



IQS Increases Support for its Growing Base of Medical Device Clients with Validation Services

IQS provides Validation services for its own quality software and other systems as well.

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IQS, the leading provider of Enterprise Risk and Quality Management Software, is raising the bar of its service levels to medical device and FDA regulated clients by growing its Software Validation Practice. FDA requirements mandate that any system (ERP, Supply Chain, Quality etc.) that electronically impacts the quality production of a product needs to pass FDA validation scrutiny. Many organizations, burdened with other daily compliance issues and growth objectives do not have the staff and expertise to meet rigorous validation requirements. Failure to meet validation requirements can result in substantial monetary penalties. IQS services group has grown its services organization with staff sporting decades of FDA experience to lead and support validation efforts.

"The knowledge of FDA's compliance requirements and validation processes was of much benefit to an organization without expert knowledge of the requirements," said Tara Lambert, Quality Engineer at Blackstone Medical, Inc. "IQS was able to provide excellent in-depth training on regulations, allowing us to develop in-house resources for the validation and continued compliance of our new systems."

IQS provides FDA validation support across the spectrum of software and machinery used to track quality data, produce and operate a medical device including IQS' quality software, CRM, ERP and inventory systems. Recent validation support clients include Blackstone Medical, Inc., ACIST Medical Systems and Alphatec Spine.

"The IQS Validation group provides FDA-specific validation and compliance knowledge to address a clients' validation projects and deadlines," said Laura Weisensell, IQS Validation Group Leader. "Our clients have different needs depending on their in-house resources and knowledge. In response IQS' services can be a turnkey validation team providing project management, procedure development/consultation, protocol development (IQ, OQ, PQ), and full documentation to meet validation requirements. For other clients looking to augment or develop staff, IQS uses a guided knowledge-transfer approach, to provide on-the-job instruction to an in-house team, leaving the system fully validated and documented, as well as a trained staff that can maintain validation."

"Our growing medical device client base is turning to IQS not only for software, but for complete solutions," said Brad Dedrick, Vice President of Services for IQS. "IQS has always been a company rich in subject matter expertise and when addressing the medical device industry several years ago, we followed that same pattern and added FDA regulated staff to address products and services. Our staff's expertise has created a 'pull' into this services space and we were pleased to step up and provide a full end-to-end compliance solution comprised of both software and services."

About IQS

IQS – Integrated Quality Systems, helps companies reduce costs and risk by improving quality throughout their enterprise and supply chain. Since its inception in 1988, IQS has been the choice of leading automotive, aerospace, chemical and process, discreet, medical device and recently high-profile manufactures such as those in the pet food industry. IQS reduces risk through a bottom-up verifiable approach to manufacturing. With countless case studies and bottom-line ROI testimonials, IQS is the industry leader in enterprise risk and quality management software. For more information, please visit www.iqs.com.

Contact: Lori Gipp, Vice President of Marketing, 440-333-1344, lgipp@iqs.com

IQS

19706 Center Ridge Road

Cleveland, Ohio 44116-3637 USA

Phone: (440) 333-1344

Toll Free: (800) 635-5901

Fax: (440) 333-3752

email: solutions@iqs.com