Use of RFID asset management systems for monitoring analytical instrumentation

Integrated active radio frequency identification (RFID) and real-time asset management systems utilise small, low-cost RFID tags to provide key instrument data in pharmaceutical laboratories yielding commercial and compliance benefits.

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The demonstration of the first continuous wave radio generation and transmission of radio signals by Ernst F. W. Alexanderson in 1906 signalled the beginning of modern radio communication and, subsequently, radio frequency identification (RFID). RFID is the convergence of radio broadcast technology and radar, although many of its early developments are not widely known due to the military significance of this technology. Most documented histories of RFID technology trace its development to the radio-based identification systems from World War II, when the British Air Force used radar to distinguish Allied aircraft from enemy aircraft.

Commercial development of RFID began in the late 1960s. Arguably the first and most widespread commercial use of RFID was in the development of electronic article surveillance (EAS) equipment to counter theft. Although this system could only detect the presence or absence of a tag, the tags themselves could be made cost-effectively and provided an effective anti-theft measure — an important application in the early commercialisation of the technology.

Research and development by academic institutions, government laboratories and private companies led to applications for animal tracking, vehicle tracking and automated manufacturing. By

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the mid 1990s, implantable RFID tags that were initially used to track laboratory animals were being marketed to veterinarians and animal shelters to identify pets.

RFID is now used for hundreds of applications including theft prevention, personnel access systems, automated parking, traffic management and library book tracking, along with the monitoring of assets in supply chain management. In fact, many attendees were focused on finding asset-tracking solutions[1] at the recent RFID Journal LIVE! 2010 event in Orlando (Florida, USA). Management of assets using RFID is the key to its application for pharmaceutical laboratories.

RFID technology fundamentals

RFID systems consist of four main elements: the RFID tags, the RFID reader, the antennas and computer network used to connect the readers.[2] The tag itself is the building block of RFID, each containing an antenna and a small chip that contains a radio receiver and a modulator to send a signal back to the reader. Tags come in a variety of shapes and sizes allowing them to be implanted into animals and humans, and they can be powered by the incoming radio signal (passive tags) or by a small battery (active tags). The advantage of an active tag is that its reading range and reliability is greater than that of a passive tag; however, passive tags can be much smaller and cheaper to produce and should, in principle, work indefinitely. RFID tags can also either be promiscuous in that any RFID reader (also known as an interrogator) can communicate with it, or secure where the reader requires an authentication credential in order for the tag to respond.

RFID readers work by sending a pulse of radio energy, which is measured using oscillation frequency and power, to a tag and monitoring the tag's response. Certain frequencies require a license to broadcast using this part of the spectrum, though most RFID systems use the so-called unlicensed spectrum, which does not require a radio license. Low-frequency (LF), high-frequency (HF) and ultra-high frequency (UHF) bands are used within RFID systems depending on the application. For example, the FDA has adopted the HF band for RFID systems that are used to monitor prescription drugs. In a simple RFID system, the reader's energy pulse acts simply as an on-off switch for the tag. In more complex systems, the pulse can include commands to the tag, such as instructions to read or write memory for more advanced monitoring.

RFID and the pharma industry

RFID can increase the safety and visibility of pharmaceutical products — from raw materials, through to manufacturing and patient consumption — by allowing the tracking and tracing of medications at the item level at each stage of the supply chain, preventing theft and effectively facilitating management of product recalls to ultimately assure pharmaceutical integrity. As such, the FDA has recommended the use of RFID tags to better integrate and improve the safety of US medical supply chains.[3]

For the analytical laboratory, managing and tracking high-end and portable equipment and associated documentation is a core requirement of laboratory management systems. Doing this 'well' with minimal resource and manual intervention and in a compliant manner is the key to successful application of RFID in the laboratory. Current systems used in pharmaceutical, biotech and other regulated environments include simple hard copy inventory lists, spreadsheets, barcoding systems and enterprise resource program (ERP) systems.

Historically, inventory lists were maintained to monitor asset depreciation or as part of various financial or laboratory management systems. Lack of information or incorrect information about location, status and usage can, however, cause delays in laboratory operations or lead to excess inventory of costly assets. Often, information is available, but is stored in different physical locations, systems or databases. As a result, the ability to defend a laboratory during a regulatory audit can become difficult. If the integrity of documentation, such as service and maintenance logs, installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ) records is compromised, then regulated laboratories are under risk of non-compliance. If documents pertaining to maintenance, qualification and change management are stored in one compliant database, defence of the laboratory becomes much easier from a holistic perspective.

Integration of RFID technology with compliant database architecture represents a significant step forward in managing laboratory assets "well", and in a compliant manner.

Features of an RFID-based asset management solution include:

- Real-time management of individual assets or groups of assets.
- Location of assets, locally, regionally or globally.
- Provision of current instrument status including service history.
- Retention of the history of an asset and audit trail of the asset's lifecycle.
- Tamper alert messaging for unauthorised movement of assets that would void equipment qualification in a regulated environment.
- Monitoring of laboratory temperature and humidity with audit trail and alerting mechanism.
- A web-based enterprise system that provides total laboratory asset management.

The benefits of an RFID system compared with traditional barcode and ERP asset management systems are summarised in **Table 1**.

Laboratory monitoring

The integration of RFID technology with a compliant database can, for example, simplify basic laboratory cGMP. In particular, the use of RFID allows real-time environmental monitoring of laboratory temperature and humidity. As many laboratory air conditioning systems are based on simple volume displacement calculations, variation in environmental conditions is inevitable; the use of RFID technology allows the environmental conditions experienced by key laboratory assets to be tracked and extended to critical temperature monitoring and alarm systems. FDA CFR Part 58, Subpart D stipulates the requirement for maintaining a controlled environment for equipment operating in a GLP/GMP setting. Documenting that the environment is suitable for a particular instrument should be included as part of the IQ and an RFID-based monitoring system provides an effective way to prove the environmental conditions are suitable should they be challenged during an FDA inspection.

Small, low-cost RFID tags are attached to analytical laboratory instrumentation, including the different components of a single instrument stack (e.g., HPLC system/LC/MS system). Rather than passive tags, active tags are used that send RF signals

Table 1: Benefits of an RFID-based asset management system compared with traditional barcode and ERP systems.

	RFID asset management system	Barcode + ERP system	ERP only
Line of sight	Not required	Required	Required
Read range	≥100 feet	Several inches	N/A
Read rate	10s, 100s or 1000s simultaneously	One at a time	N/A
Identification	Uniquely identify each asset tagged	Only identify the type of item (UPC code), not uniquely	N/A
Technology	RF (radio frequency)	Optical (laser)	N/A
Interference	Metal and liquids can cause interference with some RF frequencies	Obstructed barcodes cannot be read (dirty, worn and removed barcodes)	None
Movement tracking	Yes + alerts	No	No
Tamper proof	Yes + alerts	No	No
Temperature / humidity monitoring	Yes + alarms	No	No
Automation	Yes, no human interaction required for data collection	Most barcode scanners require manual activation	Labour intensive, each item must be matched against database
Durability	High	Low, easily damaged	N/A
Security	High. Difficult to replicate. Data can be encrypted and password protected	Low. Counterfeit barcodes. Data can be encrypted and password protected	High. Data can be encrypted and password protected
Event triggering	Yes. Can be used to trigger certain events (e.g. door opening alarm)	No	No

The authors say…

- The use of RFID technology is becoming more widespread in the pharmaceutical industry given its wide range of applications, from tracking and tracing individual items to secure supply chain integrity, through to analytical laboratory management.
- Integration of RFID into laboratory management systems offers a number of advantages over traditional systems, including real-time, two-way data communication, tamper alert messaging and environmental monitoring.
- RFID does not require ongoing maintenance or periodic asset inventory, thus reducing the time and cost related to these processes, which are required of traditional systems.

every few seconds to a small receiver that collects information from multiple instruments. The receiver in turn communicates with PC-based software through the laboratory's network infrastructure. Crucially, for GLP/GMP regulated laboratories, a real-time RFID system can provide global or multi-location inventory tracking of all laboratory instrumentation. It is also capable of tracking movement or removal of components that would void the system qualification. Without proper control and re-qualification of a HPLC system, for example, an unwanted compliance risk is presented. Instrument qualification becomes void following a breakdown, or replacement of component parts, such as exchanging a module (e.g., a detector or pump).

RFID systems ensure inventory lists are always accurate and up-to-date. Asset attributes such as physical location, contractual information, maintenance schedules and IQ/OQ/PQ compliance documents can be stored in a single database, enabling complete asset lifecycle management. For certain laboratories, where cross-contamination presents an issue, there are strict requirements for segregation of tools, instruments, clothing and equipment. RFID tagging can be used to automate and actively manage this segregation requirement.

Further, the benefit of adopting an RFID-based asset management system to aid regulatory body inspections includes proactive response to audits through accurate,

on-demand inventory reports. It is also possible to automate regulatory compliance efforts through the use of alerts for asset location changes. Preventative maintenance can be effectively carried out through rapid location of assets requiring periodical servicing to ensure instruments are qualified at the correct time intervals.

The ongoing cost of maintaining an asset management and document tracking system, as well as the cost of periodic asset inventory checking, should be taken into account when considering investment in an RFID asset management system. Barcode and ERP systems do not allow real-time monitoring and require inventory recounts to ensure assets have not been moved or removed from a designated area. This, however, is not required when integrating an RFID asset management system into an analytical testing laboratory, thus saving time and cost. Further, the number of systems or components that are 'lost' within a facility is reduced and lease penalties can be avoided *via* alerts that identify instruments approaching lease expiration.

In summary

RFID provides a tool for real-time, two-way data communication and can close information gaps in asset management for pharmaceutical manufacturing supply chain, analytical testing laboratories and hospitals.[4] The technology provides details of asset location and it can monitor critical information pertaining to each asset; as such, RFID is fast becoming an integral part of everyday life. Its application within the pharmaceutical industry is becoming more widespread for use in control of personnel access to research facilities, through to providing accurate monitoring of laboratory instrumentation and ultimately to delivering genuine, safe therapeutic products to patients. **PTE**

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