2015 Promises Major Milestones and Demands for Change

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Despite the fact that industries won't change working processes unless there is a mandatory need to do so, major milestones are expected in 2015 in the battle to adopt data and standardization in our scientific community. The need for deployment of these integration standards to enable efficient sharing of knowledge across our internal and external partners is re-enforced by regulatory bodies. Increased patterns among recent FDA 483 warning letters are wake-up calls for additional inspection activities in 2015 to focus on traceability and data integrity of data streams across the entire value chain. Excuses that technology was the limiting factor are far behind us.

I am envisioning that, in 2015, the real industry challenge is to apply mainstream technologies, in a very similar way to what already happened in other industries. To name a few:

1. **Adoption of data standards.** The Allotrope Foundation[1] and other initiatives have made significant advances to wake up the industry.

2. **Adopting a "quality culture"** to build quality into the processes instead of as an afterthought. This means a move away from paper-based systems. While pharma still debates over the need for Six Sigma QbD (Quality by Design) quality processes, other industries are already discussing implementation of seven or eight sigma practices.
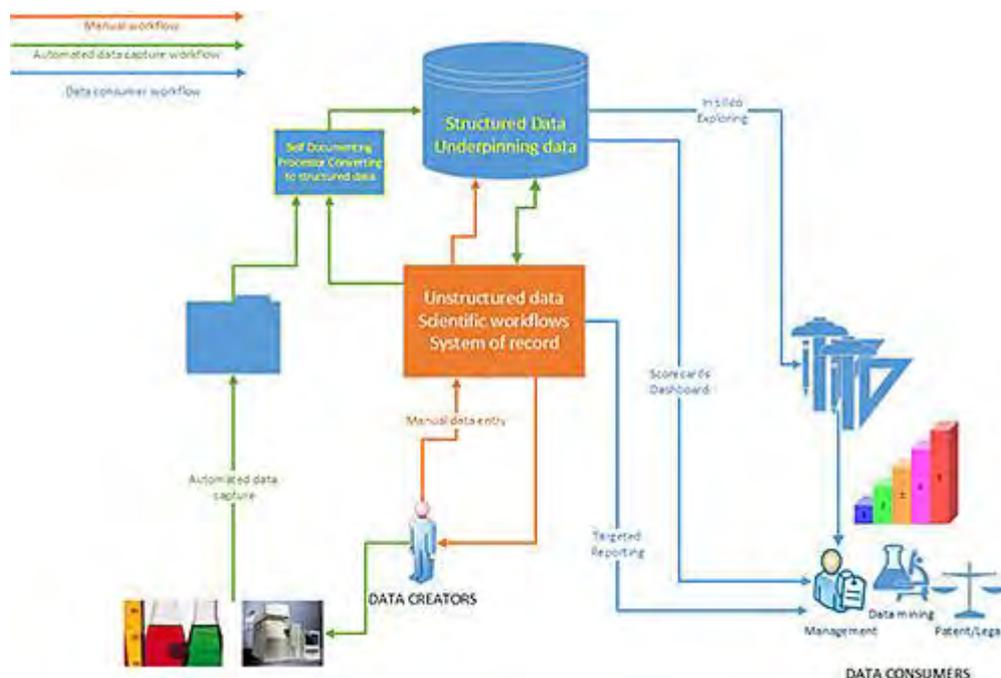

Figure 1: Scientific data will be consumed by new users in other departments.

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3. **Think with the "consumer of the data" in mind.** Scientific data maybe created in laboratories and manufacturing plants, however, the data itself also may be used and consumed in other processes. Global data mining efforts are expected to significantly grow in 2015 and beyond. The challenge in 2015 will be to create robust processes to transform unstructured experimental data into a structured equivalent. Efficient analysis and data mining algorithms facilitating business decision making and other information requirements will ultimately decrease process variability, increase revenue and decrease costs. To capture metadata at the source is a criticality to be addressed systematically. The real limitation is our willingness and mindset to make these changes.

Table 1: Types of Company Data

Type of Data[5]	Purpose
Transactional	Deals with day-to-day operations
Non-operational	Includes predictions, scientific knowledge
Metadata	Summarizes basic information about data, which can make finding and working with particular instances of data easier

4. The last thing to do is to start a project to **change a proven validated working process**. Many years of work have been spent to develop robust processes in the laboratories and beyond. So, why change the working process?

- Who is making these new demands?
- Why adopt new technologies?
- It is time to change?

This article will highlight potential trends for 2015. It is based upon findings with clients in my daily consulting activities. These trends can be categorized in four main areas outlined in Table 2.

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Table 2: Potential Trends for 2015

Adopting new mindset to address change

- Adopting automated self-documenting data capture processes
- Transform push processes to pull equivalents
- Paperless vs. less paper
- Think capabilities needed instead of technology products and services

Internal & external process optimization

- New concepts to integrate quality and efficiency with external partners
- Regulatory processes (FDA, EMA, REACH, regional regulations)
- Strategies to enable cross-functional collaboration between research, development, quality assurance and manufacturing corporation

Consolidation of systems

- Simplifying and consolidating legacy systems
- Non-invasive, end-to-end strategies to create full lifecycle traceability from R&D to manufacturing operations to ensure data integrity
- Merging LIMS, ELN, LES, SDMS, ERP/QM and PLM functions

Adoption of new technologies & processes

- Impact and utilization of tablets and mobile devices
- In-silica scientific statistical analysis and visualization strategies to unlock dark data
- Technology and operational impact due to SaaS cloud vs. traditional
- Legal landscape impact due to big data availability
- Need for scientific data standardization

Changes are enforced

Pharmaceutical and life sciences CEOs are making cost-cutting a top priority.[2] While innovation is on top for many of these senior executives in order for them to stay ahead of the competition, the reality shows a more inward focus.[3] For years, excuses such as **regulatory compliance complexity, "why change when we always have done it like this,"** and the lack of adoption of modern manufacturing techniques were used as barriers for change. In a 2004 report, the U.S. Food and Drug Administration (FDA) already mentioned that pharmaceutical manufacturing operations were inefficient and costly.[4] Opportunities for improving efficiency and quality assurance were not generally recognized. Major challenges include the patent cliff phenomena. Drugs going off patent in 2014 contribute just under $50 billion in pharmaceutical industry revenue. Industry analysts recognize that generics are already a formidable segment of the pharmaceutical industry and are on track to surpass branded drugs in sales value, as well as sales volume, within a few years.

New competition is ahead. Food companies are becoming pharma companies. Pharma-foods, the intersection between food and pharmaceuticals, represent an area of growing opportunities for the food sector. Luis Cantarell, former head of Nestlé Nutrition, stated, **"We believe that the largest drug in your repertoire is** the food that you eat three times **a day, every day of your life."**[5] Driving the need for constant product *innovations* in a legislation-complex industry, such as food and pharma, is a challenge. The push in 2015 to adopt a new mindset to stay ahead of the competition will be increasing.

Data integrity is a big concern

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Until recently, critical active compounds were produced on premise. That process is changing. More ingredients of the final drug will be produced externally. The risk impact can be significant. As a direct result, regulatory bodies will focus more on the quality of the data than ever before. In 2013 alone, the FDA issued over 300 percent more 483 warning letters in Asia.

Another trend to watch in 2015 is the increased influence of consumers debating impact, quality and price. Thanks to social media and the Internet, the general consumer interaction has significantly expanded. To create more awareness about product quality experience (thumb up or down), the value of products and services (previously called price/performance) and complaint handling are now just simple clicks on your cell phone.

In the laboratory, data integrity starts with collecting all scientific data at the source and includes all the significant metadata. Metadata summarizes basic information about data itself, which can make finding and working with particular instances of data easier. To re-use experimental data in other processes requires accurate and consistent context information. Systematized tagging of metadata to objects will significantly increase the ability to search more effectively. In the consumer industry, this tagging process is accelerating exponentially. When capturing a photo or film shot on a smartphone, this automatically systematically includes metadata with the object. Examples include GPS location, weather conditions and personal condition, such as heartbeat. Similar developments are expected to be introduced in our scientific community as well. Modern balances may automatically include temperature and humidity with the transmitting the weight. Balance and titration manufacturers are increasing their instrument value by implementing approved and pre-validated methods in their firmware. Chromatography data handling systems (CDS) can add actual instrument parameters to raw data files, such as temperature of the oven, pressure of the mobile phase and frequency of data collection interval. This may sound like a small step, but it may have a significant impact on reducing variability and validation efforts in the laboratory and manufacturing operations.

Paperless or less paper?
Enabling cross-functional collaboration internally and externally requires a solid game plan. In many cases, the technology aspects prevail above the overall organizational aspects:

- How to deal with data security?
- **To what extend should George Orwell "big brother" policies be implemented?**
- How do we communicate? Paperless approaches will allow change from a push model (sending e-mails, SMS, phone calls, etcetera.) to a pull model. Pull models are more efficient, since the requester for information is not bombarded with messages, but retrieves the required information on demand. An example we all may know is LinkedIn. Instead of using e-mail to request information, you search the knowledge database very explicitly and find (pull) the information you need. In the push model, you would have called or e-mailed a group of people.

Pay attention to the consumer of the scientific data
Integration of laboratory instruments started when instrument vendors, such as Perkin-Elmer and Beckmann Instruments, created the first laboratory information management systems (LIMS) software in the early 80s. The initial objective was to support the laboratory manager with tools to create simple reporting capabilities to enable the creation of simple certificate of analysis (CoA) reports. These systems were initially designed to support a single consumer category, namely the scientists and lab **managers. In today's world, consumers of laboratory data can be found acr**oss the entire product lifecycle, and may even include external organizations, such as CROs and CMOs

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(Table 3). A different mindset to adopt the expanded view of the world is mandatory. It is critical to first analyze who these new lab data consumers are and to get an understanding of what their objectives are. Often forgotten, but as important, is to also investigate their usability perspective. The newcomers may be a non-technical audience! **As Stephen Covey phrased it very nicely, "Seek first to understand…. And then to be understood."**[6] It may sound obvious, but it still remains a very valuable statement before starting any automation project.

Table 3: Selected Consumers of Laboratory Information Data

Consumer	Objective	Impact / benefit
Customer complaint manager	Ability to research potential deviations in manufacturing process or change of raw material supplier	Protect brand image of company
Process scientist	Re-use experimental data and leverage learnings from prior knowledge. Provide product and process analysis for product optimization	Higher efficiency and more robust quality processes. Reduction of failed manufacturing batches
Legal / Patent	Protect company Intellectual Properties	Consistent externalization processes (CRO's)
Finance	Understand overall life cycle cost of entire operation	Efficient financial planning
Customer care	Ability to research potential deviations in manufacturing process or change of raw material supplier. Manage product complaints and product investigations	Secure branding image of company
Regulatory bodies	Faster responses to compliance inquiries	Simpler mechanism to audit heterogeneous scientific data
Management	Identify areas for continuous improvement in process. Reduce costs.	Risk based information across heterogeneous data systems
Stability labs	Simpler mechanism to create e-submissions. Ability to submit standardized e-stability data packages	Faster responses during studies, Increased efficiency
CRO / CMO	Deliver more value at lower costs of operation. **Acceleration to move from paper to "p**aper-on-glass"	Efficient communication. More satisfied clients
IT	Reduce bespoke/custom systems. Consolidation of systems. Reduce costs.	Unified systems. Simplify IT processes

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Think with the end in mind. Here are a few data consumer versus data creator examples:

- For the **scientific researcher**, the ability to record data; make observations; describe procedures, including images, drawings and diagrams; and collaborate with others to find new chemical compounds and biological structures without any limitation, requires a flexible user interface. For the **QA/QC** analyst or operator, the requirements for an integrated laboratory are quite different. A simple, natural-language-based platform to ensure that proper procedures are followed will be liked.
- To professionally support a client complaint, the **customer care** manager requires a quick and complete dashboard report to look at metrics for all cases, assignments and progress in real-time, by task, severity, event cause and root cause. Significant increase in supplier risks requires full traceability and integrity of all data from start-to-finish. The devil is in the detail, and that's where the laboratory data may give significant insights.
- **Patent/Legal:** Instead of saying "we saw that a couple of years ago, but we don't remember much about it," sensitive information can searched and retrieved, including archives.
- **Product innovation and formulators** will need the capability to mine data across projects, analytical methods or formulations to create valuable insights. Transforming **unstructured scientific experimental data** into a structured equivalent will be mandatory to perform these tasks.
- Organizations with a strong consumer **marketing** focus deal with data mining techniques providing clear pictures of products sold, price, competition and customer demographics.

In 2015, the adoption of new technologies is expected to have a significant impact. Managing operating budgets will be redefined in the next decade. The days to purchase software as a capital investment (CAPEX) are changing to a new model based upon a "pay-as-you-go" philosophy (OPEX). CRM applications, such as SalesForce.com started this business model in the traditional enterprise business software segment. Popular applications, such as Photoshop and Microsoft Office 365, as well as Amazon, are rapidly following these trends. It is expected that scientific software suppliers will be forced to follow the same model in the years to come.

Traditional software suppliers are under increased pressure to maintain their maintenance, support and license revenues, while community collaboration and social networking is changing the value of traditional vendor help desks.

Conclusion
One of the most significant trends in the industry today includes implementing pragmatic strategies to convert scientific excellence into daily business value. Laboratories will need to manage the challenges presented by new consumers of scientific data outside traditional laboratory operations. Adopting automated, self-documenting data capturing processes is becoming the standard best practice to increase data integrity. Non-invasive, end-to-end strategies to create a fully traceable process including full integration of internal to external suppliers will connect science to operational excellence. Technology will be critical, but our ability to change our mind-set to enable this cross-functional collaboration will be the real challenge. Are we ready to make a start in 2015?

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