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Should Blood Establishment Computer Software be regulated any differently than the manufacturing software used by drug and medical device companies?

An East Coast Blood Banker reports that she has recently learned about a [workshop at which there are plans to discuss regulation of Blood Establishment Computer Software \(BECS\)](#).

Apparently, the **FDA is collaborating** with America's Blood Centers (ABC), AABB, AdvaMed, Alliance of Blood Operators and American Red Cross (ARC) on a **workshop titled "Regulation of Blood Establishment Computer Software (BECS): Future Directions,"** which will focus on industry and FDA concerns; a specific location for this event has not been determined, but it is expected to be held July 10-11 in the Washington, D.C., area. After surfing the Web to find more details, the East Coast blood banker found the following in the January 11, 2008 ABC Newsletter. "ABC was forming a planning committee for a late spring/early summer workshop on the regulation of software used by blood establishments. Under the umbrella of the Alliance of Blood Operators, ABC and ARC met with CBER officials in late 2006 to **request consideration for regulating blood establishment software** no differently than manufacturing software used by drug and medical device companies (i.e., **no regulation of the software provider but validation requirements of the end user**). **CBER was favorably disposed to review the current requirements, and suggested an open workshop** to discuss the issues. Initially CBER proposed hosting the workshop, but then agreed to participate in one sponsored by the blood community. Vendor regulation was put in place in the early-1990s because of a lack of sophistication of blood centers with IT. Several years later CBER added validation requirements for the blood establishments similar to those for drug companies. It wasn't clear that this "belt and suspenders approach" was currently necessary and the threat of FDA regulation inhibited companies like Microsoft, Oracle, SAP, etc., which supply drug companies with software needs, from entering the US blood market. The result was the industry was served by a handful of poorly financed specialty companies. Rodeina Davis of the Blood Center of Wisconsin and Becky See of BSI agreed to cochair the planning committee. Others on the committee would be representatives from CBER, ARC, Advamed and the trade association of hospital software companies." The East Coast blood banker **wonders if colleagues believe that Blood Establishment Computer Software should be regulated "...no differently than manufacturing software used by drug and medical device companies** (i.e., no regulation of the software provider but validation requirements of the end user)" ? This was the state of the industry before FDA began regulating the software as a medical device. She concludes asking **"Do we really want to go back to that"?**

ADDENDA April 26, 2008

1. **A certified quality auditor in Indiana** comments that "End users will always have a responsibility for validating their blood bank software package in their own environment. But I would leave the blood banking arena, rather than do it 'the old way' again!" He adds that "The difference between an 'FDA-approved' system and one that is not FDA approved lies in the extent to which the end user has to test the system. **Under the old system, the major burden reverts to us to test everything we can think of, usually with incomplete information on the software's structure.** There was always a question of how much testing was actually enough and what the response would be to a particular test event. Vendors have the source code in front of them and should have the expertise to properly test their software according to FDA requirements. Blood Banks do not have software engineers on staff, and adding **a software validation department** (or hiring a consultant to function as such) **would add even more cost to the price of a unit of blood that is already poorly reimbursed.**" He concludes saying that **he longs for the approval of "artificial blood", so issues like these become moot.**

2. **Editors' Note:** The formal announcement of the meeting mentioned in this discussion has been posted on the CBER website [HERE](#).

Please submit comments to the [e-Network Forum](#).

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