Maximizing Your Laboratory's ROI

For the Laboratory Director (LD) or Principal Investigator (PI) operating a laboratory in the clinical, life sciences research, analytical or environmental testing market is a difficult business at best these days. Assuring the availability, reliability of results and economic survivability of the laboratory is management's goal. Realizing a cost savings improvement of $25,000 per year or more for each key instrumentation system in service[1] is highly desirable. The operating savings from increased efficiency, reduced instrumentation system down time and unplanned service calls drops right to the laboratory's bottom line. Capital improvements to the laboratory's operation that yield Benefit to Cost ratios approaching 10:1 with an attractive ROI (Return on Investment), are the attributes of very smart laboratory management. The true benefit to the laboratory operation comes when the expected ROI and Benefit to Cost ratios for the improvement are achieved. Managing the operational details and critical utilities are the key elements in a smooth running laboratory operation.

Critical Utilities Impact on Laboratory ROI

The laboratory and its instrumentation represent a tremendous enterprise asset base that requires a well planned and executed Return on Assets (ROA) strategy. If the laboratory is operating as a profit center, Return on Sales (ROS) is the key parameter. When the laboratory is part of a development and production operation, a combination of ROA and ROS are the metrics that form the overall ROI. The combined ROI is the business measure that Chief Financial Officers and the investment community review as part of the fundamentals for an operation in drug discovery, production testing, and/or other analytical reporting. Maximizing the utilization of and optimizing the laboratory's ROI, as well as, attaining the effectiveness and efficiency of the laboratory staff are the main objectives of the LD or PI, and their senior management. Minimizing and managing the impact of Critical Utilities[2] to attain effective laboratory utilization is key to smart business management. By passing electrical power management as illustrated in Figures 1 and 2, the most overlooked of all the critical utilities, can economically cripple the reportable results output of the laboratory. When this critical utility fails, the direct and indirect costs of the instrumentation failure, retesting and outsourcing to complete critical tests due to lost time, must be factored into the operating costs. This also includes the cost of staff and its lost productivity. The risk to the instrumentation and automation in a laboratory that is highly automated is catastrophic, if the utility is unstable or fails. Effectively, unless backed up by an outsourcing arrangement, your ability to produce reportable results drops to zero. When this occurs, your ROI is substantially eroded.

The Laboratory is an Enterprise Information Decision Center

Essentially, all laboratories are information resource centers for their enterprises. Analytical instrumentation and other laboratory systems produce information that is used in key decision processes. The information laboratories provide, while not used directly in a clinical diagnosis or therapy in a medical application, must be critically accurate and fact based. Laboratory information is highly valued within the enterprise. In laboratories such as: clinical diagnostics, life sciences research, drug discovery and pharmaceutical production; daily operation requires special management skills with well defined and executed plans and procedures. For those laboratories that are regulated by various FDA, HHS' CMS[3], OSHA, and other governmental bodies, managing the mandated regulatory burdens, while assuring quality, reducing incident and CAPA[4] reporting management can be a costly endeavor for the unprepared.

The Regulatory Compliance Time Trap

Some industry analysts estimate that nearly 70% of the available staff time in a pharmaceutical or biotechnology laboratory involved in drug discovery is devoted to regulatory compliance[5]. This is especially true now that the FDA is enforcing 21 CFR Part 11 where the mechanisms for compliance are still not

fully understood by most laboratory operators or their executive management. More so, drug discovery and clinical laboratories have become very sophisticated operating arenas with emphasis on total automation, multiple laboratory coordination, LIMS integration, and the need for optimal utilization of instrumentation and systems assets. Laboratory systems management and work flow coupled with the human resource component of research scientists, technologists and other laboratory staff resources, has a substantial loss penalty factor the LD or PI must contend with, if the instrumentation and automation systems are not operating effectively and efficiently. This is where management of Critical Utilities, such as electrical power and water quality are so important, for not only the instrumentation and analyses, but also the overall operation and management of the laboratory.

Keeping the entire laboratory operation running smoothly, while operating at the lowest possible cost, is the primary goal of laboratory management. Lowest possible cost means operating with reliable results, effective asset and personnel utilization, a low risk management profile, and regulatory compliance. In the clinical laboratory enterprise where the income source is capitated by managed care schema, the focus is on the lowest possible cost per reportable result. New compliance and mandated patient record management requirements are forcing these laboratories to a more automated and integrated management approach. Investing in optimizing automation, instrumentation, and software is one of the ways the laboratory can become more competitive and contribute to the bottom line. Improving processes and personnel interaction with these new sophisticated laboratory assets is the best way for the laboratory manager to provide significant value added for the operation.

Comparing the Laboratory to Other Highly Regulated Businesses

In many ways, a laboratory in a highly regulated business environment is similar to the management of an airline. The airline industry is a classic case of business operation in an extensively regulated environment. The business model for this transportation industry is one that operates globally under strictly reviewed performance and adherence to schedules. Air carriers operate in extremely adverse and hostile environmental conditions. What can go wrong will and the ability to provide relatively seamless operation in such an unpredictable environment means close adherence to procedures with well thought out contingency planning and very low business risk.

The similarities between highly regulated businesses such as the FDA and life sciences and/or the clinical labs industry, as compared to the FAA and the airlines and/or aircraft manufacturers industry, are striking. In the case of the major airlines the FAA regulates the carriers; all of the aircraft, crews, airports, ground operations, baggage and cargo movements, security, etc.[6]. The air carriers essentially all fly with the same aircraft built by two global manufacturers, which are FAA approved and certificated. The FAA certifies the air carrier's business, approves their operations manuals, routes, timetables, as well as their pilots and crew capabilities. Re-currency training and maintenance are regulated and monitored by the FAA. The way any air carrier makes money is in their efficient workflow, services, scheduling, and maintenance compliance, as well as, other operations as part of a total enterprise. It is no wonder that the major air carriers are fully automated and have looked at managing all critical utility and contingency situations. Certificated air carriers have compliance and operating procedures to keep their flight operations running as smoothly as possible, while addressing profit for their respective stakeholders.

While the industry is not perfect, air carrier operations are highly efficient and a model for the laboratory operator. This is a plan-ahead type of industry, with large asset bases and high loss stakes for poor performance. Air carriers have a very low profile of risk in their management and global operational methodology. Low risk management is not only required by international law, but by their customers, the traveling and shipping public. This business does not wait for a set of adverse circumstances to occur before taking corrective action. The amazing aspect of this industry is that it is operating in real time with constant changes in its main operating environment – the weather and variations in fuel costs – its main consumable expense!

Assessing Your Critical Utility Business Weather Forecast

The analogous operating environment for the laboratory is the management of their critical utilities: electrical power availability and back-up, water quality, temperature, humidity, air filtration (laboratory weather) and reagents, controls,

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calibrators, consumables and quality control costs (fuel) as the variable per reportable result costs. If the environmental conditions are not appropriate and within specification to run the instrumentation and other laboratory systems, even higher costs per reportable results are incurred. In these circumstances, the overall efficiency of the laboratory has been compromised.

In a clinical diagnostic environment, especially in reference laboratories, as compared to other analytical laboratories, the need for efficiency, optimization, and asset utilization is nearly well understood. In these laboratory operations, efforts devoted to meeting compliance is envisioned to be substantially higher than most other non life science laboratories. This is due to interactions with pathogens and the current threat of bioterrorism throughout the US and North America. For a number of years high volume laboratories have turned to increased uses of automation and a total integration of resources, the enterprise LIMS brings. The laboratories with the lowest cost per reportable result, lowest incident of adverse reporting to the FDA and with low risk management profiles are the ones that have the highest ROI from their operations. Directors of these laboratories know that you have to keep the instrumentation systems running and effectively utilized to produce the desired and improved ROI for their business and its stakeholders. The best way to gain the most for the lowest invested cost is to add a certified Category III-3 Instrumentation Grade Laboratory Protection System (LPS) to each of the key instrumentation and automation systems.

Regulatory Requirements and More Coming!

The lowest cost per reportable result only occurs when adequate foresight, planning and effective laboratory management are melded together. The weather is literally changing for the laboratory, at least in California, as the clinical laboratory and drug discovery industry is now into its second season of electrical power rolling blackouts,[78] and the threats they bring to instrumentation manufacturers and laboratory operators to meet desired ROI and operating cost objectives[9]. Even though back up and emergency generators are in place in many facilities, the required NFPA specification 99 weekly and monthly testing of these systems will knock the laboratory offline.[10] The FDA's Health Standards and Quality Letter No. 523, CLIA and 21 CFR Part 11 expect the laboratory to remain viable during episodes of electrical power disturbances or unavailability to meet the instrumentation manufacturers specs. If the laboratory is unable to do so, all of the testing that has been affected by a power incident is subject to retest.

Managing Your Lab's Future

To avoid lost opportunity to the laboratory a certified Category III-3 Instrumentation Grade Laboratory Protection Systems should be included in the LD's laboratory management and ROI planning. Not only will the laboratory gain from improved instrumentation availability and effectiveness, the application of a Cat III-3 LPS will reduce service costs, allow the laboratory to attain the first step in CLIA and 21 CFR Part 11 compliance while generally returning a benefit to cost ratio of 5:1 through 15:1, for the LPS investment. Assuring the availability, reliability of results and economic survivability of the laboratory is smart laboratory management. Realizing an increased operating efficiency and ROI is the benefit for the enterprise and its stakeholders.

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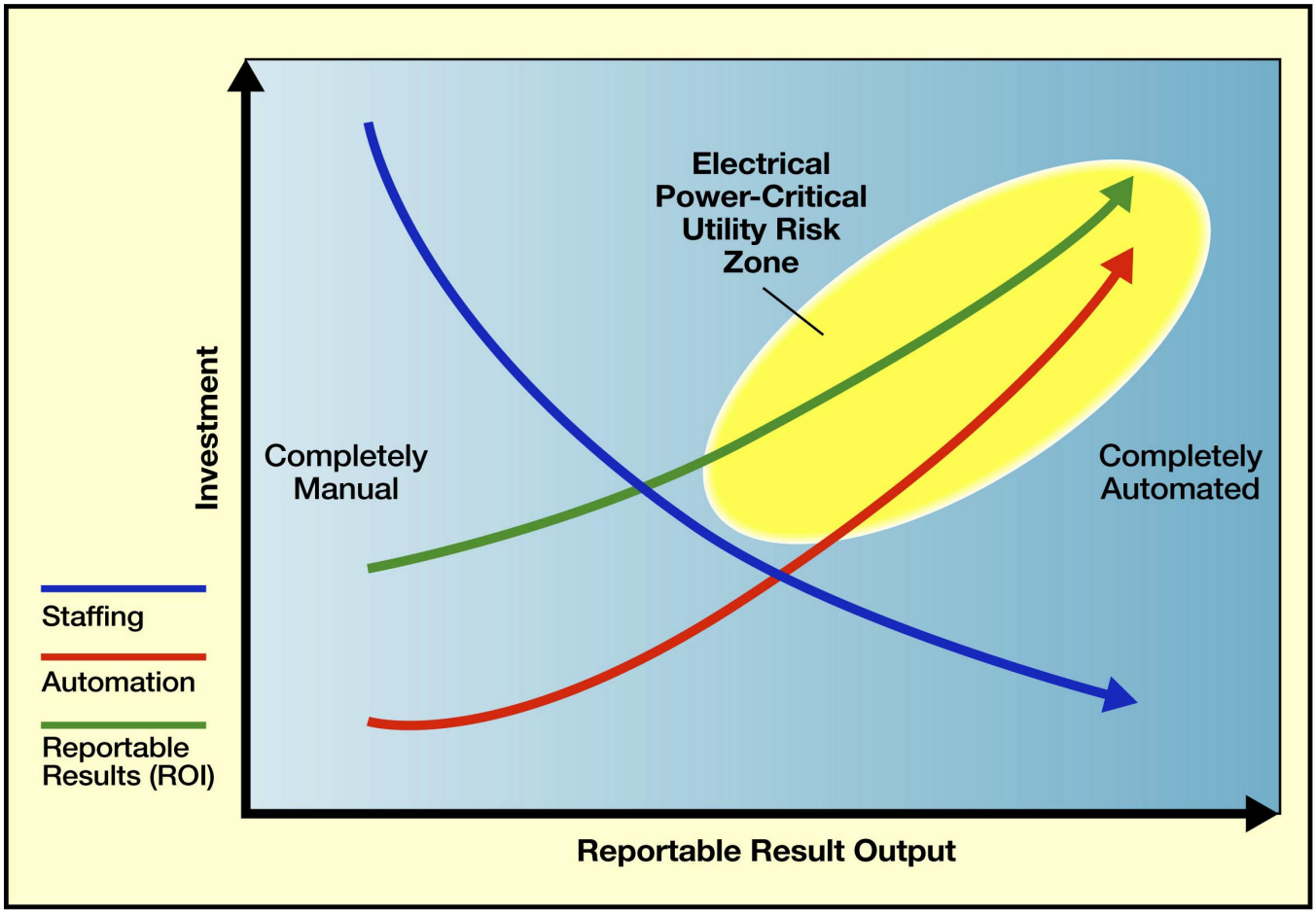

Figure 1
Critical Utilities Impact on Laboratory ROI

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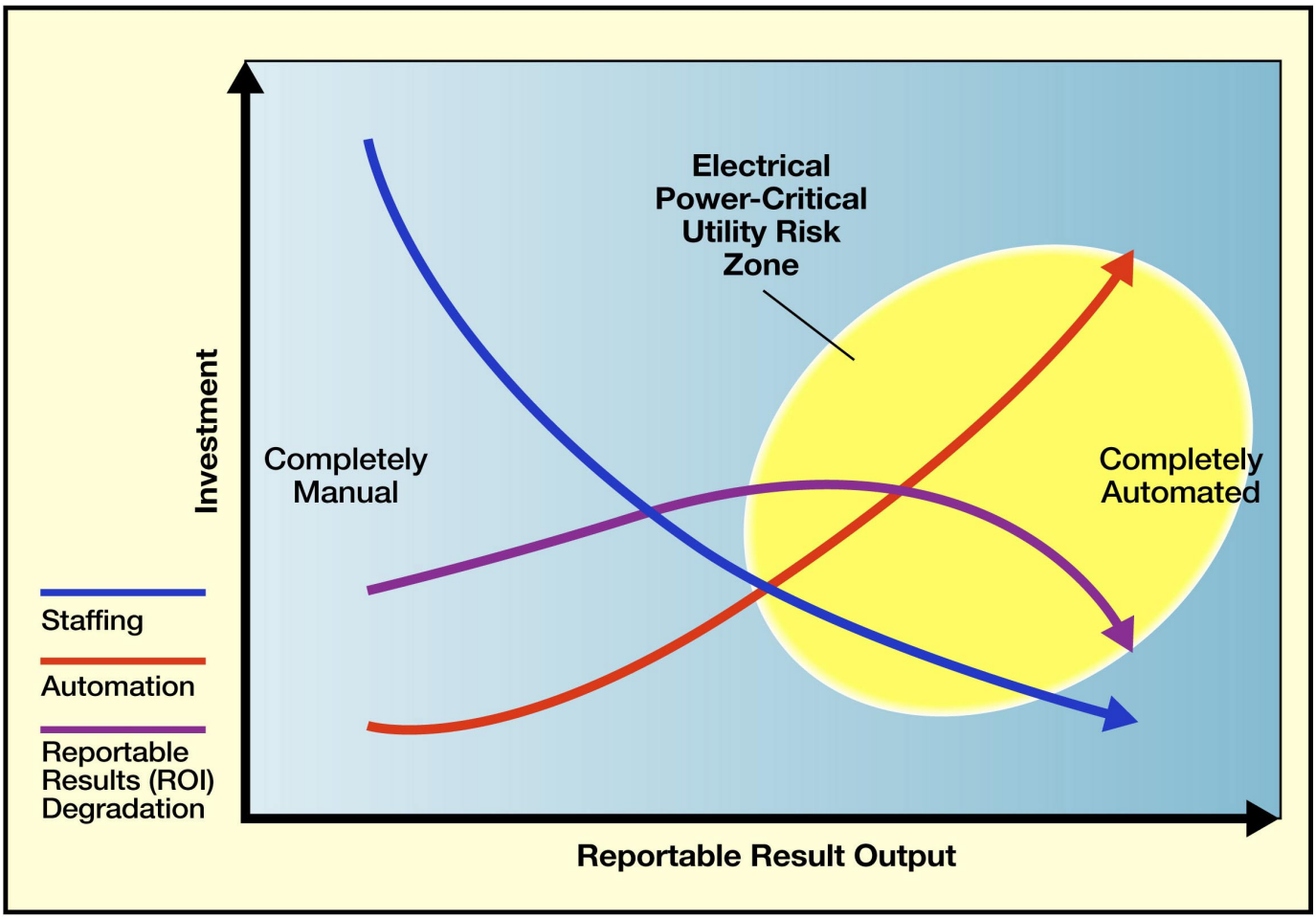

Figure 2
Critical Utilities Impact on Laboratory ROI
Unstable Electrical Power Delivery

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[1] Franek Technologies, Inc. Category III-3 Laboratory Protection System, 2001 Case Study "Clinical Chemistry Systems Power Interruption and Support Analysis"
[2] ISPE, the International Society for Pharmaceutical Engineering, US Food and Drug Administration cGLP, cGMP, et al
[3] US Department of Health and Human Services, Healthcare Financing Administration (CMS), 42 CFR Parts 493.1 through 493.1850. CLIA (Clinical Laboratory Improvement Act (1988))
[4] US FDA Corrective And Preventative Action (CAPA), American Society for Quality – Biomedical Division
[5] VelQuest, Inc 2002 "Eliminate Paperwork Bottlenecks", pharmaceutical industry assessment
[6] FAA regulations, Title 14 of the US Federal Code of Regulation, including: Chapters14 CFR Part 121 and 14 CFR Part 135 – Air Carrier Certification and Operations, and other applicable subparts
[7] CAISO (California Independent System Operators) 2002 Summer Assessment Version 1.0, Operations Engineering, California ISO, April 25, 2002 – "California ISO Cautiously Optimistic for Summer Power Supply"
[8] CAISO "Transmission Event at San Onofre Necessitates Brief Power Outage in San Diego Area", February 27, 2002
[9] Applera Corporation 2001 Annual Report "Electricity shortages and earthquakes could disrupt operations in California" – Forward-Looking Statements
[10] JCAHO (Joint Commission on the Accreditation of Healthcare Organizations) and NFPA (National Fire Protection Association) Specification 99 Technical Committee on Health Care Emergency Preparedness and Disaster Planning " Emergency Generator Transfer Switch Testing"

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