



## **BIOTEKNICA ADDS NEW SERVICE DIVISIONS TO HELP CLIENTS RESPOND TO INCREASED FDA ENFORCEMENT**

**MIAMI, Florida, June 25, 2012** – BioTeknica, Inc. is pleased to announce two new client service divisions and executive appointments. Mike Neaves was promoted to Principal and new Director, Regulatory Compliance services division and Julie Larsen, recently joined BioTeknica as the new Director of FDA Inspection Readiness Services division.

“Client demand has fueled our latest round of expansion for two new service offerings,” said Braulio Ortiz, BioTeknica co-founder and Principal. “As the FDA has increased its focus on enforcement, our new Regulatory Compliance and FDA Inspection Readiness divisions were launched as clients increasingly turn to us for practical, cost-effective solutions,” Ortiz added.

Mike Neaves brings more than 25 years experience in the medical device industry, with extensive expertise in quality, engineering, and operations including ten years as a Senior Consultant and Director of Quality Systems for BioTeknica. “As clients look to us for help with their regulatory compliance needs, Mike’s wide-ranging experience and extensive expertise with Consent Decree and Warning Letter remediation and Third-Party Certification projects are genuine assets,” said Ruben Capo. Mike was the former Director of Quality Systems at Dade Behring, Inc.

As the new Director of FDA Inspection Readiness Services, Julie Larsen, brings over 20 years of pharmaceutical and medical device quality systems and regulatory compliance expertise to BioTeknica clients. “Julie helped develop our new S<sup>3</sup> Inspection Readiness Services, a *Simple, Systematic, and Sustainable (S<sup>3</sup>)* approach to better prepare clients,” said Braulio Ortiz. “We provide established and emerging manufacturers with the proven methodology, demonstrated best practices, tools and techniques to improve their inspection readiness and increase the odds for favorable outcomes,” he continued.

Prior to joining BioTeknica, Julie was Senior Director of Compliance for the Diagnostics Division of Abbott Laboratories where she was responsible for global operations auditing, preparation, and management of FDA inspections and ISO Certification assessments for nine manufacturing sites located throughout the United States and Europe. Julie has participated in approximately 45 FDA inspections and managed 25 of them over her career, as well as countless other ISO and other Regulatory Body inspections. “With Julie’s arrival and Mike’s new focus, I can say that this is an exciting development for our clients and our company,” said Ruben Capo, Principal.

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### **About BioTeknica, Inc.**

BioTeknica is a consulting firm that specializes in the full range of quality systems and engineering services for the medical device, pharmaceutical, and biologic industries. The firm has a solid track record of working with corporations to resolve regulatory compliance issues, software, process, validation, and facility commissioning challenges.

With its seasoned staff of quality engineers, scientists, and former corporate executives, BioTeknica provides compliant, efficient, and cost effective solutions to clients. The firm's mission is to partner with clients to help them achieve and maintain market prominence by providing quality, cost, and time efficient services.

Founded in 1996, BioTeknica, has offices located in Coral Gables, Florida and Stockholm, Sweden.

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