Everything You Know about Materials Is Wrong

Posted in Medical Materials - Raw Materials by Brian Buntz on August 15, 2014

A lack of innovative materials is holding the medtech industry back, says Michael Drues, PhD, the president of Vascular Sciences. And if Drues had his way, the medical device industry would start looking for bio-friendly materials.

"Biocompatible isn't good enough any more," Drues says. "Biocompatibility just means you put something in the body and the patient doesn't drop dead."

From Teflon to titanium, many of the biomaterials, used in the body are inert. The logic behind their use in medicine is that inert materials won't interfere with the body's natural biological functions. But when you look at the human body, all of tissues, blood, and pretty much everything is reactive in special ways. "Nothing is stagnant or inert," Drues notes.

The coronary artery stent is a notable example of how an implantable device made of an inert material can pose problems. Generally made of 316L stainless steel or, more recently, cobalt chromium alloy, such bare-metal stents have been linked to major adverse cardiovascular events. The debut of the drug-eluting stent has reduced the adverse event rate, but problems with in-stent restenosis and stent thrombosis still persist for some patients. In both the cases, the artery can treat the stent as a foreign body, launching an immune system response intended to address what it perceives as a threat.

This problem, however, is not unique to stents. It affects many devices and combination products used across medicine, Drues says.

Start with the Body

Device engineers would be well served to learn about the biology of the human body from an engineering perspective. Let go of everything you think you know about conventional biomaterials, and study immunology. "The way your body responds to materials is similar to how your body responds to bacteria or any other antigen," he says. "If you understand the biology, you can better understand what you need to achieve from a materials perspective."

Having an understanding of chemistry can complement this approach, Drues says. If you were to ask a chemist what polymers were used in medicine, they might reply: "proteins, DNA and RNA, carbohydrates, and lipids," he says. Conversely, if you were to ask a device engineer the same question, they might reply: "Dacron, Teflon, Silicone, Urethane, PMMA, and so forth." In both responses, all of the materials listed are polymers. All of the latter ones, however, were designed for industrial rather than medical applications. "They might be great for use in cars or clothing, but not so great for the body," Drues quips.

Drues also recommends that device engineers look at the biotechnology industry for inspiration. "The folks in biotech are doing clever things with proteins and nucleic acids. We are starting to incorporate some of those in combination products, but it is taking so long," he says.

Getting Innovative Materials in Your Device

While it is straightforward to understand the potential benefits of using biologically inspired materials in the body, getting innovative materials into medical devices can be a challenge—for both established device companies as well as startups.

There are disincentives for anything new and novel that stem from a variety of factors, including regulation and reimbursement and blowback from the breast implant fiasco of the 1980s and 1990s.

As a result, many device firms stick to "FDA-friendly" materials that are tried and true. But the phrase "FDA-friendly" material is codespeak for more of the same, Drues says.

A further challenge is the idea of budgeting what you spend on a given material. It is important to keep in mind the material's overall value proposition and not just its cost per weight. "In biotech, there are some materials that cost thousands of dollars per gram," Drues notes. "If I put a material like that into a patient and it means that the patient doesn't have to go under immunosuppression when they otherwise would have, it will be easier from a reimbursement perspective to make the value judgement there."

The challenges of working with innovative biomaterials are very real, and frequently lead to the conclusion to stick with what is tried-and-true. In other words: If it's not broke, don't fix it.

"But if everyone felt that way throughout human history, we as a species would still be living in caves. There has got to be some balance," Drues says. "There are challenges when you want to do something differently, but they are not insurmountable. It may take more effort and risk, but it is well worth it. If you are following someone's footsteps, you will never go somewhere new. Just because we do things the way we have for along time is not a very good justification for continuing to do them that way."

Intrepid device designers wanting to develop forward-thinking products with innovative materials should charge forward. "It amazes me how many people go to FDA and ask: 'What do we do?'" Drues says. "It is much better to lead. A company can go the the FDA and say: 'This is the research we have so far, and these what we think are the three best options for a product. Based on our analysis, we think option 2 is the best and we have consultants to back us up," he says. "The FDA will have questions, but your conversation with them should be a dialogue. For many people, FDA is nothing more than a hurdle. I find that troubling. I view this as a partnership."