

How Ethicon manages materials information to develop new products and answer medical queries

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At a Granta Seminar, Jackie Anim, Principal Materials Engineer at Ethicon Surgical Care, described how effective materials information management ensures easy access to vital data, supporting product development, reducing time to market, enabling rapid responses to medical queries, as well as saving time and money.

Defining the problem

Ethicon is part of the Johnson & Johnson Medical Devices Companies. Anim explained that, historically, materials decisions were made by a number of people using often unrelated data sources, including an off-site facility 40 miles from Ethicon's office. Material decisions were based on mechanical properties only, without taking account of the environment in which a medical device would be used, or how a device was registered in a country other than the USA. This resulted in error-prone materials decisions, and redundant testing and revalidation.

Creating an 'integrated material optimization environment'

Ethicon decided to centralize its materials information in a system called an "integrated material optimization environment" (iMOE). Staff spent several months collating data and Granta helped them to create a searchable database using the GRANTA MI™ materials information system. Anim said: "The Granta solution was not just an IT solution. It was a combination of the technical element and the customer interface. We wanted to feel like the solution belongs to us. We wanted it to be searchable – all you do is type something in, hit 'search' and the result has to pop up. That's what we wanted and Granta did just that."

The searchable database provides quick access to materials information, including device-level materials contents, and information on where a material is being used across the company. Anim said this 'one-stop shop' capability enables optimized materials selection decisions, eliminates redundant testing and revalidation, and gives Ethicon a competitive advantage. Anim said: "The Granta system has given me the capability to multi-task. The system allows me to make substitutions on the fly, something that would have taken me a couple of days now can take me a few seconds."

Three scenarios illustrate benefits of new system

Anim presented three examples to show the benefits of the new system: identifying replacement materials for one that ceased production; accessing historical data for new product development; and responding to queries about the materials in a medical device. These are presented below.

ETHICON
PART OF THE *Johnson & Johnson* FAMILY OF COMPANIES

The Problems

Providing time-critical responses to medical device queries. Preventing disruption due to material obsolescence. Accessing historical data to speed up new product development.

The Solution

Material information management using the GRANTA MI™ system.

The Results

Materials data accessed with precision and confidence.

Fast, accurate answers to 'patient-on-the-table' medical queries.

Improved experience for patients and medical staff.

Optimized, holistic materials selection solutions.

Replacement materials identified within seconds.

Time and cost savings.

1. Replacing materials to prevent supply chain disruption

Ethicon was informed that production of a material in one of its medical devices was to be discontinued, raising the prospect of a disruption to its supply chain. Staff seeking alternative candidate materials were able to search the database using criteria including the material grade name, supplier name, component name, 'where used' information, material property comparison, product code, and medical device name. Within minutes, Anim said they identified 209 potential alternatives. This eliminates trial and error, and leads to an "extensive reduction" in the time taken to find a replacement candidate. This leaves more time to validate the replacement, and it speeds up the implementation process. Anim said: "This approach provides us with a consistent answer every single time."

2. Accessing historical information for new product development

Ethicon wanted to develop a new medical device with a tracker. Using a tracker in this application was new to the project team, but the tracker itself was not new – an Ethicon engineer had evaluated it a decade earlier, but it had never been incorporated into a device. It had been tested to ISO10993 standards, and full biocompatibility information was available in the database. Accessing this information saved around \$200k and the 22-26 weeks it would have taken to test it again to meet the standards. No material implantation retesting was necessary, and only device-level testing was required for full validation. Anim said: "Something that would have taken them 18 months, took them less than three or four months to get to the same conclusion."

3. Providing a rapid response to 'patient-on-the-table' queries

Ethicon deals with enquiries from around the world about the materials in its medical devices, sometimes when a patient is on the operating table. Anim gave an example of a doctor checking whether a device to be used in a medical procedure contained latex, as the patient was allergic to it. The doctor quoted the information on the device label, and one of Ethicon's staff entered that information into the iMOE system. Anim said: "At that moment, the life of the patient doesn't depend upon the hospital, it's not even in the hands of the doctor – it's in our hands, how fast can we give a response to that doctor. It is up to us to get that information to him – quick, fast, and accurate."



The database search showed that the device had 42 components, none of which contained latex. Anim said: "We were able, within a few minutes of that request, to say the product doesn't have latex and they can proceed." No special training is required to use the system, staff can use a multi-dimensional search facility (in this case, the product name on the device label), and they get the necessary information to provide an instant response to the query.

Conclusions

Effective materials information management enables Ethicon to locate materials information with speed, accuracy, and confidence. Collating materials data in one central source has given them a competitive advantage. The "transformative" iMOE system has resulted in "significant" time and cost savings, based on internal estimates. What matters most to the patient on the operating table is the speed and accuracy with which Ethicon can respond to incoming queries. Anim said a "change of mindset", cultivated by a team of engineers at Ethicon, has spread throughout Johnson & Johnson.

Anim concluded: "Our ability to put a smile on the face of a surgeon, or the face of someone who just had surgery, outweighs any savings we could have gained."

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