SOLVING THE KNOWLEDGE MANAGEMENT PUZZLE IN BIOPHARMA

A Guide for Small and Medium-Sized Organizations

WHITE PAPER

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In the ever-quickening quest for knowledge, a diversity of biopharma professionals are driven by a multiplicity of agendas spanning research to regulation. From the seeking of medical breakthroughs to the preparation of FDA submissions; from clinical trials to post-marketing pharmacovigilance, these diverse disciplines have equal responsibility for cultivating and maintaining expert knowledge in their respective spaces. But navigating knowledge management's twists, turns, and often cryptic clues can be downright riddling. On the other hand, the nice thing about puzzles is, you know there is a solution.

Indeed, mastering the knowledge complex is key to survival: realizing efficiencies in knowledge processes can mean the difference between success and failure—before and after commercialization.

Because it is both a necessary core competency and a discipline, organizations large and small must learn to effectively search, discover, acquire, and manage knowledge in ways that will consistently yield new products, competitive advantage, and legal and regulatory compliance.

Consequently, for industries operating in such knowledge-intensive arenas, a knowledge management strategy is essential—and that strategy will comprise a combination of best practices, rigorous methodologies, and the right set of tools through which the desired results can be brought to fruition.

While the locus of knowledge management is fairly concentrated and understood in the R&D space, it is much more distributed in the post-marketing realm. In the case of many smaller companies—and certainly in start-ups—the knowledge management function is typically ad hoc, that is, if it exists at all. Because of this gap, many pharmaceutical and biotech organizations look to independent literature management consultants to help them navigate the often convoluted ins and outs.

Heather Desmarais, a knowledge and information management consultant based in the Boston area, works with biotech and pharmaceutical companies to streamline access to information resources and capture institutional knowledge through the development and implementation of appropriate systems. And many of her new clients greet her with startlingly inappropriate systems.

"Many of the smaller companies," she observes, "save PDFs to a shared drive—with many of those documents having been obtained through academic affiliations or personal subscriptions, which, unknown to many of them, frequently violates copyright. I work with them to set up an annual copyright license and implement systems for managing their literature, provide guidelines on usage, establish subscriptions and pre-paid publisher token accounts, and create an overall efficient and cost-effective process for accessing the information they need."

It is generally not until these smaller companies have clinical trials in process and start gearing up to market their drugs that they develop a formal "medical affairs" group—a team with both scientific and clinical expertise to support late stage development and commercial products. As such, medical affairs works closely with various functional departments across an organization.

Regina Maxwell, of Maxwell Research Services, whose company provides both medical literature research and competitive intelligence, notes that in the smaller companies, the medical affairs function is a rather transcendent role. "Working with medical affairs," she says, "can mean I'm also working with R&D, clinical development, safety, and regulatory, as well as keeping an eye on the competition. The application of the knowledgebase in this capacity is remarkably diversified."

The extent to which the medical affairs function is so varied is a consequence of how it has evolved. While encouraged by the FDA, the role is actually a product of the industry, and not the result of governmental agency mandate. Notwithstanding, the Department of Health and Human Services does regulate communications and interactions between drug companies and healthcare professionals.

Still, things operate somewhat like an uncontrolled intersection: while physicians may prescribe drugs to treat conditions outside of the intended and labeled use as approved by the FDA, or a regulatory agency outside the United States, drug makers may not promote any such off-label use.

However, regulatory agencies cannot prevent healthcare professionals (HCPs) or consumers from asking about off-label applications. Nor are pharmaceutical/biotech companies barred from responding to, and engaging with, the inquiring HCPs. But due to federal regulations concerning the separation of medical and commercial activities within drug companies, there is much more scrutiny on the medical affairs function, which is typically charged with responsibility for such communications.

Therefore, medical affairs and medical science liaison (MSL) professionals working with healthcare professionals must be extremely well-versed in the literature—and not only with respect to their own products, but also those of competing products within a therapy area. And information must be available upon demand. To this point, Maxwell highlights the importance of maintaining specialized bibliographies for various teams. "These bibliographies" she says, "are useful in many areas: reading lists for new Medical Science Liaisons, for instance, Drug Safety, where any adverse event articles could be stored, as well as a repository for literature included in regulatory submissions for a product."

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Desmarais agrees, and adds, "Consistency in responses is also important; you would expect that an MSL in California is using the same literature to respond to healthcare professionals as one in New York." Such demands amplify the need for proper knowledge management solutions. But where does one begin in scoping such a solution? Because these communications are driven by medical literature that is largely sourced from scholarly journals, issues related to copyright loom large.

GETTING COPYRIGHT RIGHT

Copyright isn't easy, and today's dynamic and confusing copyright climate certainly doesn't help matters. And with the rise of the Open Access "free article" era, things don't get any easier. Understanding the specific permissions attached to a given piece of content can be a complicated undertaking. Are those articles for requesters' eyes only? Can they be shared internally—or even externally? Submitted as part of a regulatory filing? What about storing them in a repository, as Maxwell suggests?

Whether collaborating with peers on research or communicating with an outside medical professional about adverse drug reactions, where published content is concerned, users must be aware of the permissions, limitations, and restrictions of such use. What's more, wider permissions might be pre-granted under certain license terms; in other cases, copyright may no longer even apply, or exceptions may be allowed.

"It's because of these complexities," Desmarais explains, "that the first thing I do for a client is set them up with a copyright license. Most users are unaware of what their rights are, or how they're infringing on copyright. I then provide training on how to check their copyright permissions for each article that they're storing, distributing, or using in any way."

Maxwell adds, "A particular challenge is working with people who come from an academic background. In smaller companies the ratio of folks coming directly from academia into a corporate environment for the first time can be high. In fact, many of these companies originate in academia and it's not uncommon for R&D staff to be professors or adjuncts."

Maxwell observes that in a not-for-profit research environment like a university, it's accepted that there will be sharing, and "fair use" can legitimately come into play. "Once the line is crossed from not-for-profit academia into the for-profit corporate environment, however, copyright becomes much more complex and stringent, and infringement can be a significant risk. This can come as quite a surprise to former academics!"

Navigating such a complex landscape without some sort of automated assistance to ensure compliance can be difficult. That's where on-demand research retrieval comes in. Copyright compliance and rights management represent just one slice of the comprehensive knowledge management solution, but it is the essential place to start, as copyright underpins the entire process.

"A good solution," Maxwell explains, "will eliminate the hoops companies have to jump through to make sure they're not violating copyright, and in the process remind users of the importance of copyright."

Maxwell uses Open Access literature to illustrate. "There are varying degrees of Open Access, especially when it comes to using content for corporate purposes," she explains. "And without checking on the specifics for a particular publication—think, Terms and Conditions—it's not advisable to casually shoot an article off to a colleague. The licenses have differences in them, and if you're operating in a corporate environment, you'd better investigate what they are. Fortunately, in a platform like that of Reprints Desk's, for example, for each of the publishers whose content is available through that platform, the terms and conditions of use have been fully investigated and integrated into the system. When a user accesses a document, they're notified at that point if their particular use is allowed by the rights holder."

A librarian in a Top 10 pharmaceutical firm noted that other potential gray areas occur in medical affairs use cases when they share articles with medical professionals. "Our users ordering journal articles through on-demand research retrieval," he explains, "must indicate their intended use, whether it is for their own use, or if they intend to share it with a colleague, or are fulfilling a request by a medical professional. We pay the copyright fee based on which radio button they push. It takes all the guesswork out of the equation and also maintains auditable compliance."

THE ART AND SCIENCE OF SEARCH

Part and parcel of this entire process, of course, is the document search itself. And this process, which involves as much art as science, is potentially even less clear than that of copyright. The key is in ensuring that the search strategy is broad enough to capture all relevant literature, but specific enough that it doesn't yield a barrage of false hits. The latter condition is a significant consumer of time, as some analysts claim that for drug safety searches, up to 95% of the references screened are not germane to the purpose at hand.

Much of this is the consequence of a lack of training for literature searching—and one reason why organizations look to professionals like Desmarais and Maxwell for expert search services. "It's not always efficient or economical for lay searchers to try to perform comprehensive but targeted searches in the areas they need," Maxwell explains—"searches, for example, in support of a product they're trying to bring to market, or to monitor for safety, or to ensure that they're keeping up with what their competitors are doing."

Maxwell relates an experience with a client whose product has been on the market since the 1970s. "And now they're seeking approval for a completely different disease," she says. "Because the drug came to market before the FDA had the stringent regulations we have today, it got approved a lot more easily than any drug does now. The FDA's response to the company's application to begin clinical trials for the new use was to order a safety check on all the literature since the time of the drug's original introduction. As part of their IND [investigative new drug] application, we conducted an exhaustive literature search and ended up with over 2,000 abstracts to comb through to make sure that there were no safety issues that would affect their plans. If the search had been any narrower, we could have missed important papers."

What's more, one search does not fit all: the search syntax used varies by the database searched. "When I'm searching PubMed, for example," Maxwell says, "I may well apply different search terms and operators than when I'm searching EMBASE. I also teach users that when conducting a comprehensive search, they need to use the indexing in the database—the "tags" that have been applied to all the articles. Sometimes the terminology that you're looking for is in the abstract or article itself, often referred to as free-text searching, but sometimes it's in the metadata that's been applied to the article. So when attempting to perform a comprehensive search it's important to apply both tactics. It's funny, because many times when I get to this point in a training, I see peoples' eyes glaze over and hear them say, 'But isn't that why we hired you?!'"

It can also be very helpful to supplement one-off searches with literature alerts, which help medical affairs professionals keep abreast of the volume of information flowing within the pharmaceutical domain.

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Scientific Papers Published Every Minute

160

Million Documents Indexed on Google Scholar

SCIENTIFIC LITERATURE SEARCH - FINDING THE NEEDLE IN THE HAYSTACK

24

Million Documents Listed on PubMed

12

Million Documents Listed on Science Direct

Desmarais explains, "Medical affairs groups always need the most current information—especially if they're meeting with medical professionals. And whether it's through document delivery or their subscriptions, they need to be able to access it quickly. Setting up a product-specific alert can be as simple as defining a search in PubMed and/or other sources, and aggregating feeds from various databases into a reference management system. This allows them to monitor the literature there, order articles as necessary, as well as manipulate the information, add it to a specific bibliography, share it, annotate it, etc."

MAINTAINING VIGILANCE

As new drugs move through clinical studies and into the post-market phase, clinical data grows and adverse event cases are reported. Whether such adverse events are the result of patient noncompliance, dosage error, lack of efficacy or other factors, considerable burden rests with the drug manufacturer to determine to what extent the drug is responsible. That's where pharmacovigilance (PV)—"the pharmacological science relating to the collection, detection, assessment, monitoring, and prevention of adverse effects with pharmaceutical products"—comes into play.

Personnel charged with maintaining drug safety information continuously monitor the medical literature for signals of interest. They also prepare and file with the FDA Periodic Safety Update Reports (PSURs), which are intended to present comprehensive and critical analyses of the risks and benefits associated with the products while comprehending any new or emerging safety information, as informed by the literature.

But what about smaller companies that don't yet have a product on the market? Is PV required for them as well? Maxwell answers, "Yes, it is extremely important. You're not going to get a new drug on the market if you don't have good safety data. The DSURs (Development Safety Update Reports) and the annual reports that companies have to prepare, are very important requirements for development programs. Whether it is for capturing any adverse events in their clinical trials, or in support of a 505(b)(2) application for a marketed drug being developed in a new formulation, they're relying very heavily on the literature to support the application."

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Alerts are de rigueur in pharmacovigilance, as well. Heather Desmarais explains, "You're looking for any signal that could indicate an adverse event, and that requires setting up alerts in multiple databases, e.g., MEDLINE, EMBASE, SciSearch, and others. Using a literature management platform like Reprints Desk, the alerts can be pulled into one location where citations can be reviewed, ordered, and managed as necessary."

ON-DEMAND RESEARCH RETRIEVAL MADE EASY

This brings us back to on-demand research retrieval. But what, exactly, is that? Simply stated, it's a workflow management solution powered by a suite of software-as-a-service tools and integrations that work together to enable the most efficient and cost-effective use of literature resources. And for organizations that consume tens of thousands of medical journal articles every year—typical of pharmaceutical and biotech companies—the terms "efficiency" and "cost-effective" take on significant meaning.

Combining augmented search technology with tools that offer reference management, a research retrieval system also provides visibility into document usage across an organization. Such platforms offer comprehensive solutions to knowledge management for all the professionals who rely upon these resources, as well as present all the acquisition options (purchase, rental, etc.). In fact, without such a solution, it is, for all practical purposes, impossible for organizations to know what documents they have already purchased, let alone search them or determine the content licensing terms that apply.

In the end, what matters most to medical affairs and R&D professionals alike, is getting the documents that people need when they need them.

"No question, there are research retrieval companies that do document delivery poorly," says a librarian working with one of the top 10 pharmaceutical companies. "They charge a lot, have a lot of hidden charges, and fulfillment of exceptional items can take a very long time."

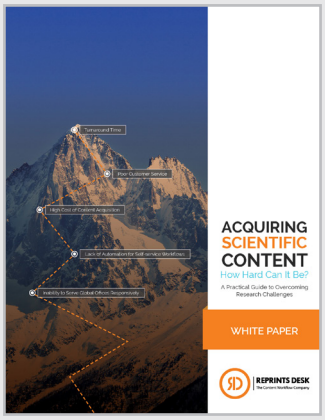
Indeed, not all document delivery solutions are created equal. A research librarian operating in the veterinary medical field noted, "Ease, speed, and cost—those are the big three things we care about. People want their documents yesterday. But some document delivery services can be not only expensive, but also slow and not user-friendly."

VISIBILITY, COST, AND OTHER MEASURES

On the question of cost, as the old Six Sigma rules show, you cannot improve what you cannot measure. And measurement with a view to lowering costs begins with visibility into the existing knowledge management processes and consumption patterns.

What's more, different groups have different perspectives on cost, depending on the objectives and conditions of the content acquisition, whether it is in support of a large project or done on an ad hoc basis; whether copyright costs are capped, absorbed, or charged to specific departments. In any case, a good platform will provide solutions for quick, easy, and reliable means of estimating, monitoring, and controlling costs, including negotiated reduced copyright rates.

"With Reprints Desk's research retrieval platform," says one R&D librarian, "we have great visibility into usage, because we're tracking by means of SSO [single sign-on user authentication], and can see who was requesting each document. That's important, because we're always challenged in terms of budget. When we're going through renewals and the budgeting process itself, we're always wondering who will be impacted if we cut a particular journal. So our previous lack of visibility was a significant pain point. Money is always a pain point!"



FOR FURTHER READING

For more information about document delivery challenges and solutions, download the free guide, **Acquiring Scientific Content — How Hard Can It Be?** Learn the strategies for cutting the costs of scientific literature, reducing document delivery time from days to minutes, as well as tips on acquiring even the most elusive content with ease.

About Reprints Desk: Reprints Desk, Inc., a wholly owned subsidiary of Research Solutions, simplifies how organizations procure, access, manage, use, and legally share scholarly journal articles, clinical reprints, patents, and other content in medical affairs and scientific, technical, and medical (STM) research. Organizations fueled by intellectual property choose Reprints Desk because of its collaborative business approach, efficient article supply system and services, and commitment to quality post-sales support. Reprints Desk has ranked #1 in every Document Delivery Vendor Scorecard from industry analyst and advisory firm Outsell, Inc. since 2008. For more information, visit www.reprintsdesk.com.

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