James draws on more than 20 years of experience in medicine and pathology in his role of research pathologist for a medical device manufacturer. A busy Research & Development professional, he routinely works on multiple teams and project types spanning all stages of innovation—at any given time he is contributing to at least 10 projects simultaneously.

James’ contribution to product development spans a wide range: It can shape early stage proof-of-concept work as well as preparations for submission to regulatory authorities. The common denominator for him is to understand disease states and product impacts on the body.

“I’m involved in how these things will interact and behave in the tissues and in the body and making sure that what we’re doing improves people’s lives or that the condition we’re treating is safe and effective,” he says.

*For confidentiality purposes, names have been changed.*
CASE STUDY: How Scopus Improves Product Development Outcomes

“Scopus helps me quickly build a basis to make a decision on next steps”

James
Research Pathologist,
Medical Device R&D, Scopus user

R&D focus: Filling gaps and coming up with “big picture” ideas for the future
Research & Development at James’ company focuses on dual innovation tracks: incremental product line improvements or additions and larger, longer-term initiatives for breakthrough new products. James juggles the different effort and scope of work required on each of these tracks.

“There are so many regulatory agencies we deal with. Roles change or they change how they look at things... I've noticed more of a trend of increased regulation.”

In this more stringent regulatory environment, expensive clinical trials may be required for medical device improvements where they may not have been in the past. The expense of trials may not be feasible for incremental product changes given a product’s relatively small surgical patient market compared to, for example, a new drug in the pharmaceutical industry’s broad market population.

Challenges posed by the evolving regulatory environment
The ever-changing international regulatory and reimbursement environments are a challenge to R&D efforts and can result in delays or postponements of potentially promising new products.

In contrast to this “fill-the-gap” approach, bigger-picture innovation starts with identifying unfilled needs and researching how these needs can be addressed.

James spends about 20% of his time on the large, breakthrough innovation projects on a team dedicated to uncovering new ideas.

“There is a whole team that often interacts with the surgeons or the clients. And that’s where many new ideas are born,” he says. “A lot of it is pure exploration - people exploring areas where we know that there is a need, either domestically in the United States or globally.”
“Speed is very important... I can easily identify what I need to know, read it, digest it, and move on to the next one.”

James
Research Pathologist,
Medical Device R&D, Scopus user

Fueling new ideas with combined team-based approach and literature review
The product innovation process starts with James’ internal team. They discuss approaches and capabilities for addressing a problem, and gather input from industry opinion leaders as well as physicians and surgeons treating the disease or injury state. Literature review plays the important role of anchoring the team to current science and sizing the potential market. “Scopus just helps us know that we are going in the right direction,” James says.

“We spend a lot of time figuring out the best way to approach that particular issue. We view a lot of literature to see what, if anything, people have done in the past,” James says. “And we also have to predict the market, so we know if it’s going to be a small or large population.”

Getting up to speed and keeping current: The role of Scopus
James relies on Elsevier’s Scopus two to three times a week as he works across multiple teams and projects. For him, Scopus is an efficient, time-saving initial step to get up to speed and identify what others have done to address the problem. “In Scopus, I use a quick search to pull up all of the articles and what is going on right now or what is being published right now in that particular area... it helps me to get familiar with different models and what people are thinking,” he explains.

“Scopus helps me to quickly build a basis to make a decision on next steps and prepare us for more extensive literature searches as we go through the process and approach submission to regulatory authorities and a complete launch,” he says. “It quickly delivers the basics that we need to understand things.”

Speed is essential when working on multiple teams in a competitive marketplace
Every day James calls upon his pathology expertise to respond to team members’ questions. He needs a resource that can quickly get him to the information needed to address these inquiries. With Scopus, he conducts a search and can usually link directly to the journal to download the article he needs.

“Speed is very important. Many of the questions I receive must be answered right away or at least the next day. So I need something to base the answer on,” he says. “Scopus is nice because it’s linked to any journals we have rights to, so we can pull up a full article online... I can easily identify what I think I need to know, read it, digest it, and move on to the next one.”