SOFTWARECPR®
CRISIS PREVENTION AND RECOVERY, LLC

Regulatory Support for

Blood Banking

Submissions and Compliance

Unique credentials in Blood Banking and Software

Blood Screening Instrumentation and Blood Establishment Computer Systems

Proven track record with CBER

Planning, review, or outsourcing

FDA Interaction and negotiation

Special, Abbreviated and traditional 510(k)s, 513(g)s

MDRs, Correction and Removals, & Recalls

Risk Analysis and Validation support

On-site Training courses

…Turn for details

For more information contact us at info@softwarecpr.com, www.softwarecpr.com, or by phone at 781-721-2921

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www.softwarecpr.com

Blood Banking Regulatory Support

- **Specialized support for FDA's Center for Biologics Evaluation and Research (CBER)**
- **Instrumentation and Blood Establishment Computer Systems (BECS)**
- **Premarket submissions and compliance**

Submission Services

- Preparation or review of 510(k)s for submission to FDA for BECS and automated testing instruments used in blood establishments
- Evaluating changes to determine if a new 510(k) is needed and documenting rationale if none is needed.
- Determining which type of 510(k) -- Abbreviated, Special, or Traditional – is best for your situation
- Representation and interaction with FDA before and during the submission process

Compliance Services

- Quality System development, improvement and auditing
- Vendor audits to assist in the evaluation and selection of potential suppliers
- Assist in responding to FDA 483 observations, warning letters, and other enforcement actions
- Risk evaluation of complaints and field safety events
- Medical Device Reporting (21 CFR 803), Recall, and Correction and Removals Support (21 CFR 806) support
- Product Risk Analysis
- Design Control, design reviews, and validation planning and review

Training

Internet based and on-site training on topics including BECS submissions, software risk analysis, software validation, quality systems, design control, corrective and preventive action, and Part 11.

Our staff has a proven track record with CBE*R* dealing with a variety of submission and compliance issues of medical device manufacturers serving blood establishments. Our group has a unique mix of blood banking functional knowledge, software technical knowledge, FDA regulatory experience, and extensive interaction with CBER. We have assisted clients in the submission of successful 510(k)s, helped clients that were stopped from marketing their product by FDA, and done extensive work in support of FDA Consent Decree required activities. Our senior staff with extensive CBER-related experience includes:

Molly Ray - a former CBER reviewer performed reviews of approximately twenty 510(k) submissions for BECS and has assisted clients in the preparation of 510(k)s. Molly is the author of the "Selection of Blood Establishment Computer Software" chapter in the Information Technology in Transfusion Medicine book published by AABB and participated in the development of CBER Guidance Documents for 510(k)s for Automated Testing Instruments used in Blood Establishments as well as the FDA Reviewer Guidance for 510(k)s for BECS.

Sandy Hedberg **-** developed the first 510(k) that was cleared by FDA for blood establishment computer software and has developed and/or assisted in the development of numerous successful 510(k)s since then. Sandy has performed software validation for medical devices requiring a 510(k) and has constructed FDA compliant quality systems and CAPA programs.

Alan Kusinitz **–** provides internal training for FDA and is an instructor for public AAMI/FDA Software Validation, Design Controls, and Quality System Regulation training courses. Alan is an expert in software validation and regulation and the author of the 21 CFR Part 11 Chapter in the *Information Technology in Transfusion Medicine* book published by AABB.