Perspectives on Device Design—Part 4

Besides "early collaboration," what tip do you have for medical device designers developing a new project that is specific to your area of the industry?

Dennis Repella, Ph.D.
Medical Device Consultant, Cyanta Analytical Services

As part of early collaboration, all company departments affected by the new project need to be involved at the onset. It sounds like a simple thing to do but internal communication is often one of the most difficult obstacles to overcome. Setting up departmental expectations and objectives at this time is also key successful device development. Additionally, a legal review of the resulting device and its labeling is important to determine that there are no patent or trademark issues to resolve.

An important early collaborator is the FDA. The FDA Headquarters has small business contacts who can provide information regarding your particular product, including Guidance Documents. This information can help organize and plan the product development activities and determine if special physical and chemical tests, and/or clinical studies are needed in a 510(k) or PMA submission.

Contacting FDA at the start of a project is especially important for Combination Products (a product which contains both a drug and device component). Contact the Office of Combination Products (OCP) at 301-796-8930 and they will direct you to the center responsible for reviewing your product and provide information to help structure your submission.

Robert A. Mitchell
Technical Manager, Fort Wayne Metals Research Products Corp.

Fort Wayne Metals produces medical grade wire, strands and cables for mechanical subassemblies that provide articulation, steering, torsion and tensioning as well as other functions demanded by today's medical and surgical devices. Medical device designers understand their project needs very well but may reach out to a vendor to gain their expertise in order to meet project goals. Typically the functional requirements are known but how to achieve them is unknown. A vendor should be selected based on a demonstrated record of success with similar projects. Budgets and timelines are tight. Designers have to communicate their needs to their subcontractor at the earliest stages of a project. The needs should include functional, test, budget, timing and future production expectations. After all, the designer has to eventually integrate the project into a wider corporate environment if the project is to be commercially successful. Designers are well served by communicating how a vendor's contribution to a project is required to perform in the finished device or system. The designer should require the vendor to prepare a project protocol reflecting the vendors understanding of all requirements. The designer can quickly gauge whether the vendor understands the application and has the engineering, manufacturing and test capabilities to deliver.

Tero Kähkönen
Vice President, Customized Products Business, VTI Technologies Oy

For over 15 years VTI has designed and supplied customized products for medical device manufacturers with zero field returns. Thanks to this solid and in-depth experience VTI knows what are the main success factors to run joint development projects. The MEMS element, or the MEMS sensor, plays a crucial role in many of the medical devices and must add value through improved device performance and/or thanks to better cost-efficiency. However, in order to succeed and to be able to develop and offer the right MEMS solution, one that truly adds value, there are a certain amount of questions to be answered in the very early stages of the development project.
As a general guideline: the more information the MEMS supplier can get from the very beginning, the better the end result will be. In order to build a preliminary requirement specification, a MEMS supplier needs to know what the customer wants to measure and in what kind of environment. It is good to be clear on what is a "must have feature" and what is just a "nice to have" feature. Are there design limits or requirements concerning, for example, the size, electrical interface, contacting and packaging?

One important aspect is to know what the device manufacturer wants or is able to do himself – is a bare MEMS sensing element die what is needed, or is it a ready plug-and-play sensor component? This provides the scope for the project: what will be done by the device manufacturer, what will be designed, manufactured and supplied by the MEMS solution supplier, and what eventually will be done by a third party or other subcontractor. Knowing the technical requirements, project scope, estimated production phase volume and project schedule, the MEMS supplier can propose the commercially and technically optimum solution for the customer's need.

Maybe more than in any other industry, confidentiality is always required in these high value medical device projects. When choosing the right MEMS supplier, medical device manufacturers must consider whom they want to trust. With its proven track record, solid reputation and market leader position, VTI Technologies knows what confidentiality is all about.

Peter F. Ladwig, Ph.D.
Staff Engineer, Hutchinson Technology, Inc.

As a precision component manufacturer with access to a variety of techniques, the best tip I can give to designers is to understand the capabilities of the materials and manufacturing processes that can be used to produce device components. This understanding can have a significant influence on device design. For example, a

small metal component may be manufacturable via machining, grinding, stamping, forming, electroplating, electroforming or chemical etching; each with their own advantages and weaknesses (as shown in the table below). Designing a part without specific processes in mind may lead to unnecessary cost and project delays. Designing a part without considering a range of applicable processes may unnecessarily constrain a design and the resulting device performance and cost. A similar case can be made for various classes of materials. Expert medical device designers use their understanding of a wide variety of processes and materials to tweak the design throughout the lifecycle; often capitalizing on the advantages of one material and process set for prototypes and another for volume manufacture. In addition, expert designers may employ combinations of materials and processes on a single component; such as chemically deburring or roughening a machined part.

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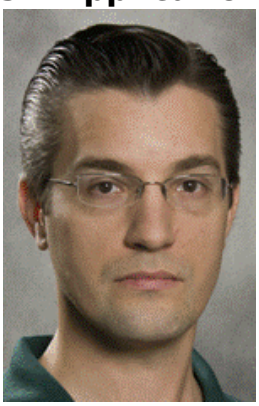

Consider your power goal. It seems like everyone is concerned about power consumption, these days. The simplest way to lower power consumption is to lower the operating voltage and/or the current consumption. Today's microcontrollers (MCUs) commonly operate at 1.8V, have sleep currents as low as 20 nA, and feature dynamic currents as low as 50 µA/MHz. Many MCUs can source 20 mA from an I/O pin, so a serial EEPROM, sensor or other external circuit component can be powered directly from an I/O pin and left completely unpowered when not needed. Newer MCUs have a Peripheral Module Disable feature that allows peripherals, and their associated special function registers, that are not being used by the application to be left unpowered. At times when the microcontroller's CPU is waiting for a peripheral to complete an operation, a blocking function will be implemented. Instead of having the CPU continue to execute code, the MCU can enter an Idle mode where the CPU will be disconnected and the peripherals will continue to operate normally. Doze is another low-power mode where the peripherals continue to operate normally but the CPU is clocked at a lower frequency. For more information on this topic, visit www.microchip.com/lowpower.

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