MedAccred℠
Advancing Medical Device Quality Through Supply Chain Process Accreditation

SPECIAL MD&M WEST EDITION

FEBRUARY 2016

INDUSTRY LEADERS TO HIGHLIGHT MEDACCRED AT MD&M WEST 2016

Conference attendees at MD&M West 2016 will be given an insight into the advantages of MedAccred, an innovative new industry managed supply chain oversight program. Executives from three of the program's participating manufacturers will present a paper entitled *MedAccred: Innovating Critical Process Manufacturing Oversight*, as part of the Enhanced Quality Assurance and Risk Management track on Thursday February 11, 2016 from 10.30am-11.00am.

The program is uniting leaders in the Medical Device Industry who are working together to accredit suppliers to deliver better quality
and enhance patient safety.

During the session, Robert Berger, Vice President Contract Manufacturing, Minimally Invasive Therapies Group, Medtronic, Ravi Nabar, Head of Supplier Quality Assurance, Philips, and Charlie Mason, Vice President of Medical Division, Sanmina, will outline the importance of the connection between the manufacturing process and the patient. They will also describe how MedAccred can be used to strengthen critical manufacturing process oversight through all tiers of the supply chain.

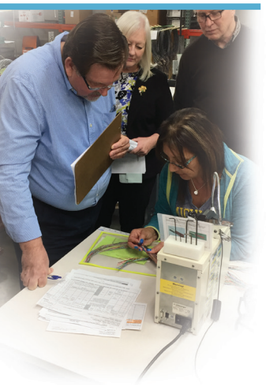
Speaking ahead of the presentation, Charlie Mason of Sanmina described the challenges created by the way the industry currently conducts supply chain oversight. Customer audits can be a weekly, if not a daily event and in many cases they all address similar requirements. These audits can be redundant, costly and time consuming for both the customer and the supplier involved. Mr Mason commented: "I believe the MedAccred model, which is based on a technical expert in the critical process conducting the audit to consistent requirements, will lead to a reduced number of customer audits for our sites and will reduce costs for us as the supplier."

Ravi Nabar of Philips, who will provide the OEM perspective on MedAccred said: "Based on observed reduction in escaping defects over time from suppliers participating in the Nadcap program in the aerospace industry, I believe the MedAccred program if adopted and expanded throughout the medical device supply chain, will result in an overall improvement in the quality of critical to quality processes and purchased parts resulting in fewer defects and ultimately a safer patient. The structure the program provides will improve the flowdown of critical to quality requirements to our sub-tier supply chain for critical to quality processes and this will mean more compliant products and our requirements being met end to end."

A number of companies including Solar Atmospheres, Synergy Health and Global Technologies have already achieved accreditation, demonstrating their commitment to quality and above all patient safety. Others, such as Sanmina Corporation and Hanson-Balk Steel Treating have completed audits and are in the process of attempting to gain full accreditation. In addition, MTD Micro Molding and BMP Medical have completed pilot audits which will be used to validate the plastics injection molding audit criteria and eventually will lead to full accreditations.

PERFORMANCE Review Institute

GLOBAL TECHNOLOGIES FIRST TO ACHIEVE MEDACCRED CABLE & WIRE HARNESSES ACCREDITATION



In February 2016 Global Technologies of Spring Lake, MI became the first company in the world to receive MedAccred Cable & Wire Harnesses accreditation.

MedAccred is a new innovative industry managed supply chain oversight program designed to improve patient safety. It does this by defining industry requirements and identifying how they apply to critical processes used in the production of medical devices.

Global Technologies is now officially the first company to be fully compliant with the MedAccred Audit Criteria for Cable and Wire Harness Assemblies (AC8121) which were developed by the MedAccred Cable and Harness Assemblies Task Group. The members of the Task Group come from companies including Philips, Stryker, GE Healthcare, Baxter Healthcare, as well as Global Technologies. The audit criteria were developed in accordance with the Class 2 and Class 3 requirements of IPC/WHMA-A-620, J-STD-001 and other industry standards.

Global Technologies was an early adopter of the program and participated in the Task Group from its inception. Jeff Olds, CEO of Global Technologies said: "We are extremely proud to be the first company to achieve the accreditation from MedAccred for Cable and Wire Harnesses. A MedAccred audit is a rigorous assessment of critical process capability and compliance to customer requirements and industry standards. I am delighted to be able to say to all our customers that Global Technologies' capabilities and compliance status have been validated through this audit process. We believe MedAccred will become an important part of the medical device industry's approach to supply chain oversight and it is fantastic to be recognized as being at the forefront of this effort."

Joe Pinto, Executive Vice President and Chief Operating Officer at the Performance Review Institute said: "We would like to thank Global Technologies for their ongoing and active participation in the MedAccred program. It is because companies like Global Technologies are willing to step forward and be the first to conduct an audit at their facility that MedAccred is able to start demonstrating the value it offers the whole industry. Being the first to achieve accreditation is not easy and everyone at Global Technologies should be very proud of their new status as the first MedAccred Cable and Wire Harnesses Accredited Supplier."

FIRST MEDACCRED STERILIZATION ACCREDITATION AWARDED TO SYNERGY HEALTH

Synergy Health in Alajuela, Costa Rica has become the first company to receive MedAccred Sterilization Accreditation, on January 5, 2016.

This follows the successful development of the MedAccred Audit Criteria for Sterilization by the MedAccred Sterilization Task Group (AC8113, AC8113/1 and AC8113/2). The audit criteria include Radiation (Electron Beam and Gamma) and Ethylene Oxide. The members of the Task Group come from companies including Johnson & Johnson, Philips, Stryker, Baxter Healthcare, Becton, Dickinson & Co., DSM Biotech, Synergy Health and Flex. The Sterilization audit criteria draw from Industry Standards as well as manufacturing best practices for this critical process technology.

Wendy Gould, VP Regulatory Affairs & Quality at Synergy Health 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".

"Achieving MedAccred status is not easy: it is one of the ways in which the medical device manufacturing industry identifies those suppliers capable of providing superior critical process manufacturing to the Device industry. Synergy Health has worked hard to obtain this status and they should be justifiably proud of it," said Joe Pinto, Executive Vice President and Chief Operating Officer at the Performance Review Institute.

MEDACCRED AND THE FDA

MedAccred, through the efforts of its Management Council has sought to keep 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 provided positive feedback and strong encouragement to pursue the development of the program. Further synergies were established in concert with FDA's Case for Quality initiative ('Critical-to-Quality' (CtQ) methodology) and MedAccred. MedAccred was 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.

MedAccred's goal is to continue open communications with the FDA, providing updates on the progress of the program as appropriate. As the program continues to mature, MedAccred will also be starting to engage with other global regulatory bodies.

MEDACCRED PLASTICS MICRO INJECTION MOLDING AND INJECTION MOLDING PILOT AUDITS COMPLETE

In January 2016 MTD Micro Molding in Charlton, MA became the first micro injection molding company to pilot the new MedAccred Plastics Injection Molding audit criteria. Three weeks later, BMP Medical of Gardner, MA became the first injection molding company to complete a pilot audit against the new audit criteria.

The pilot audits follow the successful development of "Audit Criteria for Injection Molding" (AC8160) by the MedAccred Plastics Task Group. The members of the Task Group come from companies including Abbott, Baxter Healthcare, Becton, Dickinson & Co., Boston Scientific, GW Plastics, Johnson & Johnson, Philips, Stryker, Mack Molding, Medtronic, Plastikos, BMP Medical and MTD Micro Molding. The Plastics Injection Molding audit criteria draw from Industry Standards as well as manufacturing best practices for this critical process technology.

Reflecting on her company's experience, Lindsay Mann, Director of Marketing for MTD Micro Molding said: "It was a great opportunity to look closely at our processes in the MedAccred pilot audit and measure our process against the audit criteria created by key members of the medical device industry. Our goal as a supplier is to meet or exceed their needs and requirements. We view the MedAccred plastics accreditation as a very powerful tool for medical OEMs and their suppliers".

Mike Faulkner, President at BMP Medical, stated that: "Participating in MedAccred has many advantages for BMP Medical and our customers. As always, we strive to ensure that our products are manufactured to the highest quality standards. Our commitment to support the accreditation process will take us to another level, demonstrating that we strive to stay on the cutting edge of continued process improvement as well as meeting and exceeding the requirements of our medical device partners and industry standards."

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

MTD Micro Molding and BMP Medical should be commended for stepping forward to participate in this very important pilot audit. Their efforts, alongside those of their colleagues on the Plastics Task Group, will result in a set of robust audit criteria which will be used to verify critical process compliance for injection molding across the whole of the Medical Device industry.

MedAccred℠ UPDATE

Advancing Medical Device Quality Through Supply Chain Process Accreditation

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.

LEARN MORE ABOUT MEDACCRED AT WWW.P-R-I.ORG/MEDACCRED/

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.

PERFORMANCE Review Institute

UPCOMING MEDACCRED EVENTS

In 2016, MedAccred will be represented at the following key medical device industry events:

13th Annual Medical Device Quality Congress

- March 15-17, 2016
- Rockville, Maryland, USA
- Presentation: *MedAccred Update: Devicemakers Driving Quality Standards for Their Suppliers*

3rd Annual Medical Device Supplier Quality: Efficiency & Collaboration Conference

- April 11-12, 2016
- Arlington, Virginia, USA
- Panel Discussion: *Ongoing Development of Third Party Assessments and the Impact on Supplier Quality*

Implants 2016

- June 7, 2016
- Paris, France
- Keynote Speech: Simon Adam, Senior Director Supplier Quality, DePuy Synthes (Johnson & Johnson)

AdvaMed 2016

- October 17-19, 2016
- Minneapolis, Minnesota, USA

Contact Us

Americas/International

Connie Conboy
Director, Business Development & Strategy
cconboy@p-r-i.org
+1 724 772 7153

Justin McCabe
Sr. Specialist, Business Development
jmccabe@p-r-i.org
+1 724 772 8693

Europe

Hannah Godfrey
Sr. Specialist, Business Development
hgodfrey@p-r-i.org
+44 207 034 1247

Asia

Liu Le
Manager, PRI Asia Pacific
lle@p-r-i.org
+86 10 6461 9807

PERFORMANCE Review Institute