A long-time pharmaceutical executive director shares why the wide breadth and depth of scholarly research available in ScienceDirect is essential to help overcome commercial, technical and regulatory challenges in bringing a successful drug to market.

Case Study: Overcoming commercial, technical and regulatory challenges in a global animal health company

A Senior Executive Director explains the critical role of ScienceDirect in drug discovery and development.

Summary
A long-time pharmaceutical executive director shares why the wide breadth and depth of scholarly research available in ScienceDirect is essential to help overcome commercial, technical and regulatory challenges in bringing a successful drug to market.
“ScienceDirect is very important to drug discovery and development. There isn’t a scientist I’ve worked with who doesn’t tap almost daily into this information source. It has an impact on almost every drug that comes to market.”

—Ken Balthis, Senior Executive Director

Challenge
Time and money have become more crucial factors in drug discovery and development. “If we can’t show in a relatively short period of time that an idea is going to be successful, it’s going to be killed,” shares Ken Balthis, a Senior Executive Director at a global animal health company.*

Balthis has more than three decades of experience working in the pharmaceutical industry. ScienceDirect has long served as an indispensable tool that helps him meet the challenges of his job, which include identifying new technologies for application to animal health and overseeing vaccine research.

“The biggest challenge — and the only success metric that really counts — is the number of drug approvals a pharmaceutical company can obtain,” Balthis says. “It’s a long, arduous process to develop a new idea into an approved drug, so we need to be sure we’re working on the best ideas. We have to be able to answer three critical questions quickly and effectively: Does it make commercial sense? What are the chances of succeeding technically? What are the chances of regulatory approval?”

Solution
To answer these three critical questions, pharmaceutical researchers use ScienceDirect for access to the full breadth and depth of Elsevier’s research.

Proving commercial viability
“The ideas scientists in drug discovery have regarding new drug targets to explore are not always financially worthwhile,” Balthis observes. Assessing the commercial feasibility of a new drug is an essential first step in drug discovery. “Scientists rely on various types of literature searches including ScienceDirect to identify potential targets, but we can’t actually start working on a new idea until it’s clear that the financial return can pay back the investment”, Balthis stresses. “So they would look at the markets, they would see how many animal patients there were, what the potential income is if you were successful. And then they would build a profile: if it is a good area to be in, these are the things this particular drug will have to do.”

Assessing technical feasibility
ScienceDirect is also critically important to allow for thorough technical feasibility assessments providing the confidence to stop a project or to move a project forward. “Most projects start off with a relatively low probability of technical success. That’s why it’s important to create experiments that, if successful, will increase the overall chance of success. If the technical feasibility is really low, we will most likely not proceed, even if the possibility of commercial impact is high,” Balthis explains.

“The basis of everything we initially do comes from literature searches,” he adds. “This information gives us the confidence to move forward or tells us that we should abandon the area,” he says. They have to do all this scholarly research upfront before the company invests too much.

*For confidentiality purposes, names have been changed.
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The fact that ScienceDirect offers full-text articles is also a critically important factor for Balthis. “When we analyze data from the literature, we always look at the full publications, not just abstracts or data sets,” he says. “We need to understand such details as how the experiments were set up and conducted, what the controls were, how the drugs were dosed, and the timing of the experiments. Our in-house team always reviews the statistics so we can determine whether the published approaches and conclusions are valid from our perspective.”

Attaining regulatory approval

Access to thorough research in ScienceDirect enables his teams to better understand the parameters that are important in the regulatory approval process. “Even if an idea has a large market potential and a high probability of technical success, it also needs a high chance of regulatory success to justify moving forward. I have to prove my drug has clear advantages over the existing ones and I need to address resistance issues,” Balthis points out.

Impact

ScienceDirect improves R&D productivity.

Given these three critical components and the time constraints Balthis’ teams face, ScienceDirect plays a significant role to improve their chances of success.

“Taking time to thoroughly perform the proper literature research increases R&D productivity,” Balthis explains. “It’s important that my project teams look at the data objectively and not ignore certain information.” Often, scientists are focused on proving that their hypothesis is right. However, in-depth scholarly research is especially important in looking at all the factors, not just the ones that support the hypothesis. In one example, ScienceDirect enabled Balthis and his team to link and cross check a wide variety of different studies and came to realize that one mediator that was initially proven to be beneficial in the short term, actually could cause bacterial damage in the animals in the long term. It prevented the company from investing in this mediator that eventually would have been a dead-end anyway.

“It would be impossible for my team members to do our jobs effectively without using ScienceDirect,” he continues. “We need comprehensive, high-quality literature to ensure we don’t miss things. ScienceDirect has a huge impact on the success of the process. It helps us identify new targets and understand side effects, toxicities and even adverse events. There isn’t a scientist in the organizations I’ve worked with who doesn’t tap almost daily into these information sources to help with the day-to-day activities. It has a direct impact on every single drug that comes to market.”

“IT’s important that my project teams look at the data objectively and not ignore certain information. A thorough search using ScienceDirect can help us see if a target or mechanism is tightly tied to a toxicity and can prevent us from taking a project down a dead-end and wasting money.”

— Ken Balthis
Senior Executive Director
ScienceDirect
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