INTEGRATED ASSURANCE AND PERFORMANCE

# Regulatory confidence. Supplier resilience. Measurable business value.

Firsthand audit perspective combined with supplier-quality and procurement-engineering experience for medical-device organizations operating across global markets.

**ISO 13485 | FDA QMSR | MDSAP | HEALTH CANADA | EU MDR | ISO 9001**

QUALITY & REGULATORY ASSURANCE

## Evidence that stands up to scrutiny

### 01 INDEPENDENT INTERNAL AUDITS

See the gaps before an external auditor does.

- **QMSR, ISO 13485 and MDSAP**
- **Readiness and closure verification**

### 02 SUPPLIER AUDITS

Turn supplier uncertainty into objective evidence.

- **Qualification and surveillance**
- **SCAR and quality-agreement review**

### 03 EU MDR REMEDIATION

Build responses supported by defensible evidence.

- **Notified Body finding response**
- **PMS, PMCF, vigilance and labeling**

### 04 NORTH AMERICAN MARKET READINESS

Prepare for U.S. and Canadian requirements.

- **FDA QMSR and inspection readiness**
- **MDSAP, licensing and postmarket**

SUPPLIER & COMMERCIAL PERFORMANCE

## Performance without hidden risk

### 05 PRODUCT & SUPPLIER QUALIFICATION

Confirm capability before committing resources.

- **Technical and quality due diligence**
- **Process and validation readiness**

### 06 DUAL SOURCING & SUPPLY CONTINUITY

Reduce dependency without compromising quality.

- **Alternate-source identification**
- **Equivalence, change and validation**

### 07 SHOULD-COST & SPEND OPTIMIZATION

Find savings grounded in engineering evidence.

- **Should-cost and actual-spend analysis**
- **Negotiation and savings validation**

### 08 TRAINING & AUDITOR DEVELOPMENT

Develop judgment, not checkbox completion.

- **Auditors, CAPA and process owners**
- **Role-based competence verification**

A CONTROLLED ENGAGEMENT

# From exposure to defensible action.

Every engagement begins with the decision you need to make. Scope, evidence, independence boundaries and expected outputs are agreed before work begins.

01

### SCOPE

Define criteria, products, sites, suppliers and deadlines.

02

### ASSESS

Review records, interview owners and sample implementation.

03

### PRIORITIZE

Rank exposure by regulatory, patient and operational risk.

04

### REMEDIATE

Assign actions, owners, sequencing and closure evidence.

05

### VERIFY

Test evidence and effectiveness against agreed criteria.

WHY GRZ GLOBAL

### CURRENT PERSPECTIVE

Active notified-body audit work and daily interpretation of medical-device requirements.

### RISK-RANKED CLARITY

Priorities, ownership and evidence instead of undifferentiated checklists.

### OPERATIONAL JUDGMENT

Regulatory expectations connected to supplier capability, continuity and cost.

SENIOR-LEVEL INVOLVEMENT

## Experience across regulatory, quality and supply networks.

GRZ Global engagements are led by Ziaur 'Z' Rahman, an authorized Lead Auditor for MDR, MDD, MDSAP, ISO 13485 and ISO 9001, with more than 14 years of medical-device experience.

**200+**
NOTIFIED BODY AUDITS

**50+**
GLOBAL SUPPLIERS QUALIFIED

**200+**
SUPPLIER PORTFOLIO MANAGED

**2014**
GRZ GLOBAL ESTABLISHED

## Start with a 20-minute conversation.

One service. One site. One supplier. One finding set. One decision.

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Services are subject to competence, independence and conflict review. Outcomes such as certification, clearance or cost savings are not guaranteed.