



5001 East Philadelphia Street
Ontario, California – USA 91761-2816

Ph: 909.230.5526 | Fax: 909.472.4150
www.iapmoscb.org

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Contact: Geoff Bilau
(909) 908-4794
geoff.bilau@iapmo.org

IAPMO's SCB Earns ISO 13485 Accreditation

Ontario, California (June 6, 2023) — SCB (Systems Certification Body), part of The IAPMO Group, has been accredited by the ANSI National Accreditation Board (ANAB) to a new scope, ISO 13485:2016, *Medical Devices — Quality Management Systems*, a significant milestone for the certification body.

ISO 13485 is a stand-alone QMS standard derived from the internationally recognized and accepted ISO 9000 quality management standard series. ISO 13485 adapts the ISO 9000 process-based model for a regulated medical devices manufacturing environment. Companies gaining ISO 13485 compliance demonstrate an established and maintained effectiveness of their process, while ensuring the consistent design, development, production, installation and delivery of medical devices that are safe for their intended purposes.

"This accreditation adds to the breadth of SCB's capabilities, governing a wide range of industries from aerospace and government contractors to now medical devices," said Shirley Dewi, SCB senior vice president. "IAPMO SCB understands that poor quality in a medical device is a serious issue. Through ISO 13485 certification, we offer manufacturers added reassurance their products will be recognized for the high quality necessary for safe operation."

The medical device industry, consisting of huge, diversified organizations and smaller research and development companies, produces an extensive menu of products from rubber gloves to hip replacement assemblies. Total U.S. spending on medical devices is estimated to exceed \$200 billion annually, representing more than 5 percent of the nation's health care costs. Medical device companies operate nationwide, with a large concentration residing in California.

The first customer to obtain ISO 13485 certification through SCB is Lancaster Metals Science Co. (LMS), of Lancaster, Pennsylvania. LMS produces precision metal parts and components through its photochemical machining services.

"As an organization, we are certified to ISO 9001 through SCB and it's been a wonderful partnership," said Lancaster Metal Science's Vice President Robert Ludewig. "Having them as our certification body for ISO 13485 was an easy decision and we are thrilled to be part of this wonderful achievement."

SCB is committed to meeting clients' needs and helping them stay out in front of a complex and always-changing environment. Its customer base serves industries such as aerospace and defense, information technology, medical, automotive, engineering and manufacturing, and service providers/government contractors.

ABOUT SCB

SCB is a full-service, ANAB-accredited management system certification body headquartered in Ontario, California. Part of The IAPMO Group of companies, SCB is a leader in quality management system certifications and a provider of supply chain services in the areas of inspection, supplier conformance and other environmental, health and safety standards. SCB may be reached at info@iapmoscb.org, by phone at (909) 230-5526 or www.iapmoscb.org.

