CASE STUDY

QUOSA™

Donna Sees, Information Consultant with PharmIntell Consulting

"We publish the virtual library results to QUOSA and it saves a great deal of time and produces search documentation"

SUMMARY

Donna Sees, an Information Consultant with PharmIntell Consulting, has been a librarian in the medical field for more than 10 years. In this article, she discusses post-market surveillance processes and best practices for medical device companies.

"The main importance of all of this is the patient."

— Donna Sees, Information Consultant with PharmIntell Consulting

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What is the industry trend that resulted in this role that you now hold?

Sees: It's an industry trend to eliminate corporate libraries. Pharma and medical libraries are now being outsourced. In addition, some companies don't see the need for internal libraries; they have the mindset that with Google, they can do it themselves. It really does take a professional, though, to get the kind of information that companies in a highly regulated environment need.

What types of projects do you and your company undertake?

Sees: We conduct clinical research searches for a variety of clients. I'm a very process-oriented person; I coordinate the work as it comes in. We generate clinical research reports as required, and IACUC pre-market reports, as well as post-market surveillance.

Can you describe what differentiates a pharma search from a medical device search?

Sees: In many ways, a drug search is easier. From a database perspective, we can search on specific fields to conduct a search — fields such as simple compound research and literature that's published during the drug discovery phase. For devices, you don't have that simple and straightforward search ability.

What's the importance of postmarket surveillance, and how does your team help?

Sees: Regulations in the EU and in the United States are evolving. It's part of what we do to help our clients keep track of post-market incidents — it's a much larger process than a simple literature search. Aside from the literature searches, a vigilance process and reporting

schedule process must be in place. That's how we can help. The main importance of all of this is the patient.

How are regulations different in the EU and the US, and how does your work account for those differences?

Sees: Regulations in the EU and the US are different; the EU is ahead of the US, but FDA.gov has put into place the Manufacturer and User Facility Device Experience database (MAUDE) to help track device adverse events. In the EU, regular clinical evaluation reviews are required additionally to adverse event reporting. Another thing that our librarians know how to do is to look for comparator products — equivalent products produced by competitors — and if there are adverse events associated with them.

That's not automatic. A device company is notified when an adverse event is entered into MAUDE, but comparator reports are not automatically looked for. Over time, international efforts are underway to bring regulations and reporting into line across the globe, but we're not there yet. That's why it helps to have people who know all the nuances, or how to find them, producing reports for you.

What is your surveillance process?

Sees: It does vary depending on the company we're working for and the purpose of the search, but many requirements are similar. If we've had history with this company or device, we have a structured search that we go back to. We can keep the same search strategy and can set up alerts. We also look for comparator new products and little nuances, like if a company has changed names. This is where QUOSA is a wonderful resource — we set alerts there.

We publish the virtual library results to QUOSA and it saves a great deal of time and produces search documentation.

How do you distribute the information that results from the searches? What is produced?

Sees: We can quickly produce as an export from QUOSA a spreadsheet for a medical writer, for example, that can show the citation, abstract, DOI link along with the device trade name field if it is available from the original database. If the device name is not available from the original database, we will often review the full text for any reference and add it to the QUOSA record's properties.We can produce all this in a Word document with hyperlinked titles directly to the full text in the QUOSA virtual library.

What else can QUOSA do for you?

Sees: We can get a dynamic link to the whole virtual library. We can also export to EndNote™, or produce a bibliography that's appropriate for regulatory purposes directly from QUOSA. My mantra is reuse, and this tool helps. It just makes sense. For years, we've been using an in-house database that tracks every query. Sometimes, you don't want or need a report — you're just looking out of curiosity; browsing or searching the virtual libraries QUOSA allows that reuse. It's possible to see what searches have already been done.

What trends are you seeing in your field?

Sees: The search process supporting product development is an encouraging sign. I'm glad to see that some companies are involving our team earlier in the process — we can help with the design review process on technology searches.

For example, we can help search on how tissue responds when a certain technology is applied. That's a positive trend. Other process developments are around recurring searches, and scheduling ahead so that last-minute requests are fewer. We need to work on tagging and metadata concerns in support of reuse — we're talking about it, but we're just not there yet. Development of autotagging is a massive project that is in the future. We can pull some of the data from Embase, but we could do better. Device names are simply not covered by the databases as well as drugs.

What recommendations would you offer to others going similar work to yours?

Sees: Build expertise in the areas that you are covering. Do those searches over and over. It will save time in the long run — you can see what fits. If you work on a team, rather than having just one in-house person that does everything, you can still share expertise on certain search terms. The example that comes to mind is staplers — there are so many different types and different terms used to describe them. Interchangeable expertise and experience to understand search results is so important. There's an amazing amount of technology out there to understand!
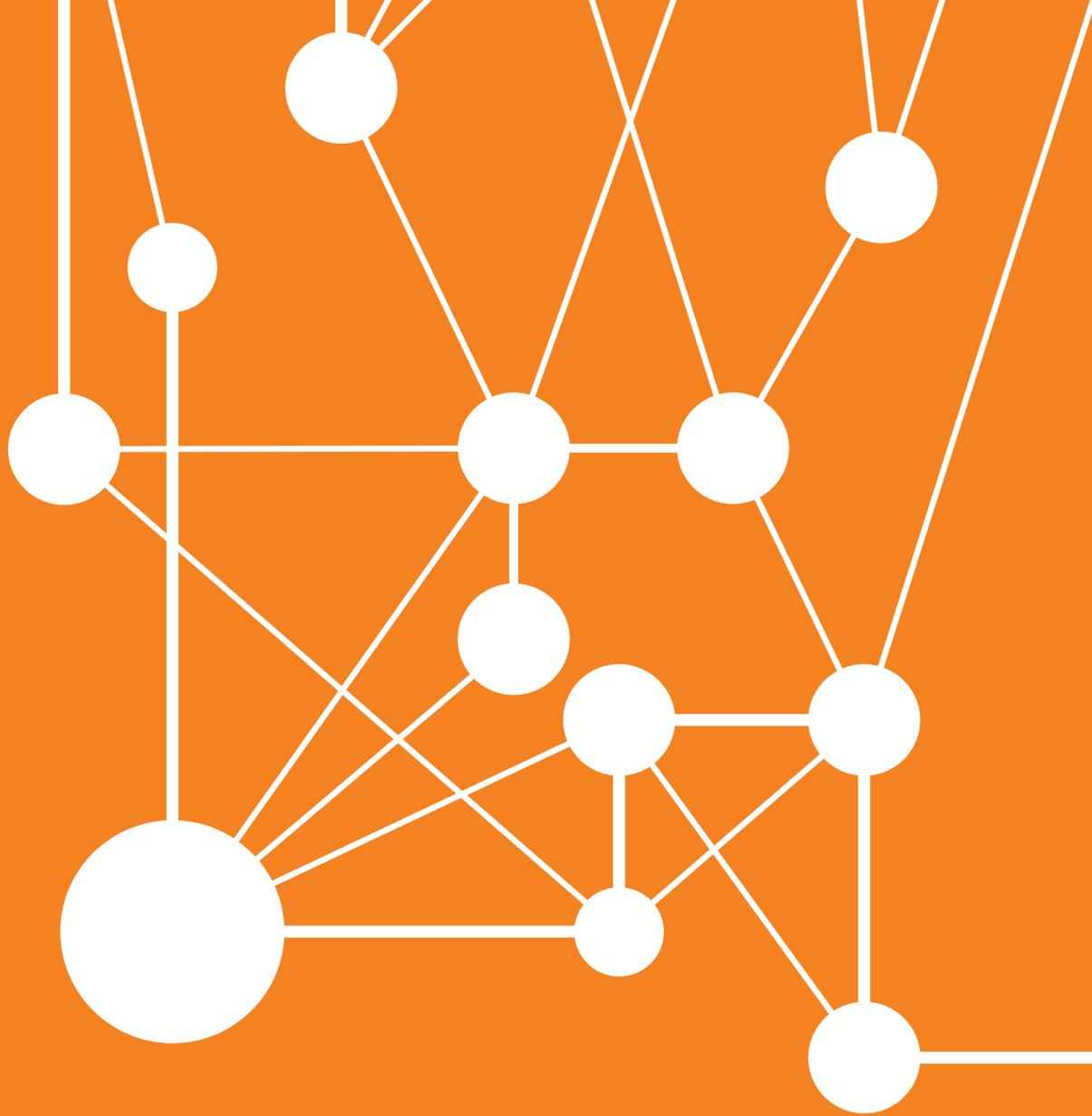
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