Synergy Health plc in Costa Rica has become the first company to pilot the MedAccred Sterilization audit criteria. This follows the successful development of “Audit Criteria for Sterilization” (AC8113, AC8113/1 and AC8113/2) which includes “Radiation” (Electron Beam and Gamma) and Ethylene Oxide by the MedAccred Sterilization Task Group.

Joe Pinto, Executive Vice President and Chief Operating Officer of PRI commented: “Being the first to pilot something new is not easy, but it is a vital part of the process. By volunteering to perform this essential function, Synergy Health plc is making a valuable contribution to MedAccred but more importantly, in the long-term, to the continual improvement of the industry as a whole, and to patient safety.”

Wendy Gould, VP Regulatory Affairs & Quality at Synergy Health plc said “We look forward to making it easier for our customers to do business with us, leveraging the MedAccred program will reduce their costs and improve audit consistency”.

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The data from the pilot audit will be used to validate the audit criteria, and make adjustments as needed, to ensure that it is a robust, relevant assessment tool that adds value to the medical device industry.

Contact us at MedAccred@p-r-i.org
MedAccred and the FDA

Since MedAccred was established, the MedAccred Management Council has pro-actively sought to keep the FDA updated on the program’s development. Briefings have been held with the Center for Devices and Radiological Health’s (CDRH) Office of Compliance and the FDA’s Office of Global Operations within the Office of the Commissioner.

The program purpose and scope was discussed, along with the results of proof of concept audits which were conducted to demonstrate the program’s viability.

The FDA gave positive feedback and strong encouragement to pursue the development of the program. Further synergies were established between the FDA’s Case for Quality initiative (‘critical-to-quality’ methodology) and MedAccred, with MedAccred recognized as an important tool in assuring critical manufacturing process quality by ensuring flow-down of critical-to-quality specifications through the sub-tier supply chain.

The goal at this early stage of the program is to continue open communications with the FDA, providing updates on the progress of the program as appropriate. As the program continues to grow, MedAccred will also be starting to engage with other global regulatory bodies.

Free MedAccred Audit Preparation Webinar Improves Industry Understanding

On August 11, 2015, eQuaLearn held the first free MedAccred Audit Preparation webinar.

This complimentary training session was developed to support suppliers, contract manufacturers and OEMs from the medical device industry who are considering obtaining a MedAccred critical process accreditation. It provided a comprehensive overview for companies that need to understand how to prepare for a MedAccred Audit.

At the beginning of the session, only 20% of the attendees stated that they had good knowledge of the MedAccred program; by the end, 100% acknowledged that their understanding had improved and they now considered that they had good knowledge of MedAccred.

The MedAccred audit process was covered in detail, including the necessary audit preparation steps, what to expect during the audit, and the post-audit activities such as responding to non-conformances. Some of the most common non-conformances were reviewed by the course instructor as part of a lessons learned approach.

Learn more about MedAccred at www.p-r-i.org/medaccred/
Solar Atmospheres, Inc. of Souderton, Pennsylvania in the U.S. has become the first company to receive MedAccred critical process accreditation. Medical device original equipment manufacturers (OEMs) are demanding that environmental conditions are controlled, processes validated, and the risk of foreign object debris reduced.

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Mike Moyer, Director of Sales at Solar Atmospheres, Inc. states, “Many companies only enter these programs when their customers mandate compliance. At Solar Atmospheres we embrace these programs as opportunities. It is a good thing when industry original equipment manufacturers and final device makers recognize the benefits that accrue when suppliers become involved in the global management of activities surrounding their special process. After all, who knows a special process better than the companies that perform it every day? These programs inevitably bring the OEMs and suppliers together at the same table where pertinent discussions lead to achieving the following goals: first, improvements in the substance and flow-down of the requirements from the OEMs, second, improvements in the performance of the supplier base, and third, improved products to doctors and patients resulting in better quality medical care with fewer complications.”

“I would like to add my personal congratulations to everyone at Solar Atmospheres, as the company has been actively involved in the MedAccred program for some time now, and volunteered to pioneer this process. Their positivity and diligence has paid off and I am delighted to award them the first ever MedAccred certificate,” said Joe Pinto, Executive Vice President and Chief Operating Officer at the Performance Review Institute.

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Upcoming MedAccred Management Council Meetings

The MedAccred Management Council meets on a monthly basis by teleconference or in person. The schedule for the remainder of the year is below.

- October 14 (Teleconference)
- November 12 (Teleconference)
- December 2 (Face-to-face) – Pittsburgh, Pennsylvania, USA

All medical device industry representatives are welcome to attend. Learn more on our website.

Meet the MedAccred Task Groups

The MedAccred Task Groups form the technical backbone of the program.

A Task Group is created for each critical process technology in which representatives from the MedAccred Management Council (MMC) wish to perform audits. Participating companies (OEMs, contract manufacturers and suppliers) nominate internal staff with an expert level of knowledge for each critical process to represent their interests.

The Task Groups are responsible for the development of the audit criteria, the contracting of auditors, the review and approval of audit packages and final decision on accreditation. The work of the Task Groups is overseen and guided by the MMC.

There are currently 7 active MedAccred Task Groups:

- Electronic Circuits – Printed Circuit Board Assemblies
- Cable and Wire Harness
- Heat Treating
- MedAccred Quality Systems
- Plastics
- Sterilization
- Welding

About MedAccred

MedAccred is an industry managed, consensus-driven approach to ensuring critical manufacturing process quality throughout the medical device supply chain. In today’s world of global manufacturing, the supply chain is multi-tiered and geographically remote, making oversight challenging and costly. To prevent output deficiencies, critical processes and products must be validated during manufacturing to prove that they are fit for purpose, satisfy regulatory requirements and reduce overall risk. Learn more on our website.

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The Performance Review Institute is a not-for-profit global provider of customer-focused solutions designed to improve process and product quality by adding value, reducing total cost and promoting collaboration among stakeholders in industries where safety and quality are shared goals.