

# Crisis Prevention & Recovery Services

**FDA representation and negotiation**

**FDA submission strategies**

**Consent Decree compliance and recovery**

**Determining product classification & regulation**

**Preparing for and managing FDA inspections**

**Response to FDA findings**

**Track record with CDRH, CBER, & CDER**

**Regulatory and software validation expertise**

**...Turn for details**



## Crisis Prevention and Recovery Services

- **Proven track record with FDA enforcement actions**
- **Recognized experts to prepare and defend your approach**

**We will work closely** with your internal staff, external vendors, your FDA counsel, and FDA itself to minimize the impact and extent of FDA enforcement actions. We help you understand FDA's underlying intent so you can develop appropriate and effective responses. If you don't already have regulatory counsel we can help you select one.

**Our approach focuses** on increasing your credibility with FDA through timely and effective communication and realistic commitments. We are sensitive to your business objectives and regulatory risk management philosophy and develop pragmatic approaches for short and long term benefit. We are also sensitive to public health risks and legal issues.

**We have special expertise** in medical device design control, risk management, software validation as well as medical device and pharmaceutical computer system validation.

**Our track record** in assisting clients includes avoiding or recovering from FDA enforcement actions including: consent decrees, denying premarket clearances, stopping product shipments, resolving inspectional issues, and responding to pre-market clearance deficiency letters.

**Crisis recovery requires** an ability to set priorities quickly, coordinate available resources, communicate across the internal and external parties involved, and negotiate effectively. Crisis management skills come from a combination of real world experience with crises and the personal characteristics of those involved. We only assign senior partners with extensive experience and appropriate skills to coordinate crisis recovery activities. Some of the credentials of the key partners involved in our crisis recovery services are listed below.

**Alan Kusnitz**, SoftwareCPR<sup>®</sup> Managing Partner provides internal training at FDA and is a trainer for public AAMI/FDA Software Validation, Design Controls, and Quality System Regulation training. Alan has been involved with a wide range of crisis recovery activities including extensive direct interaction with FDA for device and drug actions.

**Stan Hamilton**, a member of the AAMI/FDA working group that developed the AAMI Software Risk Management Technical Information Report 32. Stan has provided training, developed tailored risk management processes and performed risk management to meet FDA and EU requirements for a wide range of Medical Devices and Production software. Stan has also applied the Hazard Analysis and Critical Control Points (HACCP) approach to Production and Quality System software validation and defended client approaches during major FDA enforcement actions for both devices and drugs.

**Molly Ray** - a former FDA staff member has been involved on both sides (industry and FDA) of enforcement actions and pre-market deficiency issues.