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INFORMATION TECHNOLOGY

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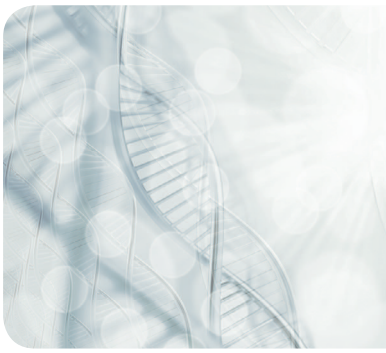

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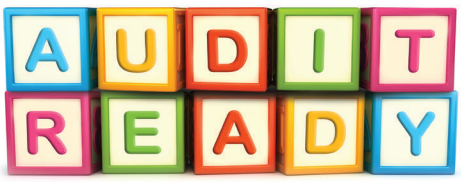

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IIoT: Buzzwords Have Feelings, Too

BY KAREN LANGHAUSER, DIGITAL CONTENT MANAGER

BUZZWORDS GET a bad rap. This is mostly due to operator error. Sometimes really valid concepts get haphazardly tossed around so frequently by people who don't fully understand them that the actual concept starts getting muddled. But this shouldn't always devalue the initial idea.

The "Internet of Things" is a good example. There are so many articles casually using the acronym "IoT" that it has become difficult to find a basic discussion of the concept.

In its most simplistic form, the IoT is a network of physical devices embedded with sensors and electronics, where all the devices speak to each other using the existing Internet infrastructure. The INDUSTRIAL Internet of Things (IIoT) is simply the Internet of Things when applied to the industrial sector (oh hey, that's you guys).

With some touting it as the "4th Industrial Revolution," clearly the IIoT is quite complex and, as I'm not a tech expert, I won't add to the confusing amount of chatter. That being said, the IIoT's applicability to pharmaceutical manufacturing is undeniable, even to the non-technical observer.

Having a network of connected devices in pharma manufacturing facilities means remote access to equipment, proactive maintenance of equipment based on actual logs and analytics, real-time plant floor visibility, the ability to recognize and respond to compliance issues immediately, and the ability to monitor and control serialization. The resulting analytics from these connected devices can be used to improve business and manufacturing efficiency, reduce risk and essentially disrupt aging business models.

As with all technological advancements, there are always associated risks and challenges. Security and data privacy are definitely big concerns in pharma. Additionally, the industry will be tasked with finding the right software and systems to organize and analyze the huge amount of data that will become available.

Nonetheless, the potential seems almost endless. The Industrial Internet of Things is no longer a futuristic notion. Those that are embracing IIoT are realizing positive, near-term benefits and creating a competitive advantage in the market. There are resources out there to help you plan, execute and optimize your IIoT implementation. Shameless plug aside, Putman Media has one of the best. Visit www.smartindustry.com and check out highlights from the recent Smart Industry Conference & Expo.

Perhaps *Wired* magazine put it best when it said, "Unlike consumer-based IoT that is trying to devise a way to make your world a better place by telling you when your washing machine needs service or letting you control all of your home's systems while you are away, the IIoT is working to make our collective world a better place by improving the monitoring, control and safety of everything around us."

For the first time in a long time, the Internet is abuzz with something that might actually eclipse the Internet in terms of impact on the world.

Pharma's Search for Operational Truth

Integration of control and business information technologies are opening new windows of enterprise transparency

By Steven E. Kuehn, Editor in Chief

As with any contemporary, complex manufacturing enterprise, information technology (IT) is a key, critical element crucial to effective and efficient operations. This is especially true for Pharma and Life Sciences. Of course it is, just ask any traditional IT operative in your organization; they're sure to tell you the whole place would come to a screeching halt without their expert guidance and technology. Pride aside, it's more or less fact. The digital age has introduced much in the way of game-changing technology to the "business" side of the house, including fundamental protocols, pervasive enterprise resource planning (ERP) platforms, and all those familiar, perennial business applications. Further, the exigencies of business operations demanded ever-more massive data-handling infrastructures, which is now increasingly outsourced and the engine that drove the rise of the cloud.

Manufacturing engineers also embraced the computer age and within just a few decades industry embraced the notion of computer-integrated manufacturing (CIM) and transformed its myriad analog, hard-wired and manual control systems into a networked ecosystem of operational technologies (OT), that is, distributed digital control networks, automation and sensing to help better understand manufacturing and processing operations. It was only natural to begin to see the possibilities of connecting all the data and information coming from these rich fields. In a recent *Smart Industry* magazine editorial, Peter Martin, president of Schneider Electric related this bit about the rise of CIM in the 1980s: "We had the idea that if we took networks and tied all the computers we had together, something good was bound to happen."

That was the vision, but Martin's comment reveals much because it captures the magical thinking that (at the time) accompanied this technological innovation. Colleague and veteran industry observer Keith Larson, editor of sister publication *Smart Industry* explained that in spite of good intentions, at the outset "Integration was hard; integration was time-consuming; integration was expensive. And, once achieved, these custom links were brittle and maintenance-intensive too. As a result, only those integration projects deemed essential to operations or those that cleared a very high return on investment bar were undertaken — and only then by the enterprises with the resources to fund them."

The dream became more a waking nightmare to some; integration and communication across domains was difficult at best and those who embarked on this path found that the initial investment was only one element of an increasingly expensive proposition that consumed operational resources and budgets, ultimately putting extreme pressure on its overall value proposition.

Networking production assets, monitoring critical and operating state process, and generally getting data flowing across manufacturing operations was hard enough, and the notion of deriving business value by integrating and sharing this data with the business systems and analytical platforms in the C-suite really did seem like magical thinking, and kept the two "technocracies" if you will, entrenched in their respective kingdoms, managing an uneasy detente.

An amazing amount of data is available from all corners of the production environment. Regulators are increasingly interested in this data to support compliant operations and identify deficiencies in quality regimes.

CONVERGENCE

For many a year, IT and OT disciplines ran along parallel tracks, introducing advancements and features that served the interests of their respective groups. Few in either camp were focused on delivering the potential of these technologies beyond their traditional roles; even after some 35 years the industry is still talking about the divide. But the gap is closing, and judging by the high level alliances between titans like Cisco, SAP, Oracle IBM and automation giants like Emerson, Rockwell, Siemens, Werum and others, OT and IT convergence is their collective solution to managing the incredible complexities associated with the global pharmaceutical manufacturing enterprise, and the cloud is where they all are convinced this utopia can be realized.

In 2015 the technical and economic barriers to OT/IT convergence are falling away, creating much stronger, more robust, reliable links. Perhaps most important has been the increasing amount of computing power end devices like sensors and controllers have built in — in other words, the availability of increasingly "smart" controlling and sensing technologies with that are capable of crunching incredible volumes of data at the edge of plant networks. Similarly, the industry developed open integration and communication standards that have dramatically improved the efficacy of the links demanded of real-time highly integrated OT networks.

The economics of these devices continue to improve as price and functionality follow inverse curves and connectivity via open, standard protocols and wireless networks make integration with legacy systems even more financially and administratively feasible. Notable also is the fact that the costs of computing have fallen dramatically as well.

As mentioned, information technologists turned to the Internet to provide the means to manage and transmit data globally. The cloud was born. And the Industrial Internet of Things (IIOT) as Smart Industry spins its core ethic. Fundamentally, the IIoT is an overarching term to describe the Internet Protocol (IP)-based communications infrastructure that connects uniquely identifiable electronic devices via the web.

As a result, all industry — including pharmaceutical manufacturing — has access to an expanding range of converged, integrated technologies, connected and available to move and exchange data to and through applications that by function and design, are supposed to reveal operational "truth" and deliver it to the organization in a timely relevant fashion.

What's to be done with all this operational truth? Well, that is the big question, now isn't it? Pharma is embracing this convergence, but like any industry that begins to adopt contemporary technologies, that uptake is accomplished in fits and starts, trials and pilots, in a fashion that serves the organization's assets as they exist and what they aspire to be. It's an enormous challenge to bring the business value from all the connectivity that the technology and its developers promise.

For those working to manage geographically dispersed manufacturing assets like Pfizer, the path to operational "truth" is paved with information, that is, all the data streaming from its production equipment's control systems and associated devices. For most enterprise, especially large complex drug manufacturing organizations, obtaining operational knowledge of its production assets is the challenge.

A company the size of Pfizer has enormous challenges, largely due to its complexity, due mostly to the fact that it manufactures pharmaceuticals, and not just one kind, but several — both patent-protected like Viagra, and biologics — as well as over-the-counter medications which have an entirely different economic/production model dictating their profitability.

It's within this context that Pfizer has steadily structured and refined its manufacturing assets to support and implement GMPs integrating them into Pfizer Global Supply (PGS), the internal organization tasked with supplying the company with the products it develops and markets around the world. According to Pfizer Global Supply's John Kelly, VP sourcing & network strategy and transitioning operations, "Pfizer Global Supply [is] a critical element of Pfizer's success … We've always been a very vision-focused organization … Our purpose is to supply quality products for a healthier world."

Fulfilling PGS's mission and vision, as Kelly succinctly described, is entirely dependent on managing its production assets as efficiently as possible, a task that is even more dependent on the operational truth derived from the Enterprise Manufacturing Intelligence (EMI) it derives from the vast amounts of data streaming from its control devices and production and processing equipment and the subsequent reports provided to PGS executive management. Pfizer continues to rely on Rockwell Automation's platforms and applications to bring the benefits of connected operations to the organization.

Increasing demand for more sophisticated formulations, dosage forms and supply chain security continues to prompt comprehensive integration of operational technologies and information technologies to achieve a holistic view of the enterprise and its operations.

SEGMENTS, VENDORS DRIVING CONVERGENCE

With operational excellence so critical to managing Pharma manufacturing risk, the industry's vendors continue to respond with technological collaborations that foster integration and enterprise connectivity. For instance, GE Healthcare's Life Sciences business and Emerson Process Management announced a collaboration aimed at increasing productivity and improving the process efficiency of biopharmaceuticals such as monoclonal antibodies and vaccines.

According to a recent press release, the two companies will collaborate to integrate Emerson's distributed control system with GE Healthcare's enterprise offerings and start-to-finish technologies for the global biomanufacturing industry. According to the companies, biopharmaceutical manufacturers are increasingly looking to automate production processes, driven by the industry need to increase efficiency and reduce costs.

GE Healthcare's Emmanuel Ligner said: "Healthcare providers and the biopharmaceutical industry are facing enormous pressures. Emerson and GE share a vision that an integrated and automated approach to manufacturing has the potential to help drive improvements in production efficiency of these life-saving medicines." These vendors believe that the combination of Emerson's automation technologies and GE's FlexFactory offerings will support "more predictable processes that eliminate unnecessary work, which translates into a reduced time to market for our customers."

A CMO INTEGRATES

Leading mid-sized contract manufacturer Losan Pharma is implementing Werum's PAS-X to support the production of solid dosage forms at its main plant in Neuenburg am Rhein, Germany. According to Werum, Losan is implementing a full-scope MES system that includes warehouse management and fully integrated Track & Trace capability.

Losan specializes in contract research and manufacturing of innovative solid dose forms for an enviable list of international pharma and biotech clients. Werum says its platform will be implemented out of the box in several stages as a full-scope MES interfaced with the Infor Blending ERP system. "The integrated Track & Trace functionality ensures a consistent flow of information from the ERP to the automation level. So we do not need an additional third-party product for serialization," says Dr. Marco Klingele, head of administration, Losan Pharma GmbH. "PAS-X will help us to significantly increase the efficiency and quality of our processes and provide our customers with even better products in an even shorter time."

SPENDING ON IT

Recently *Pharmaceutical Manufacturing* attempted to gauge spending priorities of those in operational roles by asking: "What sort of systems (associated with process/manufacturing operations) is your company investing the most capital dollars in on the shop floor?" Among the 121 responders, 47 percent indicated "Higher speed, higher-capacity processing systems and equipment to meet increasing product demand or new product production." About a quarter, 24.4 percent, chose "Adding process analytical technologies to existing lines to understand critical processes better."

In our 2015 study, fewer respondents seem to be working at organizations making investments in informatics and data managing technologies. Just 14.8 percent chose "Production-related informatics and process data acquisition and handling platforms." Lest we judge too harshly, these folks may be working for companies that already invested in IT and their responses indicate this segment of IT spending is no longer a priority.

"Industry trends," we asked, "reveal that to better manage the costs and expenses associated with drug manufacturing operations, managers are looking for innovative ways to shift from traditional capital expenditure models and turning to operational expense models in pursuit of operational improvements and new or extra capacity. Most of the converged offerings by the major players offer a host of opportunities to allow clients to take advantage of OpEx balance-sheet opportunities. Do *Pharmaceutical Manufacturing*'s readers agree that this is a strategy worth pursuing?" Two-thirds (63.8 percent) said yes, it's worth pursuing.

For those who answered in the affirmative we asked, "Where are manufacturing-related operating expense dollars being applied?" and asked them to please pick all that apply. "Information Technology systems and infrastructure (Outsourced IT providers), was the most popular choice at 41.7 percent.

While the results of the study provide only a snapshot how the industry is spending its money, it's clear that the industry continues to pursue operational excellence via this technological channel. But the benefits the community of technological vendors purports this connected utopian omniverse will deliver is still being viewed with a certain amount of reticence and skepticism by manufacturers of all stripes, including Pharma. But operational experience will win out and that's being gained every day. The connected enterprise is a technological reality now, and likely standard operating practice for years to come.

Deciphering Key Engineering Documents for Process Safety

Process safety information is fundamental to any PSM initiative

By Walter Kessler, senior specialist process safety, Chilworth Technology

In 1992 the Occupational Safety and Health Administration (OSHA) issued the Process Safety Management (PSM) program and required chemical facilities that contained over the threshold quantities of hazardous chemicals to comply with its requirements. The overall objective of the OSHA PSM program is to prevent or minimize the consequences of the catastrophic release of toxic, reactive, flammable, explosive or highly hazardous chemicals. One of the main aspects of this program is to keep and maintain the Process Safety Information (PSI) as "living" documents.

Process Safety Information (PSI) is a very critical building block of the PSM program. PSI must be correct and kept up to date so the employees in the PSM covered facility have the accurate and vital information they need to properly handle any highly hazardous chemicals, as defined by OSHA, in their facility. PSI contains numerous engineering documents that are critical for Process Safety. PSI forms the base arch between the two pillars of the PSM program to cover and protect the personnel under that PSM program arch. As shown in Figure 1, PSI is the basis and the key foundational building block for performing Process Hazards Analysis.

PSI is also the connecting block to other PSM elements, such as Pre Start-up Safety Reviews (PSSRs), Mechanical Integrity (MI) programs, Standard Operating Procedures and Training.

PSI is actually broken down into three categories: Chemical Hazards, Process Technology and Equipment and Specifications.

The first category, chemical hazards, is essential to have documented and available so everyone working in the PSM covered area knows and understands the hazards of chemicals they are working with. The Safety Data Sheet (SDS), formerly referred to as material safety data sheets (MSDS), for the materials or chemicals being utilized contains some basic information for health, flammability, reactivity hazards, fire-fighting measures if applicable, and what to do if there is spill or exposure to the chemical. The SDS also provides some of the basic toxicity information, permissible exposure limits, physical data, reactivity data, corrosivity data, thermal and chemical stability data. The SDS should be reviewed for updates, maintained and accessible to all employees within the organization. This requirement falls under the right to know clause of the Hazard Communications Standard (HCS), which is now aligned with the Globally Harmonized System (GHS) of Classification and Labeling of Chemicals. The Globally Harmonized System is an internationally agreed upon and accepted system that standardizes the information in the safety data sheets.

It must be noted that many types of information are normally employed in managing process safety. For example, information on the flammable properties, toxicity and reactivity of chemical substances, and on the compatibility of chemicals with each other and with the equipment is critical to the understanding of risk and determination of adequate risk control. Information is derived from data, and data must be validly obtained and appropriate to the situation. The validity of information should not be accepted without understanding the validity of the underlying data on which it is based. Additionally, data, and therefore information, can change with time and context. Operating conditions, material properties and contaminants, equipment characteristics, and processing sequences can all impact the validity of data for a specific use.

The second category under PSI is process technology, which contains all the vital process information including the:

- Block Flow Diagrams (BFDs) and Process Flow Diagrams (PFDs); process chemistry and operations
- Chemical inventories with the maximum intended inventory of each chemical listed
- Safe operating conditions of the process with upper and lower limits stated; and consequences of deviating from the specified limits.

Both OSHA and the Environmental Protection Agency (EPA) require that deviation from normal action steps be included in the operating procedures, where applicable, so they are more easily accessible to the process operators.

The third and final category, the equipment and specifications, contains the following information:

- Materials of construction
- Process & instrumentation diagrams (P&IDs)
- Hazardous (electrical) area classification
- Relief system design and design basis
- Design codes and standards
- Material and energy balances
- Safety systems — including all interlocks, detection and/or suppression systems
- Any Recommended and Generally Accepted Good Engineering Practices (RAGAGEP).

PSI must be complete, up-to-date, and maintained throughout the lifecycle of the process.

ENGINEERING DRAWINGS

Engineering drawings are also key documents and part of the PSI program. The drawings are a visual tool and present a graphical language that is used to fully and clearly define all engineered items within a facility. Through an engineering drawing, an engineer can communicate his or her ideas and convey information, very precisely and without ambiguity, to the workers and operators who will build, erect and operate the facility.

It is important that people can identify and correctly decipher the information in these engineering drawings as they are the fastest way to learn about a facility or process, learn how things work or function, build or fabricate the object or equipment, and troubleshoot potential problems within the facility.

There are four main types of engineering drawings: mechanical, civil, electrical and chemical. Mechanical drawings include general arrangement or plot plan drawings, assembly drawings, detail and fabrication drawings for equipment and isometric drawings for piping, conduit, etc. Civil drawings can include grading and concrete foundation drawings; landscaping drawings; and architectural drawings for buildings, bridges and other structures. Electrical drawings can include power/electrical lines; lighting and electrical schematics and communications drawings, which include DCS (Distributed Control System) and SIS (Safety Instrumented

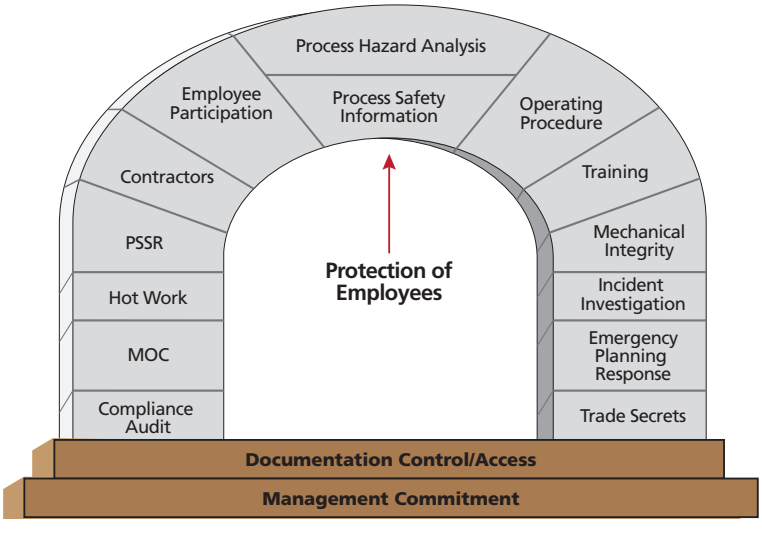


Figure 1: Process Safety Management Arch. Notice the location and therefore criticality of the Process Safety Information (PSI) block. It forms the bridge for the two arch pillars of PSM and also the core foundation for the Process Hazard Analysis for the process safety management system for the protection of the employees.

System) system drawings and electrical loop diagrams. Chemical and process drawings include BFDs, PFDs and P&IDs. With advances in CAD (computer aided drafting) programs, a lot of drawings have now become 3-dimensional drawings and depict actual plant layouts. Examples of all the types of drawings are shown in Figure 2.

After determining what type of drawing you are looking at and its purpose, a key factor in understanding any engineering drawing is to first look for the scale and a legend for the drawing. This information is usually found on the first page. The scale will give the relative size of the drawing to "real life."

Besides having an understanding of the legend, it also helps to understand what the symbol actually looks like in the plant or facility. This is very important from a construction and operational standpoint to ensure the right parts and equipment are installed in the correct position during the construction phase of the project. It is also helpful for the operators to have a better understanding of what they are controlling and how changes may impact the operation of the process.

It is crucial that engineers, operators and maintenance personnel know and understand what these valves do and in what type of situations each valve is best utilized for process control. It is also important to know what the materials of construction and various functional parts are from a process compatibility, inspection and maintenance point of view.

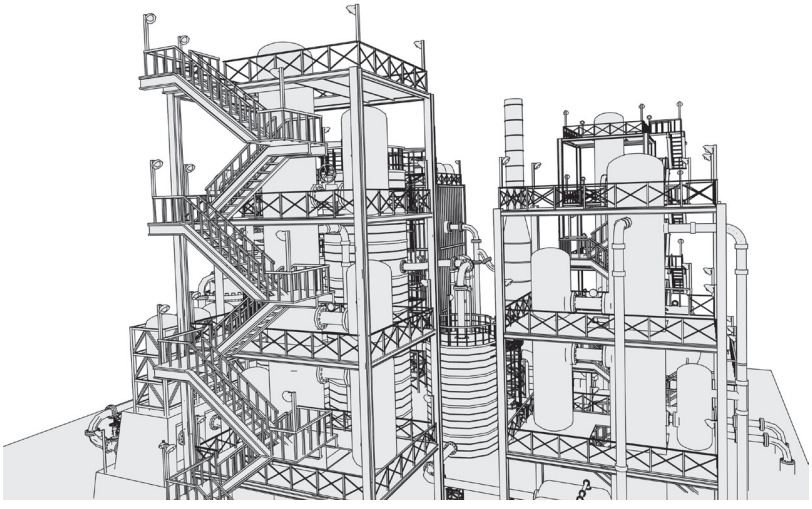


Figure 2: Example of 3D drawing.

The information contained in this short article is only to provide a little insight on the criticality and importance of process safety information and the knowledge and understanding of how to decipher key engineering documents. It is very important to remember that PSM programs contain "living" documents that must be developed and generated and kept up to date. These documents provide the required data for hazard identification and analysis review purposes before beginning fabrication and construction. It also provides information that can help with pre-start-up safety reviews, operation procedure development and training before starting the process, operation or facility.

Incomplete drawings can raise operation and safety questions, which may lead to stopping the PHAs and doing equipment walk-downs to confirm the process and operational procedures. Completed and up-to-date drawings help ensure that the process can be operated and run safely without the loss of containment or release of a hazardous chemical, which can impact personnel, the facility and the environment. Drawings are also valuable in training personnel on the process or operation of equipment. Familiarity of drawings can give valuable insight in investigations should an incident occur at the facility.

These engineering drawings and documents, all part of the PSM program, must also be maintained and updated when impacted by Management of Change (MOC) and other modifications made throughout the life of the facility. When changes are not documented and the engineering drawings and documents not updated, it may lead to both minor and major incidents with resulting loss of life, injuries and facility damage.

Understanding Engineering Drawings

There are generally six main steps to understanding an engineering drawing:

1. Identifying the type of drawing and its purpose.
2. Familiarizing yourself with the scale of the drawing (if applicable).
3. Identify the basic symbols on the drawing using the legend.
4. Identify the abbreviations.
5. Paying attention to the line weights, styles and colors.
6. Look for directional arrows, detail blocks and other marks.

Building Better Drug Submissions

Regulatory submissions are often managed using default email and fileshare tools, but a purpose-built solution provides advantages over this traditional approach

By Steve Scribner, principal consultant, EMC Corp.

Pharmaceutical manufacturers and similar life sciences organizations must keep current, complete records of all submissions and communications associated with drug applications submitted to regulatory agencies — both directly and through their affiliates. Access to complete records of exactly what was submitted wherever a company has applied to conduct business is essential. This includes related communications such as emails, meeting minutes and phone records. These documents are typically scattered across a variety of electronic document management systems (EDMS), laptops, collaboration spaces, email and shared drives — making a comprehensive view challenging.

The tools typically used for the archiving and retrieval of these items simply cannot meet today's business requirements. For example, companies need to respond quickly to agency queries, requiring immediate access to relevant, up-to-date information. In addition, regulatory compliance dictates that records are protected and access controlled — functionality not normally available with methods such as fileshare sites.

But there's a better way; namely implementing a purpose-built solution. For example, when working through this process, what if all of your regulatory submissions for medicinal products over time (paper, non-eCTD and eCTD) were centralized and easily searchable, allowing you to view all regulatory documentation and related activity at one time? What if you could look at various submissions for a product, select the one of interest and see all the submissions, queries, telephone calls, meetings and email exchanges along a single timeline?

This article will compare the two main ways of managing submissions to regulatory authorities: using fileshare tools and email, or with a purpose-built solution. Although the first method is perhaps more widely used, it has its distinct limitations. But before we look at methods for managing the records for regulatory submissions, let's examine the industry's current state of affairs in this area.

INDUSTRY RECOGNIZES CHALLENGES

The submissions management process is sure to increase in complexity. To get ahead of the curve — and in an effort to improve overall efficiency — companies are beginning to look for alternative approaches to managing regulatory information and communications.

In fact, the recent report "Managing Regulatory Information as a Corporate Asset — Industry, Health Authority and Vendor Trends" makes it clear that life sciences companies are revising their business and technology plans for global submission management. The report, based on an industry study conducted by Gens and Associates Inc., highlights an increasing focus over the next several years on health authority communications. As managing partner Steve Gens explains, "… global expansion is requiring consistency of interactions across regions. … The ability to provide consistent information across global health authorities is critical and difficult to achieve." Survey responses showed that only 40 percent have an authoritative source for health authority correspondence, indicating a need for additional IT investment in this area.

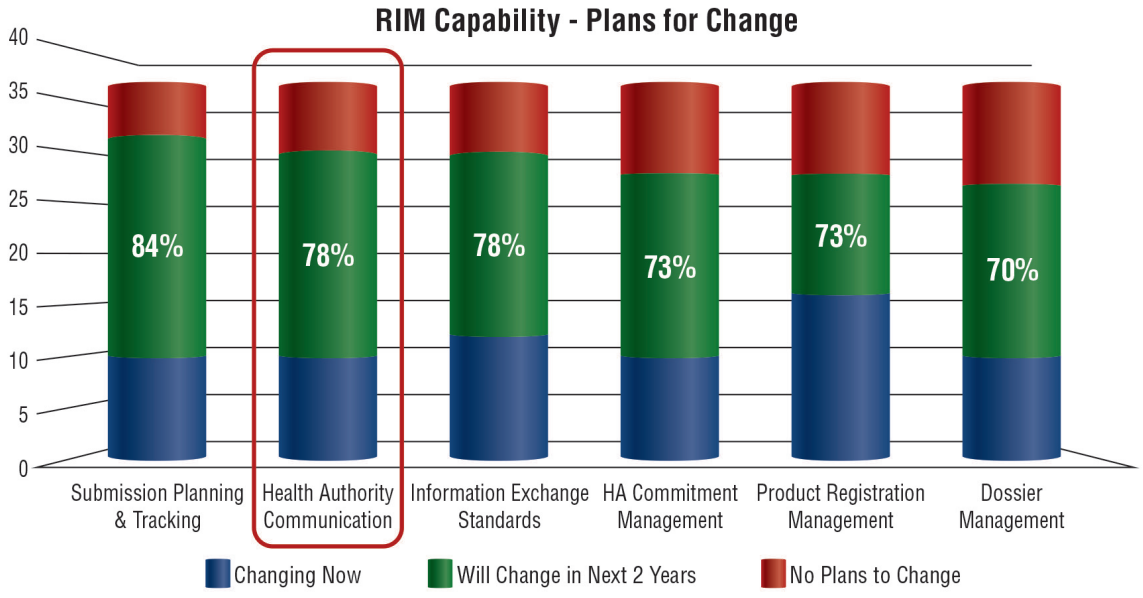


Figure 1. In a recent survey, 78 percent of respondents said they were looking to change the regulatory information management (RIM) system they use for health authority communication.

Thus, the drive toward a much more dynamic approach to information and communications management is an understandable development. "Global submission management is predicted to be the top area of change over the next two years," according to the report. Figure 1 from the survey shows the areas forecast for greatest change.

To meet today's complex business requirements, you will need a 360-degree view of all submissions, along with fast access to agency correspondence concerning every product that your company has in the market. Agency representatives will continue to assume that you, the sponsor of a given product, have visibility into everything submitted for that product, along with complete access to previous queries. And because most organizations store regulatory correspondence across multiple repositories, you will need a comprehensive view of all agency interactions in chronological order (Figure 2).

To fulfill these requirements, many companies have defaulted to email and fileshare tools, which are readily available, but more often than not have considerable limitations.

EMAIL AND FILESHARE ISSUES

Today, the most common way to share business information within a company, and among a company and its partners, is via email and fileshare platforms. With this method, information is shared among parties through email transmittals and fileshare sites. Emails are typically used for sharing smaller scale attachments such as Word and Excel files, while fileshare sites are used for larger attachments as these often exceed email system limits.

The main advantages of sharing information using email and fileshare sites are their familiarity, ubiquity and low cost. Virtually everyone is used to working with these basic tools, and most every company has the necessary software installed for email communications. Fileshare sites range from free to very low cost, although costs can climb rapidly as required features are added.

But sharing data via these methods has some serious inherent limitations, particularly for life sciences companies with respect to regulatory submissions.

Fileshare sites provide a convenient, consolidated

Why a Purpose-Built Solution May Be Right for You

- Works with information from a variety of sources
- Simplifies storing and viewing of submissions
- Speeds access to submitted information and related correspondence
- Highly secure
- Access controlled
- Built-in regulatory compliance features

location for pushing a submission to an agency through a gateway or via physical distribution. All current commercial publishing tools send their output there as a default. But these sites are intended to be temporary locations, not an archive of the submission. This approach prevents compliance with key business requirements, for instance, securely controlling all submission information for easy and rapid recall.

And there are other serious limitations. For example, these repositories are not capable of protecting the integrity of a submission with role-specific, version-control functions and audit trails. This functionality is necessary to comply with 21 CFR Part 11 for electronic records.

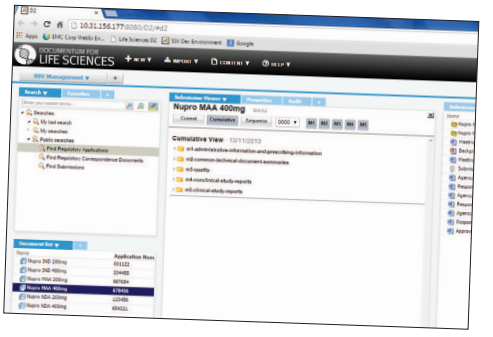
With email and fileshare tools, numerous agency queries and response documents, meeting materials and telephone conversation records are saved in emails, shared drives, laptops or collaboration tools. Responding to inquiries and keeping track of communications between the sponsor and the agency can quickly spiral into a complex, unorganized mess — with hours wasted searching multiple systems, and with repeated calls to affiliates asking for the latest information or status. Integrating all related correspondence thus becomes a serious challenge.

When you combine the constraints of email and fileshare tools along with highly fragmented correspondence management, the result is duplication of effort, inefficient business processes, and lack of confidence in the quality of information.

PURPOSE-BUILT SOLUTION

There is a way to overcome the limitations of email and fileshare tools, but it does require IT investment for software purchases, host hardware and training. This method relies on software running on the sponsor's servers, generally the life sciences company. This software can be internally developed, but it's more common to purchase a software solution from a third-party.

A purpose-built solution is more expensive upfront than using email and fileshare tools and it requires time to implement, but it has a number of advantages as listed in the table. These advantages will typically result in a lower total cost of ownership, more than justifying initial implementation expenditures.



A purpose-built EDMS can offer users a chronological view, providing an integrated look at all interactions.

To realize the advantages listed in the table, the selected purpose-built solution should have the following capabilities:

- An integrated chronological view with correspondence linked to the submissions, providing an at-a-glance look at all interactions to date.
- Import and store current as well as legacy submissions in eCTD (electronic common technical document), NeeS (Non-eCTD electronic Submissions) or paper formats.
- Make submissions navigable and viewable from the repository with functionality equal to a regulatory review (enabling the sponsor to see the submission exactly as the reviewer sees it).
- Provide standard eCTD views — single, current and cumulative — of the full regulatory submission lifecycle, including navigation of hyperlinks.
- Out-of-the-box integration with Microsoft Outlook, allowing users to drag and drop emails and attachments directly into the repository for automatic import.
- Archive submissions for long-term retention while providing easy

Figure 2. Regulatory submissions for life sciences plants must be prepared, submitted and tracked on a regular basis.

information search and rapid recall, fully in compliance with 21 CFR Part 11 for electronic records.

- Makes possible true closed-loop reporting between affiliates and sponsors so everyone knows exactly what was submitted, to whom and when.
- Search for archived submissions via faceted navigation or based on metadata properties such as product, country, submission type, manufacturer or date.

The correct solution should have all these capabilities, and it must also be flexible, dynamic and rapidly responsive to changing business conditions and requirements. For example, if regulatory agency requirements change, the solution should offer software updates to facilitate compliance.

STRINGENT NOW AND LATER

Regulatory submission requirements are stringent today, and will become increasingly so in the future. There are two main ways to meet submission challenges, but the default email and fileshare approach has serious limitations. Pharmaceutical and life sciences companies are therefore looking to implement purpose-built solutions, as these have the capability to meet regulatory submission requirements, now and in the future. These solutions are available in the marketplace and have existing successful implementations, so a good path forward is to contact and evaluate relevant supplier solutions.

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Cloud Computing in Pharma

It's never too late to reap the benefits

By Raju Singit, senior consultant, and Sridhar Murthy, senior architect, Infosys

Pharma is known for its late adoption of new technologies. The industry thoroughly studies risks, pros and cons, etc., before adopting any new technology. But now as companies are being compelled to streamline their process and reduce costs, they are finding new ways to optimize complex processes by adopting cloud computing. The benefits of the cloud "pay as you go" model, low capital investment and low run costs will drive innovation in products and bundled services quick to the market[1].

Over the last 10 years the technology industry has changed dramatically; there is advancement in technology, but the manufacturing industry is facing business challenges centered on improving performance of applications and infrastructure while controlling the cost of doing business. One ray of hope for controlling industry's mounting challenges is Cloud computing. Pharma enterprises are trying cloud analytics, automation and marketing, and exploring the benefits of emerging technologies[2].

Cloud software solutions are taking on several different tasks in the pharmaceutical industry. Its implementation can mean improving the quality of data to support sales, or providing practical ways for clinical trial site managers to communicate across wide geographic divides. It's also making it easier for companies to merge without the problems that invariably arise when data between disparate computer systems is aggregated[3]. But looking ahead, there are also some intriguing applications that involve combining the cloud with big data from public and private sources and applying analytics.

To make the best use of existing systems, the sales force needs the most up-to-date and accurate information about stocks of the product, physicians contact details, social media networks they favor, whether their practices are accepted and help in avoiding duplications.

In addition, sales force shares databases that are helping drug developers and manufacturing identify principal investigators. Principal investigator contact details used to be considered proprietary information. Regardless, there are a number of risks and challenges Pharma faces when it comes to adopting cloud-based computing solutions:

- Data/Information Security (VPN and Encryption) because the industry is highly regulated.
- The other risk to be considered is service providers as they don't understand Pharma security[4] and regulatory requirements.
- Data migration problems when changing the cloud provider (security validation, etc.), since the validation of the system involves rigorous process.
- Surveillance of the Internet; due to spying on people's private data, the regulatory agency will come under pressure to do more to protect private data. The agency will tighten data protection laws. They will come out with strong solution information technology so the industry can offer alternative ideas to be explored, like secure cloud computing and better links between technologies.

- Requirements on GxP - The service provider offers capabilities to facilitate the validation of a Pharma-specific solution using the cloud service. The validation remains; accountability of Pharma needs to be defined in a validation plan[5].
- Risk Management - legal, compliance and reputation risks. Vendor transparency and audits are a "must." Cloud vendors leaking, breaching, losing, damaging, or impeding access to various types of sensitive or valuable information.
- Operational risks - IT security, performance or availability with strong encryption, access control, monitoring and physical separation of resources.
- Security incidents - most logs and documentation is in the control of the cloud provider. The cloud user will rarely have access to this data to determine security incidents.
- In shared environments the irreversible erasure or anonymization of data is difficult, and since the cloud user has not had access to the computing environment, it cannot be verified.

MITIGATING THE RISK; ADOPTING THE CLOUD

Those in Pharma looking to adapt cloud technologies can avoid risks by setting clear qualification and validation goals to help manage these risks and provide auditable evidence of how this has been done.

Best Practices for risk mitigation include:

- Data protection and encryption.
- Segregate operations with respect to GxP, SoX, business confidential data.
- Regulatory compliance.
- Virtual machine level security.
- The GAMP (Good Automated Manufacturing Practice) forum could provide guidance on Infrastructure Qualification, as well as validation of applications risks around security need to be identified, managed and documented.
- Differentiate the regulatory and security requirements to manage financial, legal and IP data from what the regulators require of GxP.
- To maximise effectiveness and minimise risk (and ultimately cost), security and privacy must be considered from the outset of any cloud implementation not after implementation and deployment
- There should be careful evaluation of sensitivity of data being managed and its security (like clinical trial data) with due consideration.
- The service provider needs to be frequently audited, like any other contractor, to have quality of service and well maintained documentation with respect to GxP requirements.

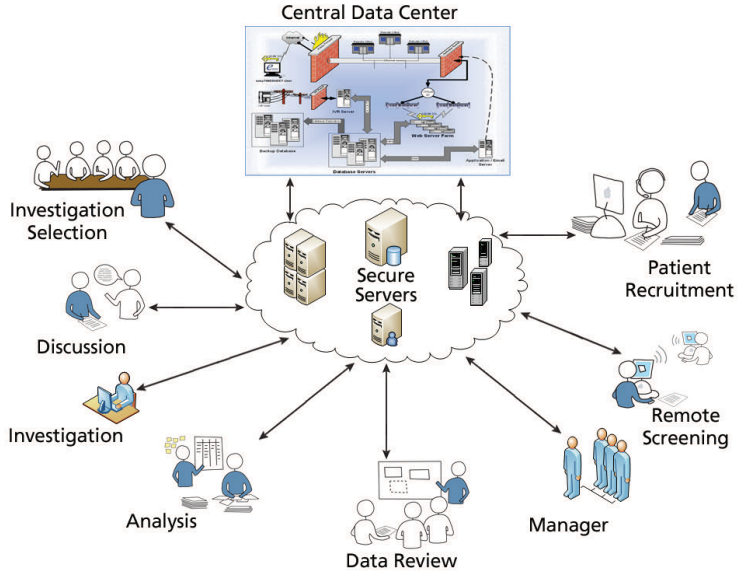

Figure 2: SaaS solution for Clinical Trial.

CLINICAL TRIAL SUCCESS

Clinical trials are an organized set of tests in medical research and drug development conducted on human beings to provide adequate information on its intended use as a therapeutic agent including its safety, efficacy data, and adverse effects on human-beings[6]. Clinical trials are conducted only after satisfactory data has been gathered on the quality of the nonclinical safety, and health authority/ethics committee approval is granted in the country where approval of the drug or device is sought. A trial must be conducted according to a protocol that describes the objective, design, methodology, statistical considerations and organization of the trial. An electronic document designed to record all of the protocol-required information to be reported to the sponsor on each trial subject. During a clinical trial, data privacy of the patients is to be maintained as per Good Clinical trial Practice.

ELECTRONIC DATA CAPTURING SYSTEMS

Case report forms are manually filled at site and mailed to the company for which the trial is being performed. The data on forms is transferred to the Clinical Data Management System (CDMS) tool. The most popular method being double data entry

where two different data entry operators enter the data in the system independently and both entries are compared by the system. In the case where the entry of a value conflicts, the system alerts and a verification can be accomplished manually. The data in CDMS are then transferred for the data validation.

Many drug manufacturers are using Web-based systems for capturing, managing and reporting clinical data. This not only helps them in faster and more efficient data capture, but also speeds up the process of drug development.

SCALABLE AND COST EFFECTIVE CLINICAL RESEARCH SERVICES

Previously, enterprises had to buy or build and maintain sophisticated IT infrastructures, incurring great costs in the process and required to support all kinds of application from web to legacy systems. Software-as-a-service (SaaS) computing also can provide an effective alternative, and enterprises can now plug-in and utilize software services whenever they need them, use them for as long as they need them[7].

A system that can deliver clinical solution as a SaaS with an on-demand approach is best suited for the pharma needs. This system can rapidly and efficiently deliver the core value of the clinical research application with the ability to capture, manage, share efficiently and effectively across thousands of investigators and among all stakeholders will help reduce the time for the whole clinical research cycle.

Employing the SaaS model can help reduce necessary investments, dedicated IT resources and other expensive IT infrastructure. With the inherent features of software solutions distributed in the cloud, one can expect the following advantages:

- On-demand service across geographic areas
- Dynamic computing resources
- Rapid scalability
- Lower operational costs
- Increased security such as PCI DSS, HIPAA, SOC2
- Measured services
- Fault tolerance
- Disaster recovery and business continuity
- Uptime

There are various advantages for the pharma and biotech industry in utilizing Cloud computing. It is about choosing the right solution which can offer them the balance of data protection, structuring and maintenance of data.

KEY BENEFITS

It provides seamless and transparent integration with database, middleware, web frameworks, security and virtualization services. Platform-as-a-Service (PaaS) significantly improves developer productivity by removing integration challenges inherent in a traditional software development model. Additionally, shorter software development lifecycles or faster delivery times are possible with PaaS since software development and testing can be both performed on a single PaaS platform as opposed to maintaining separate development and test environments for in-house software development.

Dynamically scale up or scale down computing resources with changing demand levels. This ability to rapidly configure and scale computing, storage and other infrastructure resources on-demand, as opposed to buying more infrastructure capacity than needed upfront in anticipation of future growth, is what makes this delivery model so compelling in nature.

SaaS allows companies to do what they are good at, i.e., research, develop and manufacture medicines to manage applications and data. But SaaS can't evaluate and manage suppliers and hold them accountable for fixing problems. As with most all regulated computing applications, i.e., 21 CFR Part 11, electronic records are to be as trustworthy, reliable and generally equivalent to paper records. Classifying the data into Infrastructure-as-a-Service (IaaS), Platform-as-a-Service (PaaS) and Software-as-a-Service (SaaS) will benefit the pharma industry at large.

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Optimizing Global Engineering Efficiency

Across major geographies, under-budget projects are the exception rather than the rule

By Andy Weatherhead, manager, global engineering, Rockwell Automation

Globalization and disruptive technological advancements, such as virtualization, cloud and big data, are continually altering the industrial landscape. To succeed, innovative companies must re-envision where and how they do business so the right resources are applied regardless of their location. In the past decade, concepts like virtual teaming and multi-office execution began to play major roles in the operating strategies of engineering, procurement and construction (EPC) and global engineering firms. Offshoring is no longer isolated to manufacturing, data processing and call-center positions, as a growing number of firms move engineering, design and development work overseas as well.

IN PURSUIT OF COSTS TO CUT

Cost reduction is a primary driver for these moves and a top concern for both facility owners and EPC contractors, given today's complex global environment. To further minimize costs, many owners also are tightening requirements for EPC contractors — they want firms to assume more risk while meeting tighter project schedules.

On top of cost pressures, the increasing difficulty of finding qualified engineering personnel looms large for owners and EPC firms. After all, even the most advanced virtual teams and multi-office capabilities cannot succeed without the right people in place.

The skills shortage has received significant visibility in developed regions, such as North America and Western Europe. This deficit is driven by trends, such as downsizing, EPCs refocusing on core competencies other than automation, and the increasing wave of retiring baby boomers. The growing skills scarcity even extends to newly advanced economies, such as China. While that nation graduates large numbers of engineering students annually, too few highly trained and qualified personnel are available to fill the requirements of process industries.

Companies are implementing multiple strategies to simultaneously reach cost-reduction goals for capital projects, while finding experienced and qualified personnel to execute projects, and operate and maintain their plants, including :

- Teaming with automation suppliers to provide this knowledge and fill the skills gap.
- Sourcing engineering services globally.
- Tapping global virtual engineering teams for around-the-clock engineering support.
- Locating services close to the project location or equipment and vendor locations.

The global nature of many of these strategies means that execution will necessitate collaboration from locations with varying levels of IT infrastructure, different engineering tools and best practices, diverse engineering backgrounds, and varied industry domain expertise — not to mention cultural and communication differences. The reality is that most companies do not have the proper tools and infrastructure in place to effectively address these complexities.

Overcoming these project challenges overwhelms some manufacturers. The 2012 PricewaterhouseCoopers (Global

Project Management Survey) found that "poor estimates/ missed deadlines" was the greatest factor contributing to poor project performance. Additionally, research found many of these projects exceed budgets by at least 50 percent.

Investing in front-end engineering and design can help companies overcome project cost overruns, as well as help develop a detailed project scope, budget and timeline to reduce risk and uncertainty during a project's design and commissioning phases. Trusted third-party service providers can help companies navigate complexities related to global project execution through the entire project lifecycle. Rockwell Automation, for example, relies upon a unified, flexible work environment comprised of a standard delivery toolset embedded with domain expertise, rigorous project methodology and detailed governance processes. Regardless of a company's access to qualified talent or location, this approach helps minimize risk and drive efficiency and consistency into projects.

The QMS helps reduce any inconsistencies in project delivery and reduces project risk via quality gate reviews and risk assessments.

GO HOLISTIC

Industry libraries: a core element of effective execution. Companies embarking on global projects face a myriad challenges related to schedules, start-up time, cost, productivity, quality and safety. Overcoming these challenges can be difficult. In their quest to deliver consistent project outcomes, many engineering companies rely on industry libraries containing engineering content. These standard software modules of industry functionality are critical for standardizing complex designs in a repeatable way. Industry libraries are just one element to successful project execution — a holistic approach also includes project methodology and governance processes.

With most large organizations that deliver automation solutions, engineers are designing and implementing solutions for multiple customers around the world on turnkey projects that require the coordination and management of the scope from multiple vendors, and for the same customer at multiple locations around the world. (See Figure 2)

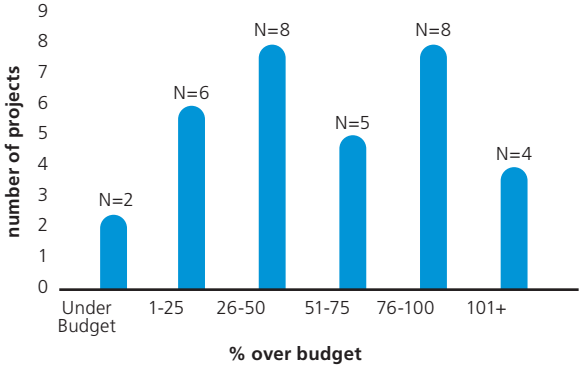
In the past, it was standard practice for two developers to design the same software module in different ways. The process can be simplified if the developers instead agree upon the fundamental function and desired output. Then the code is consolidated into a standard, repeatable solution that can be stored and re-used in the future. The library grows as multiple, repeatable functions are defined and stored.

Creating libraries of content drives efficiency in engineering because developers can reproduce code automatically rather than starting from scratch or re-testing the same code multiple times. In addition, global engineering teams can tap into industry-specific domain expertise, regardless of who is executing the project. This efficiency and access to expertise drives repeatability, scalability and a higher quality standard.

The process and quality standards involved in creating a robust library are critical to success. When a re-usable piece of content is identified, multiple domain experts must help define fundamental requirements and contribute their domain expertise to understanding broader requirements as well. Additionally, all library content should undergo a rigorous lifecycle-management process. Content is continually refined and updated with each project, which means end-users not only benefit from schedule improvement inherent in using a library approach, but also receive better quality and a reduced risk profile.

Project Methodology: Creating a Common Work Environment. A well-defined project methodology is critical to consistently and efficiently develop a robust

NUMBER OF PROJECTS WITHIN COST OVERRUN CATEGORIES



Source: "Insights and Trends: Current Portfolio, Program, and Project Management Practices." 2012. PricewaterhouseCoopers LLP

Figure 1

library, and apply it to customer-specific applications. For Rockwell Automation, a common, flexible work environment serves as the foundation and a single point for engineering data.

The traditional approach to engineering involves gathering inputs from a customer, writing a functional specification, designing, writing application code, testing and commissioning. Multiple sets of data are maintained throughout various stages of the project. When new or updated data comes in, it is generally only applied to the current deliverable, which has a ripple effect, and can erode quality and affect timelines.

By using a common work environment, there is a single source of data used to create and update customer requirements, which improves consistency of output, improves data quality and minimizes risk. Standardized engineering content from industry libraries is available within the tool. A collaborative environment allows engineers — including contracted engineering resources — to access this content and work concurrently. Plus, a common database for the project is updated automatically.

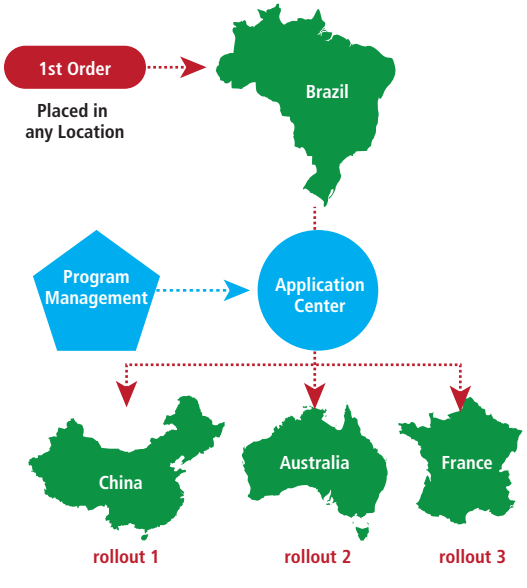
Global teams can design and develop the control strategy and work independently to increase delivery speed. For example, an engineer at a pharmaceutical plant in Mexico designs and debugs a bioreactor unit's operation controls, as an engineer in India works on the site's process control platform. All the while, a hardware engineer is working on hardware design, testing and procurement to support the deployment of the application. The company's lead engineer then takes the results from all sites, and can integrate them remotely with minimal effort. This approach creates a consistent output based on industry best practices and domain expertise, and drives standardization across teams, locations and knowledge levels.

Engineering outcomes can vary from project to project, and industry libraries can include a variety of content — such as process control code, visualization information, documentation and testing — all scalable across geographies. Using a common work environment also helps automate the capture of project requirements more accurately, regardless of the outcomes. Data, such as configurations and alarm limits, is gathered electronically and automatically input into the work environment accessed by engineers throughout the project. End-users save time and money because the engineering content being applied to their project already has been tested on multiple projects and refined along the way.

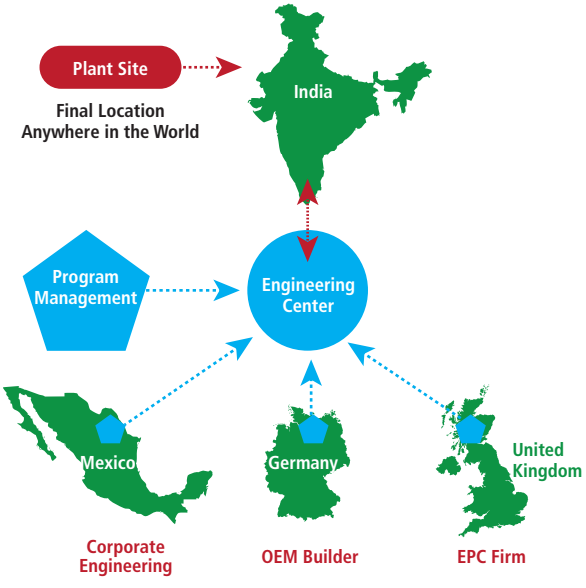
CONSISTENTLY MANAGING QUALITY

Rockwell Automation's approach to global project execution is supported by delivery standards and processes governed by a quality management system (QMS) that helps minimize risk by driving quality through the project process. This system regulates how project deliverables are

DELIVERING SOLUTIONS AROUND THE WORLD



Same Solution / Mulitple Rollout Sites



Single Site / Multiple Stakeholders

Figure 2

defined and specifies the procedure for executing them.

Every engineer is required to follow the QMS and processes in place when executing work to help embed consistency across all projects. This includes following defined work instructions for key process steps, using templates for engineering deliverables, and using defined work packages when transferring work to regional centers for customization. To further reduce risk, project teams participate in quality gate reviews and internal audits of active projects.

The QMS helps reduce any inconsistencies in project delivery, helps ensure a standard deliverable that fully meets the end-user's expectation, and reduces project risk via quality gate reviews and risk assessments. To use a consumer example, if a customer is buying a car, both parties will naturally expect a vehicle that will move them from Point A to Point B. However, there are many questions related to how this will happen. Will they have control over shifting? Will there be air conditioning? Will the windows roll down automatically? These questions need to be answered ahead of time — and the functionality of each individual "extra" needs to be clearly defined.

The QMS helps eliminate any gray area. For example, if the buyer wants air conditioning, there is no need for the buyer and the dealer to discuss how air conditioning is defined. They both know what to expect, and there is a standard deliverable.

THE HOLISTIC APPROACH IN ACTION

Industry challenges related to regulatory compliance and speed were particularly important in a recent project executed by Rockwell Automation for G-CON, a builder of biotherapeutics-manufacturing facilities. The holistic approach to project execution helped overcome these challenges.

PODs provide flexible manufacturing environments for both new and traditional therapeutics.

Traditionally, drug manufacturers have built inflexible and expensive production facilities that take three to seven years to complete and even longer to validate for production. With the advent of single-use technologies and process improvements, a paradigm shift is occurring, making such large-scale facilities a thing of the past. Instead, modular, scalable, flexible manufacturing solutions are the industry's goal. G-CON created the POD platform to respond to this need.

G-CON and Rockwell Automation collaborated to develop a severely compressed schedule that called for many steps to occur simultaneously. The POD concept was key to making this tight schedule a reality. While the shell of the facility was under construction, the downstream process PODs were built and commissioned at G-CON's neighboring manufacturing facility.

The Rockwell Automation life sciences toolkit of engineering content made rapid development of "smart" systems within the POD possible. Additionally, they were able to train G-CON's engineers on how to use the toolkit, allowing them to take advantage of pre-validated code. The common work environment made it possible to codevelop new applications and products remotely from multiple locations. The Rockwell Automation QMS mandates that all documentation aligns with GMP guidelines for the life sciences industry. The team was able to reduce testing time and validation costs, further impacting the ability to deliver the project on budget and within a tight timeline.

CONFRONTING REALITY

Many manufacturers today are confronting the reality that they lack the proper tools, personnel and infrastructure necessary to successfully navigate the complexities inherent in global project execution. Finding the right help and enlisting firms that subscribe to a holistic methodology will help manage risk while breathing efficiency and consistency into far-flung projects — regardless of their geography.

Pharma 4.0 – Quality Management in the Digital Age

An operational approach that connects all resources via the Cloud can be a really good thing

By Ethan Smith, senior director, Vault QualityDocs, Veeva Systems

Rapid changes in molecular science have ushered in a new era of innovative biopharmaceuticals. The emergence of targeted therapies, the increased prevalence of large molecule medicines, and huge growth in the number of treatments for orphan diseases are just some of the factors that are having a significant impact on how medicines are created and manufactured on a large scale. Life sciences companies are replacing the one-drug-fits-all approach for average patient populations with more personalized therapies. In fact, 42 percent of drugs in the pipeline today are personalized medicine, according to a survey by the Tufts Center for the Study of Drug Development.[1]

These specialized drugs that give smaller patient groups the best therapies based on their genetic makeup and other predictive factors are replacing blockbuster mega-drugs designed to treat larger populations. For instance, the few drugs used to treat high cholesterol in the past have since splintered off into many targeted therapies based on the genetic variables of specific patient populations. This approach springs from discoveries in genomics — the structure, function and mapping of human genomes — and it's giving rise not only to targeted therapies, but also to highly specialized diagnostic tools and personalized therapeutic drug monitoring.

A powerful example of personalized drug development in oncology is Zykadia, an inhibitor designed for patients with advanced non-small-cell lung cancer who have a specific gene mutation that causes tumors to become resistant to existing treatment. The drug, developed by Novartis, is targeted at very specific patient populations. The approval was lauded by the FDA, whose director of the Office of Hematology and Oncology Products noted, "today's approval illustrates how a greater understanding of the underlying molecular pathways of disease can lead to the development of specific therapies aimed at these pathways."[2]

VAST POTENTIAL FOR TARGETED DRUGS

Due to the enormous potential of these therapies, the White House has requested an initial budget of $215 million for its precision medicine initiative. President Obama believes "the possibilities are boundless" for specialized drugs, and his administration aims to collect genetic data from one million Americans so scientists can develop therapies tailored to individual patients.[3]

In response to the shift to targeted drugs, many large life sciences companies have started to diversify their product portfolios to include these medicines. One powerful motivation for this change is financial returns from traditional drugs are shrinking in the face of increased competition from generics. Nearly 88 percent of prescriptions are now filled as a generic in comparison with just 49 percent in 2000.[4]

While specialized therapies can produce better

outcomes for patients, they also present manufacturing challenges. For example, targeted biologics are typically larger than small-molecule medicines and are often derived from living cells, resulting in significant challenges to manufacturers. Personalized medicines are typically made in small batch sizes and have a wide variety of product variants. Small-batch production can be cumbersome because after every production run, equipment must be stopped, reconfigured, tested and validated before the next batch can be produced. The downtime from such stoppages impacts efficiency and time-to-market. The FDA has tried to address batch-to-batch quality requirements for years and plans to provide incentives to companies that raise manufacturing quality. When it comes to regulating small batch sizes, documentation is especially critical because it helps capture a detailed picture of each step for staff and outsourced teams globally, and for inspectors.

Accessing information stored in the cloud via smartphone enables managers to work more efficiently by reviewing quality content and data virtually anywhere.

CHANGE IS ESSENTIAL

Life sciences companies that don't make changes to stay at the forefront of targeted medicines will struggle. A major part of those changes is revamping operations by implementing "Pharma 4.0," a concept which has the potential to revolutionize drug manufacturing from the inside out.

Pharma 4.0 is an operational approach that connects all resources — human, informational and technological — in one virtual network. This connectivity extends from within the company to beyond its walls and combines diverse technologies such as cloud computing and big data analytics. Pharma 4.0 helps companies transition from robust but inflexible mass-production processes to more agile, highly automated methods that create tailored products quickly and cost effectively.

In contrast to Pharma 4.0, many life sciences companies still store and disseminate manufacturing information on paper. This increases risk and slows down quality-control processes by limiting knowledge sharing and hindering collaboration among employees and partners alike. The latest cloud-based content management applications free managers to quickly route quality content and data throughout the entire company and vendor ecosystem using an efficient system for review and approval. Because all data are in cloud-connected systems, staff have the visibility and access they need to monitor key performance indicators, guide the manufacturing process, and respond to incoming patient data that triggers the production of personally tailored medicines.

Pharma 4.0 also aligns with the business world's migration away from the desktop to the flexibility of mobile devices. Accessing information stored in the cloud via smartphone, for example, enable managers to work more efficiently by reviewing and approving quality content and data virtually anywhere.

In recent years, scientists' deepening understanding of the biologic causes of disease has created unprecedented opportunities while simultaneously changing many aspects of drug development. There is huge potential for personalized medicine to revolutionize the treatment paradigm for patients, but the development of these increasingly precise treatments is also highly complex, resulting in changes in the way medicines are identified, studied and manufactured. It requires nothing short of an operational transformation from the outbound flow of goods to the information flow back of real-time patient data. Such a drastic change can lead to disruption and uncertainty, at least for a time. But by adopting Pharma 4.0, companies can successfully evolve and safely manufacture high-quality, precisely tailored medicines that give patients better lives. PM

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Bringing Mobility into IT Strategy

Flexibility of operations and performance agility add new dimension to Pharma IT strategy

By Chetan Pathak, corporate operations director, Tectura

Pharma is undergoing tremendous changes on many fronts. Stringent regulatory hurdles, evolving health care programs and faster delivery are putting more pressure on pharmaceutical companies to adapt to new technologies to mitigate the current and future challenges. Increasingly these companies are fine-tuning their IT strategy to build up a seamless operational ecosystem in which transparency in operations becomes a key driver for enhanced productivity. As technologies evolve, the pharmaceutical companies look into the latest trends in IT innovation and aspire for bringing them into practice.

As mobile adoption progresses, pharmaceutical companies are leveraging the technology to empower their employees with smart mobile apps to work with greater flexibility. The frontline workers of a company have already experienced the maximum benefits of enterprise mobility. As innovations in mobility space are evolving faster, the transition from a desk-mode job to mobile workers has captured the imagination of pharmaceutical companies. Today, these companies are briskly moving into a mobility ecosystem to engage employees with a seamless work culture that never stops after office hours. Even in production, inventory, warehouse and quality control mobility plays a major role by bringing in flexibility in the decision-making system.

ROLE OF MOBILITY IN PHARMA

Today, with the pressing needs of business, the pharmaceutical companies are bracing themselves for developing seamless technology capability. With disruptive innovations in mobility space, the pharmaceutical companies are ready to integrate mobility into their enterprise solution. Agility of business communication, minimized or zero paperwork, increased employee productivity, augmented operations, improved production control, and data-driven business decisions are the key benefits that compel pharmaceutical companies to "go mobile" at the enterprise operations level.

While mobility becomes a priority in IT strategy, pharmaceutical companies ensure that the mobility strategy gels well with their core enterprise-level applications such as ERP and CRM. Developing a mobility strategy on ERP and CRM can facilitate efficiency in operations. When mobility enters into the IT strategy, pharmaceutical companies enhance the process automation, increase the agility of operational workflow, shorten process cycle, and help managers make intelligent decisions faster. For instance, in operations, a mobility solution built upon ERP can reduce the time lag in the decision-making process.

Integrated messaging is an indispensable part of the CRM system. With advanced mobile messaging, personalized communication with customers can be more pertinent from a business point of view. Businesses can focus on data-driven mobility services on top of CRM. Customer intelligence can be a prime driver for pharmaceutical companies to concentrate on their mobile strategy. Better customer analytics derived from customers' collective knowledge and understanding can notice a sea-change in the real-time

services. Mobility can expand from the organizational silos to seamless customer engagement thereby bringing in more value to the overall customer strategy of a company. With mobility in place, consumer needs can be more predictable. Pharmaceutical companies realize that mobility can drive better customer engagement and deliver powerful insights into customer preferences and can help them deliver better products with faster market turnaround time. Pharmaceutical companies can adopt mobility to devise an integrated approach to drive sales efficiency, improve customer experience, increase productivity and optimize ROI. Mobility on CRM provides huge opportunities for the pharma industry to improve sales and increase productivity. For example, the field forces gather market information and forecast demand based upon direct interaction with doctors, retailers and distributors, which can provide instant insights to the production staff via a mobile solution.

ENHANCING PHARMACEUTICAL VALUE CHAIN

From drug discovery to manufacturing to distribution of drugs, the pharmaceutical value chain is quite complex. Each stage has its own challenges. Mobility has a great potential to improve the pharmaceutical value chain. Pharmaceutical companies can achieve operational agility and lower operational cost by introducing mobile technologies in their enterprise operation. Mobility can "smarten" the decision-making process in the pharmaceutical business by providing real-time insights. It can improve the productivity on the shop floor as well as in field operations. For example, a pharmaceutical manufacturer can analyze why a particular drug is selling better in a specific location and not selling in another location by engaging the stakeholders in the value chain — distributors, retailers, doctors and patients — through a mobile application. Similarly, a pharmaceutical manufacturer can compare the performance of two different plants on the fly by connecting the employees via a mobile app integrated with ERP. The information agility can help pharmaceutical companies to make decisions faster and build a collaborative ecosystem to improve operational excellence, which brings a competitive advantage to the company.

IMPROVED VISIBILITY

Traditional business applications inherently carry the limitation of space-time availability, which restricts the companies to leverage the full potential; whereas the enterprise-level next-gen business solutions such as CRM and ERP having mobility capabilities can offer a wider platform for pharmaceutical companies to access information anytime, anywhere. Having access to critical business information, executives of different departments can make faster decisions. Most importantly organizations banking on mobile CRM have improved customer relationships. A 360-degree view of customer interactions can lead to superior customer engagement. It's not only the customer-centricity that drives the benefits, but also the collaboration among employees and other external stakeholders offers a powerful ecosystem for improved visibility across the organization. Similarly, a mobile ERP can allow the stakeholders in the extended supply chain to access the real-time information on the fly. Improved visibility can help pharmaceutical companies to make the right decisions at the right time.

ENHANCED PERFORMANCE AGILITY

Whether employees work on a production floor or in field, their performance largely depends on enterprise facilitation. Having enterprise mobility IT strategy, pharmaceutical companies can reduce the information lag across the organization. For example, a problem on the production floor can immediately be flagged to the respective stakeholders by a production executive. As mobility curtails the accessibility hurdles, an instant response from the responsible authority can be expected. Similarly, in customer service, promptness of response has significant impact on the customer experience. According to a report published by Gartner, global CIOs prioritize on mobile CRM to build agility in the system. In the fields of marketing, sales and customer service, mobile CRM offers real value to organizational growth. The level of convenience and portability delivered by mobile CRM is remarkable. With a faster decision-making opportunity, companies can provide quality service to their customers. Agility builds faster response to customer queries, which in turn develops improved performance.

INTEGRATING A SUCCESSFUL STRATEGY

The success of integrating mobility into IT strategy depends upon how the enterprise-level applications like ERP and CRM are seamlessly unifying various functions in the pharmaceutical industry. From decades of experience in implementing ERP and CRM solutions across numerous global pharmaceutical companies, Tectura believes that building a mobility platform along with enterprise-level applications has significant competitive advantages for pharmaceutical companies. Since pharmaceutical companies are facing significant challenges in drug discovery, manufacturing, operations and distribution, it's the right time to adopt mobility in their enterprise IT strategy to accrue big benefits.

Avoiding Collaboration Failure in Bio Pharma

Is it possible? With the Cloud it is.

By Matt Hahn, Ph.D., senior VP and CTO, Dassault Systèmes BIOVIA

With the drug patent cliff continuing to cast a long shadow over biopharma, the industry is radically reinventing itself by embracing globalization and focusing on innovation and operational excellence. Most importantly, biopharma organizations are expanding externalized collaborative relationships beyond traditional boundaries and creating flexible networks of researchers — some in-house, others with industry and academic partners, research institutes and contract research organizations. These networks are increasing in size and complexity with many combining numerous partners with diverse project objectives. Externalized projects like this raise important data security and project management challenges.

Partners need to exchange scientific data pertaining to chemical and biological structures along with information resulting from experiments, biological assays and ADMET studies. In a world used to doing this through some form of document management or file exchange, incompatible data formats have become a significant issue, along with the need to prepare and curate files manually and meet required data quality standards. Multi-partner teams struggle to produce common views and reports on project data with time-consuming and error-prone reporting often resulting in poor decisions. Finally, today's collaborations are fluid, and many companies struggle with the dynamics of project lifecycles, where quickly spinning projects up and down is a requirement.

Working in a cloud-based information management and collaboration workspace provides a level of business agility and security that is not available with server-based, on-premises infrastructure. Operating in the cloud means organizations can get up and running in days rather than weeks or months, and with minimal IT involvement. Most importantly, by sharing a common collaborative space, scientists can spend less time performing mundane data preparation and manipulation tasks and can focus more closely on the scientific aspects of their project workflow.

Understandably, data security is top of mind for organizations collaborating in the cloud. Existing standards like the ISO/IEC 27001 certification standard for information security management can help ensure that cloud-hosted systems offer strong data safeguards for globally networked drug research.

SUPPORT THE END-TO-END PROJECT LIFECYCLE

From rapid project spin up through supporting research workflows and ultimately, closing out a project, the cloud workspace supports end-to-end collaboration dynamics throughout the project lifecycle. New collaborations and individual partners can be added and removed quickly. All data is live and data exchange occurs in real time. The security model should protect each participant's intellectual property while controlling and auditing access and ensuring that all project team members see only the information they need and are authorized to access. Intellectual property should be held in a secure "neutral zone" until

ownership is clear. This is important because there are many contractual models for collaboration and some do not resolve the ownership of intellectual property until final results are known. Finally, the cloud system should connect with in-house systems to enable data synchronization with existing on-premises applications, enabling scientists to see in-house and networked data from their preferred environments.

With no software to manage and no hardware to maintain, organizations gain improved operational excellence in globally networked research with significantly reduced IT cost and effort through the ability to access integrated hosted applications supporting a range of scientific workflows.

- **Collaborative Project Management.** Virtual teams should be able to access, search and share real-time project information and stay in touch using social networking.
- **Experiment and IP Capture.** The system should include a low-cost-of-ownership electronic lab notebook that enables sponsors and network partners to share experimental methods and results.
- **Custom Business Rules and Integration.** The system should facilitate the creation and management of scientific services, implement standard business rules and enable integration between cloud and on-premises systems so that data flows from one environment to the other.
- **Data Analysis and Visualization.** The system should include scientific analysis, visualization and charting capabilities, enabling scientists to construct and automate informative workflows from pre-built services in chemistry, biology, imaging and other scientific domains.
- **Publishing and Sharing Services.** Ideally, a hosted collaboration space should function as an open portal where team members can publish and share scientific services, best practice approaches and research tools within the larger scientific community.

For many organizations, cloud adoption will be a staged process in which scientists collaborate using both in-house (on-premises) systems and a hosted collaboration system. The cloud workspace should support this hybrid environment in which data flows between on-premises and hosted applications. For example, a design team should be able to start an experiment in an on-premises ELN and then transfer the information to the cloud for execution at a partnering organization; or molecules registered into a cloud database should be automatically synchronized into an organization's on-premises corporate registration system.

THE EUROPEAN LEAD FACTORY

A cloud-based collaboration workspace is currently being used by the European Lead Factory (ELF) project — a pan-European drug discovery consortium of 30 commercial and academic partners. Backed by the Innovative Medicines Initiative (IMI), the goal of the project is to facilitate the collaborative, high-throughput screening of previously safeguarded, high quality corporate small molecule compounds against novel biological targets to advance the discovery of new drug lead molecules. In 2015 the ELF announced the synthesis of more than 50,000 new, high-quality compounds based on public proposals.

The ELF's successful, open innovation model would not have been possible without the ability to give external researchers access to screening compounds that were normally locked behind company firewalls, while assuring the compound owners that their intellectual property was secure. The ELF addressed this challenge by giving all members shared access to chemistry and biology project data within a secure, cloud-based information management and collaboration environment. Biological data has been restricted to the target owner, and chemical structures are generally not disclosed. Instead, early stages of decision-making use derivative data from the compounds. Once the compound list has been reduced to a few hundred molecules, structures are revealed to certain team members for follow-up studies and allocation to the Qualified Hit List.

The ELF cloud system provides a project data and documents repository; an electronic lab notebook for capturing, accessing and sharing experimental information; interactive visualization, analysis and scientific authoring capabilities; and a social portal for progress reporting and team discussions. The secure, ISO/IEC 27001-certified system is scalable (able to support 20 organizations, over 500,000 compounds and millions of assay results) and has been deployed with minimal organizational impact. One of the beneficiaries of this project said that access to ELF has fast-forwarded their oncology drug discovery work by several years.

Although the ELF is currently focused on life sciences research, overall cloud solutions will eventually extend to the entire innovation lifecycle from product ideation to manufacturing. The cloud environment offers life science research organizations great potential for increased agility and best-of-breed resourcing, while also providing extensibility beyond traditional industry boundaries to rapidly impact patient outcomes. Ultimately, the cloud shows great promise for empowering life science organizations to adopt and leverage new scientific discoveries and open technological innovation.

IT Systems Enhance Operational Productivity

Innovations include an integrated architecture portfolio for a connected enterprise, spectroscopy software, serialization solution, portable data loggers and intelligence software

BY KATIE WEILER, MANAGING EDITOR

ROCKWELL AUTOMATION

The new Integrated Architecture portfolio reduces complexity while helping users meet future capacity and throughput needs as they design systems for a Connected Enterprise. The portfolio includes a next-generation Allen-Bradley controller, graphic terminal, servo drive and distributed I/O system, as well as the latest release of Software Studio 5000 and FactoryTalk software. The ControlLogix 5580 controller provides up to 45 percent more application capacity and includes an embedded 1-gigabit Ethernet port to support communications, I/O and applications with up to 256 axes of motion. The new port and additional capacity cuts the amount of hardware required, reducing system complexity, costs and required panel space. The expanded portfolio also has many security features.

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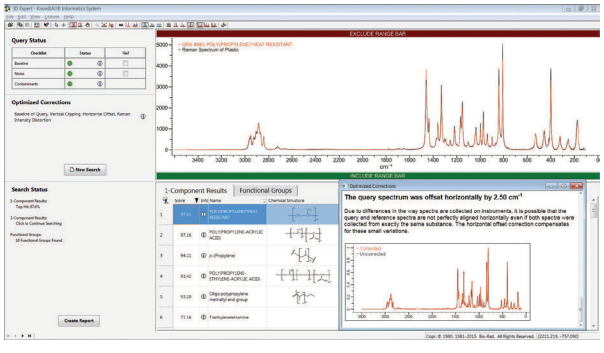
KnowItAll spectroscopy software features "Optimized Corrections," a patent-pending technology that performs a computationally complex set of corrections on all query and reference spectra in a search to find the optimal match between the query and each reference spectrum. Multiple corrections are applied automatically to compensate for differences between spectra caused by the variability of different instruments and accessories as well as other factors including human error, according to the company. This feature is critical as the inflexible mathematical algorithms traditionally employed in spectral searching cannot compensate for errors in spectra that are flawed. KnowItAll 2015 also features two new software applications as well as the addition of spectra.



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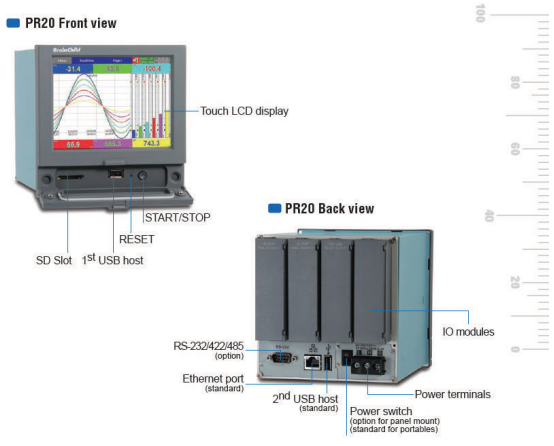

critical values from remote locations. These portable data loggers are ideal for use in monitoring experiments in laboratories, for temperature monitoring in hospitals and clinics, and for process monitoring in factories. The built-in, high-resolution display allows users to get a clear review of their data using flexible screen configuration and multiple display formats. Brainchild's portable solutions feature 6 to 48 inputs for measuring voltage, current, thermocouples or RTDs, providing useful information: for example in lab experiments such as heating liquids at different volumes. These paperless recorders also offer six user-configurable, plug-and-play I/O card slots. Three models are available.

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The new PAS-X V3.1.7 Manufacturing Execution System (MES) software offers new levels of usability and serves to improve overall operational efficiencies. The dialog for electronic batch recording was given a new design to optimally support production plant personnel in performing their tasks. Despite the complete functional scope of PAS-X, the information is displayed in a way that allows operators to work intuitively and efficiently. Depending on the device,

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