Less is More: Adopting a Self-documenting Paperless Mindset

Scientists are no longer only in the lab, but integrated into the entire process life cycle

Peter J. Boogaard

The paper versus paperless discussion is as old as the existence of commercial computers. In 1975, just after the introduction of the first personal computer Scelbi (**SC**ientific, **EL**ectronic and **BI**ological), *Business Week* already predicted that computer records would soon completely replace paper. We all know that it took over 25 years before paperless operations were accepted and successfully adopted in our daily work.

While paperless operations in electronic banking, airline check-in, patient and healthcare, and retail industries, have been accepted as the preferred way of working, in our scientific high-tech world, they lag behind. In research and development laboratories, adoption has been significantly slower, with several large pharmaceutical companies still predominantly paper-based. Even with the enormous potential for compliance and efficiency gains with fully electronic labs, significant barriers to a successful paperless lab implementation remain. McKinsey stated that operations performance in the pharmaceutical industry compares poorly to other industries, most notably in overall equipment effectiveness, labor add-time (20 versus 70 percent) and direct/indirect labor.[1]

In this article, I will share experiences and observations on how, in the scientific high-tech community, paperless adoption is lagging behind. Is it because paper doesn't require any significant investment budget, or is it the low barrier to access, since paper even works without power or the need to have access to an information infrastructure, or is it just simply that the "what's in it for me" question hasn't been answered satisfactorily for the scientists?

PAPER IS FAMILIAR AND COMFORTING

People and paper have had a long and close relationship. Traditionally, researchers were individualists and working in *their* laboratories on *their* discoveries. A study showed that, although documents are current when printed, they "age rapidly during the day." Similarly, "versioning," occurs when multiple versions of a paper document exist, leading scientists to wonder which document has the latest information: "We feel it's safer to go to the original document or spreadsheet in the computer."[2] Paper documents hold static information that loses timeliness with age.

Another study concluded that filing costs are averaging $20/document, each misfiled document costs approximately $125 and a lost document $600.[3] But, even more significant, is that when an employee leaves a company, 70 percent of his knowledge walks out the door. Paper documents are always at risk due to loss or damage. A simple spill or a careless misfiling of a document can result in hours of time wasted trying to find or recreate the test results. It may sound obvious, but destroying paper to comply with retention policies is more costly and cumbersome than we may think.

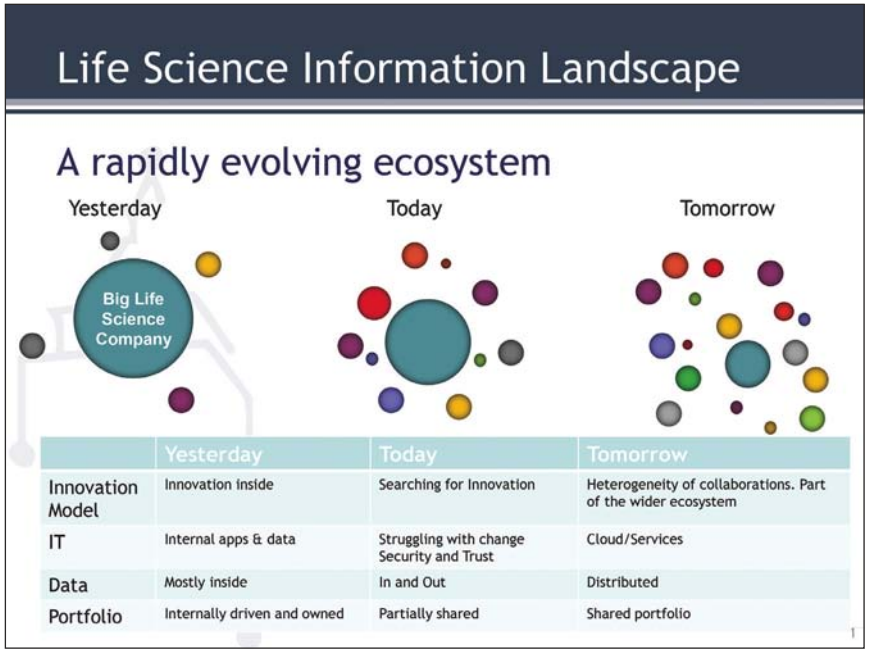
So, why did we not change for the better? The Pistoia Alliance, a global, not-for-profit, precompetitive alliance of life science companies, vendors and publishers, realized that their organizations were all individually tackling the same precompetitive problems — issues around aggregating, accessing and sharing data that are essential to innovation,

but provide little competitive advantage. They realized that, in today's global and networked society, the life science information landscape is a rapidly evolving ecosystem (Figure 1).[4]

Transforming from an "innovation inside model" toward a "distributed heterogeneity collaborations model" is applying pressure to adopt new knowledge-sharing processes. For years, laboratory operations have been struggling to adopt strategies to replace paper documentation with electronic alternatives. For years, laboratory data management IT backbone architecture complexity resulted in expensive, inflexible and non-standard software layers. Waiting is not an option anymore. The time to act has arrived.

PAPERLESS LABORATORY IS A RESULT OF A MINDSET CHANGE

Stop thinking technology when considering moving toward paperless operations! Despite what some vendors want you to believe; moving toward a paperless lab is not about gimmicks, new instrumentations or other (fancy) software platforms. The power of a paperless laboratory is the ability to enable organizations to implement self-documenting processes that produce both non-and GxP-compliant documentation that eliminates unnecessary tasks from the workflow to result in a significant re-use of knowledge in research, as well as a reduction of cost to support corporate cost of goods sold (COGS) targets.



	Yesterday	Today	Tomorrow
Innovation Model	Innovation inside	Searching for Innovation	Heterogeneity of collaborations. Part of the wider ecosystem
IT	Internal apps & data	Struggling with change Security and Trust	Cloud/Services
Data	Mostly inside	In and Out	Distributed
Portfolio	Internally driven and owned	Partially shared	Shared portfolio

Figure 1: Effective collaboration requires new knowledge sharing processes. *Courtesy of Pistoia Alliance*

The case for change needs to be supported by the business drivers. While the six sigma concept is the standard in many industries, the quality by design (QbD) equivalent is becoming mainstream in the life science industry.[5] The volume of data transcriptions becomes so large that it will reach the fundamental limits of what humans can expect to do.

"On average, each single production batch requires approximately 1000 data transcriptions in more than 15 different documents to complete," says Patrick Drumm during the Paperless Lab Forum. He continues: "fundamentally manually intensive data transcriptions cannot be made 'highly capable'! Real-world data in the best labs can only still achieve around 2000! But six sigma (QbD) is just a handful per million opportunities! As a result, transforming towards a paperless process resulted in a 90 percent reduction."[6]

TECHNOLOGY GAPS DECLINE

Instead of discussing just individual technology trends and behaviors, a combination of complementing technologies will multiply impact significantly. Cloud technology, smart mobility devices, big data and social media will be important to watch in the future.

"Research labs need to be able to take advantage of the right methods and tools that are appropriate to the problem they're trying to solve," says Peter Herz, CEO of Irisnote, a company heavily investing in paperless mobility solutions. "The challenge that labs face is the diversity of data sources that are held as discreet islands of data, making the advancement of their work very difficult and some analyses and inquiry virtually impossible. Paper has endured to provide an open and flexible platform for storing and manipulating your work. Labs need the equivalent — an open and flexible environment to collect, manage and collaborate around their work."

A serious concern is the lack of

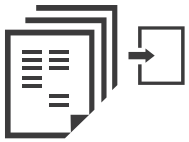
Paper Legacy Integration Strategies	
Paper archive	
Maintain legacy system	
Convert legacy system	
Integrate legacy system	
Consolidate legacy system	
Reengineer legacy processes	

Table 1: Paper Legacy Integration Strategies

data standards. It may seem a boring topic these days, but the need for standardization in our industry has never been higher. Without these standards, automating data capture from instruments or data systems can be challenging and is expensive. Initiatives, such as the Allotrope Foundation, are working hard to address these badly needed common standards. The deliverables of the Allotrope Foundation, sponsored by Pfizer, Abbott, Amgen, Baxter, BI, BMS, Merck, GSK and others is a framework that defines a common standard for data representation to facilitate data processing, data exchange and verification.[8] A potential industry wake-up call.

LIFECYCLE PROCESS IMPROVEMENT

Cross-functional collaboration between research, development, quality assurance and manufacturing is all about optimizing and integrating multi-discipline distributed processes and is badly needed to create a start-to-finish understanding of the full drug lifecycle. Reducing process variability by implementing QbD processes will be the norm within 10 years to significantly improve manufacturing efficiencies. A paperless electronic record keeping system will add significant value to support these goals.

"LIMS, CDS and ELN products all reduce variability, transcription error (double bookkeeping)" says Jörgen Blixt, Senior Scientist at Chemovix AB, previously managing ELN deployment at AstraZeneca. "The transition is not about removing sheets of pale starch from the offices — it's a quiet knowledge revolution."

"Managing the "from paper to paperless" process requires an in-depth investigation of how to migrate from the "as-is" to the new, desired situation."

— Dr. Gernot Göller / Bayer Healthcare[7]

Adoption of an integrated product quality lifecycle process (PQLI) facilitates innovation, continual improvement and strengthens the link between pharmaceutical development and manufacturing activities. Do we believe that just a paper system could support these complex processes?

SUSTAINABILITY

With growing eco awareness, paperless processes also may decrease the environmental footprint. An increased number of global companies include sustainability plans in their corporate business plans. Studies showed that, for a typical midsize 100 FTE company with an average of 1600 releases a year, a paper stack of almost 750 meter (1/2 mile) will be created, which is higher than the Eiffel Tower in Paris and slightly lower than the Burdish Chalifa in Dubai![9] New studies are underway to identify the net impact of energy, paper and waste reduction targets.

GOOGLE GLASS, HERE WE COME!

It is not likely that paper will disappear. What will change is the way and when we use it. Despite all of the high-tech instrumentation, the scientific community has been reluctant to adopt new paperless approaches until now. The new networked scientific community has transformed itself to be part of a wider global heterogeneous ecosystem. Cross-boundary communications to build trust and create knowledge are here to stay. The role of paper will change from an archival medium to a dynamic communication medium, filling gaps in current technology. Finally, less will be more in the paperless scientific community. SC

Paper vs. paperless checklist		
Business	***IT***	***End-user***
Ability to consolidate best practices processes and re-engineer legacy processes	Ability to assure consistent data archive processes	Enables self-documenting processes
Enabling cross departmental knowledge building	Apply corporate security and e-sig/digital signatures	Reduce transcription errors to zero
Reduce variability (integrity throughout entire lifecycle)	Ability to integrate cross departmental systems	Live data to support collaborative workspaces
Dashboard	Tracing	Automatic date/time stamps
Support agile innovation processes. Pro-actively anticipate and adjust KPIs	Project management	Ability to clone experiments (re-use information)
Ability to adjust to new budget processes (CAPEX vs. OPEX)	Enables single point of truth process architecture	Enforcement to consistent workflows
Ability to integrate CROs and CMOs		Automatic witnessing
Sustainability reduces environmental footprint		Extensive intelligent searching

Table 2: Paper vs. Paperless "What's in it for me" Checklist

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