

Materials Database Helps Stretch R & D Budgets

As pressure mounts to improve product development times while maintaining low costs, device designers are constantly seeking tools that can enhance the efficiency of their processes. This search is even greater when developing combination products due to the addition of the biologic or drug element. This article examines a materials database that promises to aid in the R&D phase of the product development cycle.

By Michael N. Helmus, Ph.D. and David Cebon, Ph.D.

In medical devices—as in billiards, figure skating, and cliff diving—a combination adds considerably to the degree of difficulty but even more to its value.

Combination devices have the potential to create potent new therapies by utilizing the best properties of drug-device, biologic-device, or drug-biologic combinations. Understanding and controlling the unique interactions that occur between these combinations can be significantly more challenging than designing for a single-purpose product, because of the need to optimize the safety and performance of two or more components—not just one.

From a regulatory perspective, this raises the question, “Who has jurisdiction over a combination product?” The FDA's Office of Combination Products has broad responsibilities covering the regulatory lifecycle of drug-device, drug-biologic, and device-biologic combination products, while the primary regulatory responsibilities for, and oversight of, specific combination products are handled by one of three product centers—the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, or the Center for Devices and Radiological Health. Even though the various centers cooperate well, the road to regulatory approval is commensurately complex, compared to a single-purpose product.

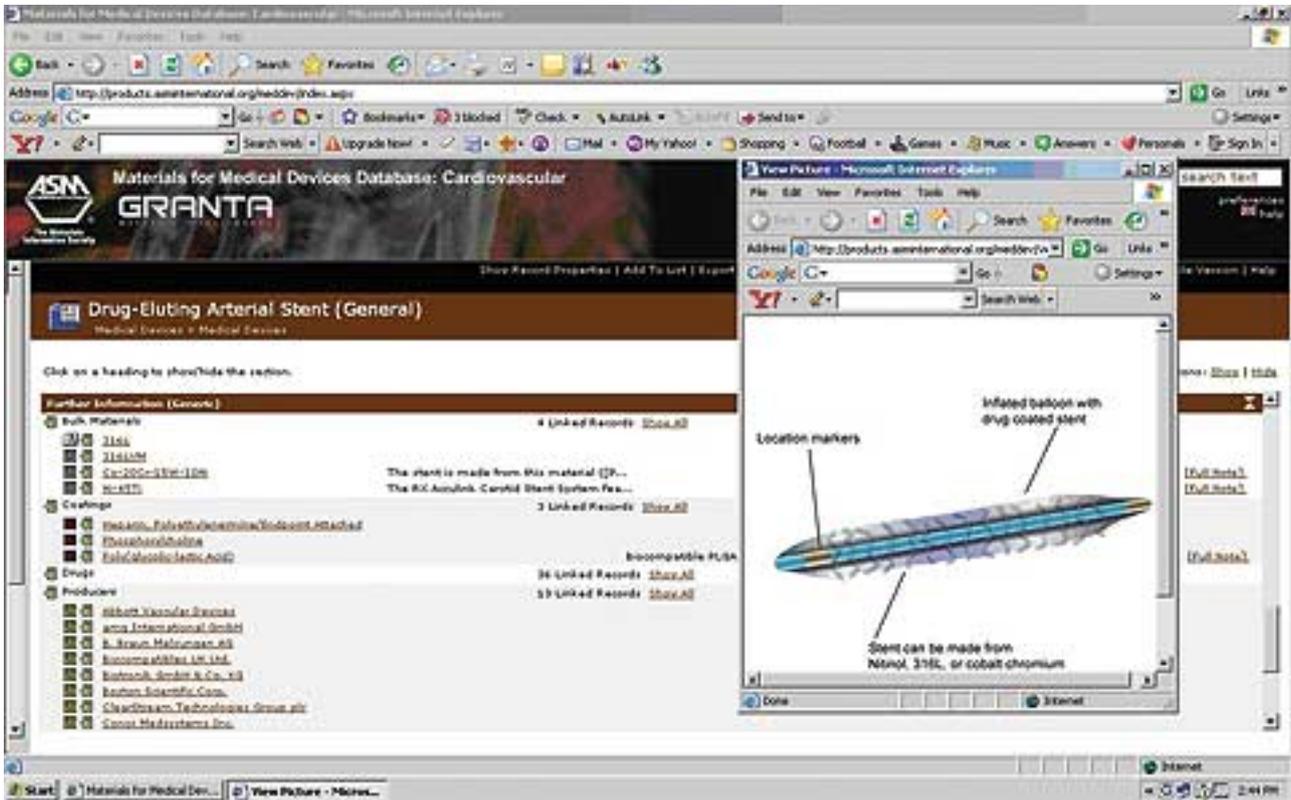
Fortunately, the outcomes are well worth the effort. As an example, both the Taxus and Cypher drug-eluting stents have shown significant reduction of restenosis in clinical trials and in the field. The ability to select polymer carriers that are compatible with the vasculature, allows the drug to be compounded and released in a controlled fashion from the polymer, and also allows the drug/polymer mixture to be conformally coated on the stents. These are enabling properties that make these combination devices clinically and commercially successful. The understanding that the polymer carrier is an excipient agent compounded with drugs allowed the proper pharmaceutical test methods to be utilized that enabled regulatory approval of these devices.

Thanks to the Freedom of Information Act, much of that work is in a matter of public record. But because the information is scattered throughout the FDA and professional literature, it's difficult to find the pertinent details required without access to an entire department of researchers.

Materials Database Helps Stretch R & D Budgets

Published on Medical Design Technology (<http://www.mdtmag.com>)

To dramatically reduce R&D expenses and accelerate the development of new devices, the first materials database created specifically to support medical device design has been developed by ASM International and Granta Design. The Materials for Medical Devices Database: Cardiovascular Module gives researchers and designers access to a comprehensive and authoritative source of mechanical, physical, biological response, and drug compatibility properties for the materials and coatings used in cardiovascular device and combination product applications.



The database provides a tool for rapid screening, analysis, selection, and sourcing of candidate materials, coatings, and associated compatible drugs.

"The database is specifically designed for the identification, screening, and selection of material grades, coatings, manufacturing processes, and suppliers, and includes a comprehensive presentation of interrelated information, all fully traceable to primary sources. For example, detailed information on Taxus and Cypher from the FDA is presented in one place, along with information about the materials and coatings used in these products and other diverse data that can provide further details on evaluations done by researchers. Medical device engineers have needed this breadth and depth of information for a long time. It helps them understand what is known about previously used materials, so that existing data can be utilized and potentially allow shorter and more cost-effective R&D programs. There have been attempts to create biomaterials databases for some time. About a decade ago, the FDA had a concept for a biomaterials compendium that linked databases of materials, properties, and relevant literature to the material and the devices. This undertaking was difficult because of the reluctance of manufacturers to provide data and the lack of the technical infrastructure to access existing data. By placing information into the hands of the designers who need it, the ASM-Granta "MMD" database provides a comprehensive solution to this materials challenge. The unique combination of information upfront will lead to more efficient development of

Materials Database Helps Stretch R & D Budgets

Published on Medical Design Technology (<http://www.mdtmag.com>)

combination products.

ONLINE

For additional information on the technologies and products discussed in this article, see the following websites:

www.asminternational.org [1]

www.grantadesign.com [2]

www.taxus-stent.com [3]

www.cypherusa.com [4]

*Before joining Advance Nanotech as senior VP of biopharma, **Michael N. Helmus, Ph.D.** served as VP of advanced biomaterials at Boston Scientific. Currently, he is also chairman of the ASM Medical Devices Database Committee. Dr. Helmus can be reached at 508 767 0585 or michael.helmus@Advancenanotech.com [5].*

***David Cebon, Ph.D.** is managing director of Granta Design Ltd. where he has spent 12 years developing software systems for material data management and materials selection. He is also Professor of Mechanical Engineering in Cambridge University Engineering Department. Dr. Cebon can be reached at +44-1223-332665 or michael.helmus@Advancenanotech.com [5].*

Source URL (retrieved on 09/19/2014 - 3:51am):

<http://www.mdtmag.com/articles/2007/05/materials-database-helps-stretch-r-d-budgets>

Links:

[1] <http://www.asminternational.org>

[2] <http://www.grantadesign.com>

[3] <http://www.taxus-stent.com>

[4] <http://www.cypherusa.com>

[5] <mailto:michael.helmus@Advancenanotech.com>