Fachverlag für die Polymerindustrie

Controlled, consistent and compliant surface engineering for catheters

The medical device market has experienced unprecedented growth over the last 30 years, with devices giving patients access to more accurate and timely treatment in ways previously unimaginable to healthcare professionals. In line with this boom, the quest to make ever-more innovative, safe and reliable medical devices is increasing demand for modification of polymers to achieve surface engineering.

Polymer modification generates new possibilities in functionality and design. It can improve the way a device performs or patient comfort; for example, making it easier to administer biologics that have higher viscosities than traditional medications. Modification of the polymer adds the colour necessary to aid identification; or boosts the visual appeal of devices such as insulin pens, inhalers and self-testing equipment aimed at the expanding self-administered medication market.

Catheters represent one of the most challenging applications for polymer design in medical devices. Often they consist of multilayer thin-wall extrusions using several different polymers designed to be soft and flexible in one place, and rigid elsewhere. In addition there are new demands to change functionality of the polymers by 'surface-engineering', for example, to reduce friction, to allow visualisation inside the body, or to provide antimicrobial surfaces.

However, the drive for medical technology innovation is taking place in an environment of rising scrutiny from regulatory bodies. More than ever before, device manufacturers are being asked to evaluate the potential risk factor of the materials used in their products, and changes to these materials in the supply chain.

The risk factor

The supplier of colour and performance masterbatches and compounds to the medical and pharmaceutical markets, Clariant, is pioneering the introduction of ISO 13485 at the masterbatch and compound supplier level, alongside a dedicated range of sector-specific materials, to support producers of medical devices to address risk potential.

Steve Duckworth, Head of Global Marketing Segment Consumer Goods and Medical at Clariant Masterbatches explains: "Before we can help customers to achieve the device functionality they are looking for, it is vital that all parties have a clear understanding of the design criteria, e. g. sterilisation method, and regulatory aspects. This is fundamental to the whole product development process particularly as we see the FDA increasingly challenging manufacturers to demonstrate possible extractable scenarios and impact of changes, for example. We combine our extensive material and market know-how with the customer's expertise and desires to conduct a risk assessment and design review process with that helps meeting stringent regulatory requirements."

The many different forms of catheters share a common invasive function that makes them a high risk, USP Class VI regulated item. The potential for migration of materials from the catheter into the patient is therefore a serious consideration. Clariant's catheter materials contain ingredients that have been biologically evaluated using the test protocols of USP part 87, 88 for 'Class VI' devices, or ISO 10993 parts 5, 10, 11, and 18.

For example, Clariant recently launched a range of tailored products for catheter tubing based on polyether block amide (PEBA). With catheter tubing often based on several extruded layers, the PEBA materials can be tailored to provide different functionality for each layer, taking into account safety and regulatory compliance.

With ISO 13485 as the global quality standard for Clariant's three centers of competence for medical and pharma, and line segregation for highest risk applications, the company helps to assure controlled, consistent and compliant products.

Functional innovations

Visualisation can be a key focus area within the catheter sector, particularly in light of the increasing use of catheters in minimal surgical interventions to provide a transport conduit for devices intended for placement deep inside the body. Duckworth comments: "The addition of radiopaque materials to enable medical professionals to trace the positioning of a catheter inside the body is on the increase. However, the difficulty for the device manufacturer lies in being able to achieve the necessary thin catheter wall together with the right amount of radiopaque material, of which there are several, without compromising the catheter's performance".

Clariant's expertise starts with identification of the right material solution to fit the particular design of the catheter, and then examines how to disperse the radiopaque filler in the polymer matrix itself to achieve the desired characteristics. Dispersion is critical to the thin-wall extrusion process if uniform wall sections with smooth surface finish. This allows manufacturers to more easily develop thin-wall catheters engineered with radiopaque substances, and with pre-evaluation of raw materials, they can be assured that potential extractables have been minimised.

Catheters also may require marking with identifications, logos or gradations to give visual indication of the depth of insertion. In this area, there is a need to eliminate inks and potential solvent residues. Laser marking offers an alternative, and the company's knowledge in formulation laser marking additives helps achieve this.

Other developmental areas in surface engineering are also benefiting from the company's approach of combining materials with the desired characteristics into the polymer itself. This brings advantages to both manufacturing process and helps patient comfort.

Advanced lubrication to reduce catheter friction is an important consideration in patient comfort. Traditionally surface coatings have been applied to lubricate the catheter surface. This adds a coating step into the manufacturing process, with the potential for the coating to become unfixed over time. Clariant's fluorine-free lubricants are incorporated directly into the polymer to improve the friction characteristics of the surface of the polymer helping to reduce the potential for migration.

Safety first

The scale of interest in health-related modifications can be illustrated by the serious concern about secondary infections. In the USA it has been reported by the Centre for Disease Control and Prevention that there were approximately 2 million cases of secondary infections in hospitals. 50 % were related to catheters at an estimated additional treatment cost of over USD 5 billion. In Germany, it has been estimated that more people die from catheter-related infections in hospitals than from accidents on the roads. Between 4–10 % of all hospital patients contract a catheter-related secondary infection, such as a urinary tract or blood stream infection, meaning between 350,000 to 1 million people are affected each year.

"Antimicrobial agents are being seen as a way to help reduce the potential for catheter-related infections," comments Duckworth. "The market is reporting a 17–18 % growth per annum in antimicrobial coatings, despite discussions about the impact on the device from the cost of the raw materials and the secondary operations to apply the coating. We have experience of antimicrobial masterbatches across a wide range of industries, and we are working closely with the manufacturers of these agents to find a solution to incorporating the agents into the catheter materials thereby eliminating the need for a coating."

Compliant innovation

Duckworth concludes: "Surface engineering through polymer modification will open up more and more doors for advances in catheter technology. Clariant's know-how lies in helping customers to achieve the functionality and processability they require to meet regulatory requirements."

Clariant's masterbatches and compounds used for catheter applications are part of the company's "Trusted Color and Performance" package of dedicated service and expertise, product reliability and innovative material performance for the medical and pharmaceutical industry.

Steve Duckworth
Head of Global Marketing Segment Consumer
Goods and Medical

Clariant Masterbatches
steve.duckworthhu@clariant.com

Adresse:
http://www.gupta-verlag.com/general/news/k-2010/8759/controlled-consistent-and-compliant-surface-engineering-for-catheters