

The new Medical coatings facility at Whitford headquarters in Elverson, PA, already ISO-3485-compliant.

Whitford's new Medical Coatings Group's facility is complete and operating under ISO 13485

August 2015, Elverson, PA. Whitford Corporation, manufacturer of the world's largest, most complete line of fluoropolymer coatings for industrial and consumer industries, has formed a new Medical Coatings Group dedicated to the supply of fluoropolymer coatings for use on medical devices.

The construction of the Medical Coatings Group facility has been completed at the company headquarters in Elverson, Pennsylvania, and validation work is commencing. The facility is slated to be fully operational by the end of the 3rd quarter or beginning of the 4th quarter 2015.

An ISO 13485 compliant quality system has been put in place, and Whitford Medical Coatings expects to be certified by the end of fourth quarter 2015. "The importance of product quality is clear. Adhering to the ISO 13485 standard will ensure we are supplying the Medical Device industry responsibly" said Dave Willis, Whitford's president.

The Medical Coatings Group has set in motion a full validation program to ensure it is fulfilling its responsibility to the medical device industry. "Device manufacturers know the importance of validation: it's part of the ISO standard, FDA regulations, and is good practice. Too many coating and chemical-component suppliers have



The Discovery Hybrid Rheometer predicts the behavior of a material in a finished coating in more than 10 ways (including wettability, stability, sag, elongation, etc.).

been lax in this sense. If you want the same exact coating for your medical application for the life of your medical device, you should be working with Whitford Medical Coatings," said Greg Lundell, Industry Manager of Medical Coatings for Whitford.

"Whether it's catheter guide-wires, scalpel blades, surgical instrumentation, or other devices that may benefit from a PTFE, FEP, or other fluoropolymer coating, device manufacturers should look to Whitford as a committed partner," said Lundell. "We're going above and beyond what the coating industry is used to, because we believe we have a deeper understanding of the needs



Bipolar forceps and catheter with guide wire: two typical applications for Whitford's medical coatings.

of OEM device manufacturers in terms of coating supply than our competitors. Supplier audits will be welcome any time once we're up and running. We want our medical customers to be able to see for themselves what we've done here."

The medical facility includes new, dedicated equipment, as well as its own quality-control laboratory with management and operations personnel. "Our aim is to become a global leader in medical-coating supply," added Lundell. "Having a dedicated facility reinforces our policy of providing exceptional quality and security of supply at a time when many other coating manufacturers are struggling to meet the rising regulatory demands of the medical industry."

For more information, call Greg Lundell at 484-986-8328 or visit www.whitfordww.com.