europe, and other international markets.

Our Services Include:

Regulatory Strategy Development

Remediation Activities – Addressing FDA warning letters, conducting FDA mock audits

FDA Product Submissions – Supporting MDR technical files, design controls, and validations

Quality System Development – ISO 13485 certification, MDR certification, audit services

Software Solutions – Implementing document management and training systems

U.S. Market

Specialized Services

FDA Representation (Official Correspondent, U.S. Agent)
We handle your establishment registration and device listing, managing all FDA inquiries on your behalf.

GUDID Representation (Coordinator, Labeler Data Entry)
Our team assists in registering your company with GS1 or HIBCC, establishing your FDA GUDID account, validating and submitting UDI data, and providing label review and recommendations. This service is essential for all labelers, whether manufacturers or not.

Submissions (eSTAR Submissions)
We support the submission process for device classes I, II, and III, including PMA, De Novo, 510(k), 513(g), and Q submissions. Our services cover everything from design review and testing requirements to protocol/report review, labeling, documentation, and negotiating the submission with the FDA.

Regulatory Assistance

Our expertise covers the full spectrum of regulatory compliance, including:

- **Labeling** (21 CFR 801)
- **Medical Device Reporting** (21 CFR 803)
- **Corrections and Removals** (21 CFR 806)
- **Registration and Listing** (21 CFR 807)
- **Recall Procedures** (21 CFR 810)
- **Quality System Regulations** (QSR/QMSR) (21 CFR 820)
- **Postmarket Surveillance** (21 CFR 822)
- **Unique Device Identification** (UDI) (21 CFR 830)
- **Device Classification** (21 CFR 860)

At Mansour Consulting LLC, we are committed to helping you navigate the complex landscape of medical device regulations and quality systems with precision and confidence. Reach out to us for tailored solutions that ensure compliance and facilitate your success in the global market.

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