



Innovative Blood Resources implements a modern donor and blood management system thanks to BC Solutions.

Situation

Innovative Blood Resources (IBR) collects blood for transfusions. The organization was formed out of a partnership between Memorial Blood Centers and Nebraska Community Blood Bank. IBR was implementing a new donor/blood management computer system that would take the place of their two existing computer systems. In doing so, they realized they needed help to build and design a software that would best incorporate the needs of both blood banks. The new software would also require validation to ensure regulatory requirements were met.

"This process is very time-consuming and very resource-intensive," said Kendra Reynolds, IBR's Director of Quality and Regulatory Affairs. "Typically, if we'd been doing it all in-house, it would have been at least a three-year project. We needed a fast turnaround."

IBR needed experienced consultants who could hit the ground running and successfully fulfill the project requirements in a short amount of time.

Solution

IBR chose to partner with BC Solutions because BC Solutions had expertise in the field and the ability to speak the same language.

"They have knowledge of the different computer systems within the blood-banking world," said Kendra. "Many of their staff actually have come from different blood centers, so they speak our language, but they also maintain a current knowledge-base of all the requirements that we have to follow that are set forth by the FDA."

“ [BC Solutions] already understood the scope and the depth of the testing that needed to be done.

They had tools already in place, with tasks identified for different risk evaluations, and they were able to quickly define the scope of their work. ”

CASE STUDY



“ Everyone [at BC Solutions] was easy to work with. They understood the challenges that we were facing. If we had crazy schedules or had to reschedule conference calls, they worked on our schedule. They'd follow up and always communicated, on time, even though they're in different time zones. They were very attentive and attuned to our needs. ”

KENDRA REYNOLDS

Director of Quality and Regulatory Affairs
Innovative Blood Resources



Results & Benefits

Completed Project Within

18
Months

Thanks to the expertise of BC Solutions, IBR was able to complete the project within an 18-month timeline. IBR was also able to seamlessly pass three different U.S. Food and Drug Administration (FDA) inspections regarding the data conversion.

Kept Project On Track



BC Solutions kept the project on track. "They provided a weekly status update, which was great because we knew the exact progress," said Kendra. "They met all their deliverables, too, on the timelines and everything."

Comprehensive Data Transfer



Kendra "had confidence that the data moved over correctly. All of our scripts and things for moving that data over were successful."

Subject Matter Experts



BC Solutions provided IBR with access to subject matter experts in EIDorado Donor design and build as well as compliance testing and validation.

Regulatory Experts



BC Solutions' consultants are seasoned medical technologists trained in regulatory compliance including FDA and AABB regulations. "Three different sets of FDA inspectors reviewed the OQ documentation, including the work that BC Solutions did," said Kendra. "We didn't have any issues with showing the FDA how we tested the system and implemented it and converted the data over."

Services Provided

- ▣ Consultations on design and build of the EIDorado Software
- ▣ Unit testing for high-risk and high-build areas within the software, ensuring their database tables functioned as expected
- ▣ Risk-based, FDA-compliant, operational qualification validation with issue reporting
- ▣ Interface validation between IBR's donor ID software and EIDorado Donor software
- ▣ Data conversion from BBCS to EIDorado Donor
- ▣ Validation of Converted Data from both BBCS and SafeTrace Donor to EIDorado Donor