Focus Compliance & Validation Services

Risk Assessment/Risk Management Services

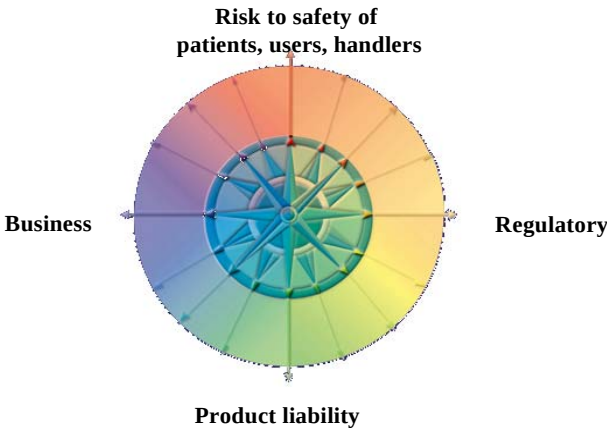
www.FocusCVS.com

AN INNOVATIVE AND NO-NONSENCE SOLUTIONS PROVIDER

The FDA's 21st Century Initiative is intended to integrate quality systems and a risk management approach into existing systems. The goal is to encourage the use of modern and innovative manufacturing technologies *(risk-based approaches)*.

Focus Compliance and Validation Services, delivers services and tools helping clients understand how to implement a Risk Assessment/ Risk Management Program within their company. Focus CVS can provide training to your staff on the benefits of risk-based approaches, help develop quality policies on risk assessment for your company, and then revise any necessary existing guidance documents and SOPs.

Quality Systems, Risk Management, and Risk Assessment are the waves of the future. Dedicate your resources to the areas where they are truly needed and reduce your overall efforts and costs. *Let Focus CVS assist your company with meeting the FDA's 21st Century Risk-Based Initiatives.*



FOCUS CVS AREAS OF SERVICES INCLUDE…

- ✓ **Compliance with the FDA's Design Control Requirements for Risk Analysis**
- ✓ **Risk Management and the Product Life Cycle**
- ✓ **Compliance with the FDA's requirement for Hazard Analysis for Submissions**
- ✓ **Compliance with FDA and ISO 13485:2003 requirements.**
- ✓ **ISO 14971 and meeting FDA & ISO/EN requirements**
- ✓ **Methods of documentation for Risk Analysis & FMEA**
- ✓ **Top-down Fault Tree Analysis (FTA)**
- ✓ **Bottom-up Failure Modes and Effects Analysis (FMEA)**
- ✓ **Risk Analysis as part of Software Verification and Validation**
- ✓ **Identification of Potential Hazards and Sources of Harm**
- ✓ **Estimation of Probability of Risk and Degree of Severity**
- ✓ **Generating Critical Components and Critical Process Lists**

APPLICABLE INDUSTRIES…

Pharmaceutical

Biological

Medical Device

REGULATORY STRATEGIES BASED ON...

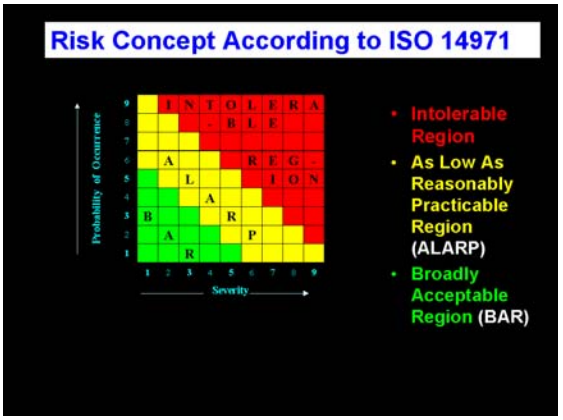
- **U.S. FDA Regulations for Risk Assessment—GMP-QSR Guidance Documents**
- **ISO 14971**
- **IEC 601-1-4, IEC 15026, EN 1441**
- **Global Harmonization Task Force Guidance—ICH**
- **Compliance Program Guidance Manual (CPGM) 7346.832**

AN EFFECTIVE RISK ASSESSMENT/RISK MANAGEMENT PROGRAM WILL...

- Prepare your company for an FDA Design Control Inspection or ISO 13485:2003 Audit
- Provide Conformance to FDA and International Requirements
- Assist implementation for 510(k), IDE, PMA, CE Mark, and European Directives
- Provide Faster Approvals and Compliance with U.S and International Agencies
- Reduce Product Liability and Recall Risks
- Reduce Re-design and Quality Costs
- Increase Competitiveness with Safer Products and Faster Approvals
- Provide Earlier Management Awareness of Potential Design Issues

BENEFITS OF A RA/RM PROGRAM INCLUDE...

- Being prepared for an FDA Design Control Inspection or ISO 13485:2003 Audit
- Conformance to FDA and International requirements for Risk Management
- Implementation requirements for 510(k), IDE, PMA, CE Mark, and European Directives
- Faster approvals and compliance with U.S. and International agencies
- Reduced product liability and recall risks
- Reduced re-design and quality costs
- Increased competitiveness with safer products and faster approvals
- Earlier management awareness of potential design pitfalls



Why Choose Focus?

Immediate Impact

Because of our hands-on experience, Focus will develop a program where your company's resources are directed to where they are needed the most. Critical items will be given priority while time and effort ($costs) savings will be realized for low-impact issues. Your team will benefit from our knowledge of industry best practices as well as building these practices into your approach for your projects.

Lasting Impact

While improving their competencies, skills, and confidence, your organization's participants will benefit from the excitement of directing their energies to critical areas of concern, while meeting the FDA's 21st Century Risk-Based Initiatives.

Give Us A Call

If you have a specific need but cannot find it within our brochure, please give us a call or visit our Website – http://www.FocusCVS.com — we believe we can help you find the right solution.

Corporate Office

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