CRITICAL INSIGHT FOR BETTER DECISIONS
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MedPro MONTH

BLOOD TRANSFUSION MANAGEMENT: READY FOR CHANGE

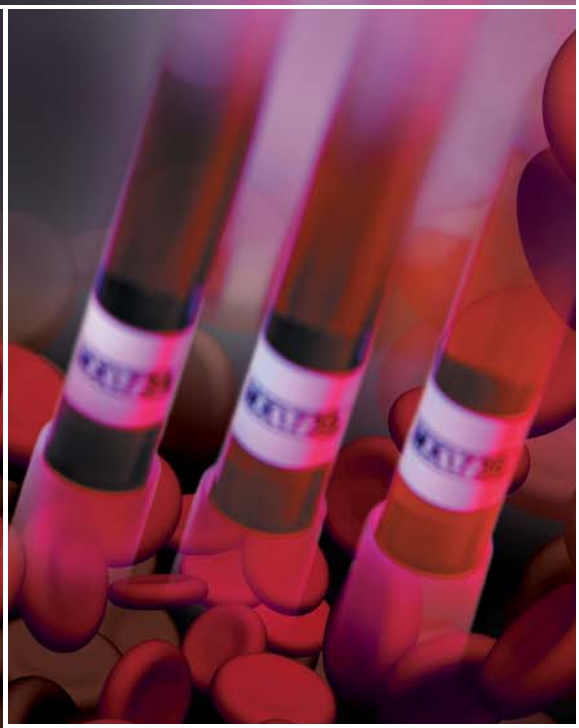
A diminishing supply of donor blood has medical companies rushing to be the first to develop a blood substitute

PERIPHERAL AND NON-VASCULAR STENTS IN EUROPEAN MARKETS

Various applications vie for success similar to that earned during the boom of coronary stenting

OPPORTUNITIES IN CANCER RADIATION THERAPIES

Continued technological advances work to unravel a largely unsolved etiological puzzle



Laboratory Management Contingency Planning: The New Paradigm

In days past, contingency planning was generally left to the laboratory operator or the hospital risk management group, to assess products, processes, procedures and protocols. Depending upon the urgency of the laboratory, specific action plans were installed and others passed by as not being required. For California-based laboratories—especially those hardest hit by rolling blackouts in the spring and early summer of 2001—the need for contingency planning to protect analysis of immunoassays, genomics and proteomics associated with diagnostics and drug discovery made everyone take notice. It was apparent to all Californians that even U.S. energy sources and power delivery were at risk. This new threat was obvious; a loss of power within the laboratory would not be staved off by the laboratory's switchable emergency generator back-up systems.

Once an under-protected analyzer goes off-line (and it only takes a 1/2 cycle, or 9 milliseconds, for that type of incident to occur), the instrumentation system's control is lost until a reset or restart. The remedial action for coming back online is always a system reset, diagnostic analysis, recalibration, re-testing, reporting and quality control review, as well as the loss of key unrecoverable samples. It is also possible that the instrumentation system may have been damaged due to an abrupt power failure and/or restart, if the recalibration indicated a shift in values. Within the realm of forensic testing, as an example where samples are extremely limited, the reportable results may have been compromised or the laboratory may have been left with a precariously small residual sample for re-analysis. While the California rolling blackouts have waned from the scene for now, the contingency planning and laboratory productivity issue has only intensified due to current regulatory requirements, the laboratory operating environment and national security threats.

How much risk are we talking about, when an instrumentation system goes offline?

Most laboratory operators fall under the realm of the FDA's cGxP, which includes the current GCP, GLP, GMP to describe their level of activity and involvement with the FDA. Manufacturers in biotechnology, medical devices and pharmaceuticals are acutely aware of the reporting regulations that are required to meet FDA *21 CFR Part 11* compliance. While this is a secondary referenced regulation, it is really covered by a multitude of other clinical practice, manufacturing and production regulations. *Part 11* is an all-encompassing issue in the industry for electronic information (informatics) that is generated and reported to the FDA. The FDA's Corrective and Preventative Action (CAPA) and Medical Device Reporting (MDR) related issues are also covered by *Part 11*.

In a recent study by the **Electric Power Research Institute** (EPRI), the cost within the U.S. for a two-cycle power interruption (36 milliseconds) was estimated at $50 billion—a substantial figure by anyone's calculation. But the real threat to laboratory instrumentation and productivity is not in the cost of the predictable occurrences, such as the required weekly test to *NFPA Standard No. 99, Testing of Emergency Generator Transfer Switches*, or a scheduled rolling blackout, but in the unforeseen problems induced by neighboring instrumentation and key medical equipment. The overall productivity of the laboratory is at risk and this is where the contingency planning must focus as the new paradigm. The reason for a renewed look at risk assessment is multi-fold with key impacts for the cGxP operator and instrumentation manufacturer. Not only does it cost in time, material and lost opportunity, there is most likely a regulatory compliance issue that must be addressed with meeting the criteria of *21 CFR Part 11*. At this time, the cost for *Part 11* compliance is a true unknown.

While the FDA is working with key, well represented groups in the pharmaceutical, biotechnology and medical device sectors, key guidance on interpretation is lacking on how to best deal with the compliance regulations concerning informatics. Laboratory informatics issues are all tied to and associated with analytical instrumentation and their owners/operators. Many organizations are working toward informatics solutions regarding regulatory compliance to *Part 11*, but assurance and prudence has to enter into the analysis to avoid building an elegant solution to a problem upon weak fundamentals. Without a well thought out Laboratory Productivity-Protection System (LPS) and risk management foundation, any subsequent informatics solutions will be inadequate. Many organizations are developing their analytical informatics compliance solutions as well as building their risk management and contingency planning on shallow foundations in the sand.

How do you assure the risk management plan and foundation is built correctly?

An example of a failure in advanced planning for form and function is before us in the observatory in Pisa, Italy.

While the "Leaning Tower of Pisa" is now a tourist attraction, it is also an example of failed planning by the original architects/builders to produce an adequate scientific investigation observation platform. The tower now represents the "elegance" of any solution that is built on a poor foundation in the sand. Its form and function has been changed forever. It still requires substantial engineering and maintenance to function in it's current role, as a salvaged observation platform and tourist attraction.

A fundamental environmental issue in risk management consideration is in the quality of the power provided to the laboratory. While the local utility generates highly regulated power, medical equipment and other equipment with collapsing inductive loads within the local laboratory environment, induce undesirable waves onto the delivered power. These induced random cycling and transient collapsing loads (waves) are noise generators, i.e. surge, spike, high-line and low-line conditions that reside on the distributed power circuits. The problem is similar to driving your car on a very long and rough road. Eventually you are going to damage something. Additional errant signals on any power line are undesirable under any circumstances. Instrumentation manufacturers may also be subject to a MDR and be potentially involved in a CAPA as a result of incipient and spurious instrumentation system failures. Suspect informatics data may also be the result of induced power failures. Lastly, like your car, critical instrumentation system electronic components cannot tolerate out of specification conditions for very long. Eventually these components will fail, which results in costly downtime and expense for everyone.

The first step is to assure that the instrumentation and informatics system risk management solution is built on a solid foundation. Consideration for the development of a substantial foundation requires a review of the operating environment for the energy and power delivered to the laboratory. The FDA, within *Part 11*, has noted in its draft guidance that the environment is a factor that has to be evaluated and managed to assure appropriate operation of any instrumentation system. There is a long standing opinion within the FDA regarding critical systems that may be reset during power interruptions, to the extent that the FDA issued its *Health Standards and Quality Letter No. 523* a number of years ago. Following these recommendations, the addition of an LPS application for critical systems may be a very prudent and low cost consideration in the laboratory's overall risk assessment strategy. Diagnostic testing should be considered mission critical for any laboratory reporting informatics results that are utilized to develop or influence a medical therapy. If an LPS is being considered as a component of your risk management plan, then selection of an appropriate instrumentation manufacturer qualified or certified LPS system is the best choice.

The second step is to evaluate how much loss your laboratory can tolerate in terms of service to the customer base, timely performance, availability, reporting and profit. An economic analysis should be performed to determine your loss tolerances, opportunity cost and the cost to add certified LPS capability to your laboratory. The value of the instrumentation to the lab, the cost of not meeting regulatory compliance and the possibility of generating suspect data during low-line conditions, would suggest a significant business risk, if an LPS unit were not factored into your operating equations. The quality of results and the potential for loss of reputation of a cGxP laboratory operator, really dictates that a total review of your contingency planning and risk assessment be made in view of the new paradigm.

The third step is to assure that your analysis is robust and meets typical due diligence requirements. If necessary, consult with engineering specialists in laboratory power and protection systems for scientific and medical instrumentation. Proceed with a trusted name in the industry and consult with other laboratory operators to assure that your protection solutions are viable and will perform under worst-case conditions.

Lastly, consulting the *21 CFR Part 11* Web site (www.21cfr11.com) for analytical instruments and software solution provider assistance will be a strategic advantage for the risk management team. With the proper assessment and development of a strong and fundamental operating foundation, the new *21 CFR Part 11* paradigm cGxP Laboratory Operator will be on the right track toward timely and effective laboratory management contingency planning.

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FTI specializes in providing Laboratory Productivity/Protection Systems (LPS) for medical, analytical, diagnostics, pharmaceutical and biotechnology instrumentation systems applications. The key scientific and medical LPS applications are in:

- Drug discovery
- Oncology
- DNA-PCR, Genomics and Proteomics research
- Pharmaceutical production
- Clinical chemistry
- Immunology & cytometry
- Diagnostic imaging
- Hematology and blood banking
- FDA 510(k) patient contact applications
- Forensics
- Scientific / Biotechnology commercial research & production

FTI provides an energy technology bridge between the energy production and distribution sector (utility and associated distribution network) and the end user analytical laboratory (GxP) operator. The application of FTI's certified purpose built and application specific power systems (Category III LPS/UPS) provide assurance that the instrumentation system(s) and the resulting data analysis/reports continuously meet the performance standards originally established for the instrumentation.

Power quality problems represent a large cost to the healthcare and scientific research industry in terms of lost productivity, expensive re-testing and re-calibration, as well as lost reporting time. Data integrity is suspect during episodes of inconsistent energy availability, which is so prevalent in the United States today. FTI's primary goals are to protect the integrity of the analytical results, laboratory or surgical productivity and to safeguard against undesired transient power that can cause equipment damage to sensitive instrumentation. Additionally, by providing a reliable energy source, instrumentation system power integrity and availability is achieved.

FTI has over 20 years of laboratory and medical instrumentation systems applications and several Billions in protected instrumentation and system assets. FTI is uniquely qualified to provide solutions to organizations desiring to meet the electronic reporting requirements of the FDA's 21 CFR Part 11, as well as meeting the current needs of bioterrorism technology preparedness. FTI may be viewed at:

www.21cfrpart11.com/solution_providers/analyt_instr_softwr.htm

Or

www.franek-tech.com

Franek Technologies is a Working Group member of AdvaMed's Medical Technology Preparedness Council and is a FDA 21 CFR Part 11 solution provider