

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.

- Plastics
 - Injection Molding
 - Compression Molding
 - Injection Blow Molding
 - Insert Molding
 - Micro Molding
 - Overmolding
 - Transfer Molding
- Sterilization
 - Ethylene Oxide
 - Radiation (Gamma & E-Beam)
- Welding
 - Fusion Welding
 - Laser Welding
 - Welding Operator Qualification

There are currently 6 active MedAccred Task Groups:

- Electronic Circuits – Printed Circuit Board Assemblies
- Cable and Wire Harness
- Heat Treating
 - Pyrometry
 - Metallography and Microindentation Hardness
 - Hardness & Conductivity Testing



UPCOMING MEDACCRED EVENTS

MedAccred will be represented at:

AdvaMed 2016

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

Q1 Productions Conference

- October 2016
- Minneapolis, Minnesota, USA

FIRST ACCREDITATION FOR MEDACCRED IN EUROPE AWARDED TO BODYCOTE



The Bodycote facility in Derby, UK has become the first company in Europe to receive a critical process accreditation from MedAccred. The site received accreditation for Heat Treating after successfully completing a demanding audit which included a thorough review of the facility's vacuum heat treating compliance to customer requirements, rigorous industry standards and best practices.

MedAccred is a new and innovative industry managed approach to supply chain oversight. The program conducts in-depth critical process audits on behalf of the medical device industry. Through supply chain accreditation, MedAccred improves overall standards of supplier quality and most importantly enhances patient safety. MedAccred is administered on behalf of the medical device industry by the not-for-profit Performance Review Institute (PRI).

For Bodycote, the benefits of MedAccred to the supplier are evident. The process provides for consistent and standardised critical process audits which result in fewer redundant onsite audits by multiple OEMs and first tier customers. The accreditation from MedAccred should reinforce customer confidence in Bodycote as a premier quality provider of Heat Treating and HIPing.

Speaking about Bodycote's success, Joe Pinto, Executive Vice President and Chief Operating Officer of PRI said: "I would like to congratulate the entire team at the Bodycote

Derby facility. This accreditation from MedAccred demonstrates that Bodycote is able to consistently meet or exceed the requirements of their medical device customers. The fact that Bodycote has become the first company to gain accredited status in Europe is a significant achievement and an important step forward for the MedAccred program in terms of its global reach."



Image of Bodycote Derby facility courtesy of Bodycote

Bodycote is already extending their participation in MedAccred with audits scheduled at their facilities in Ipswich, MA, USA in July 2016 and Nogent en Bassigny, France in October 2016.

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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 is an important tool in assuring critical manufacturing process quality by ensuring flow-down of CtQ 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.

SOLAR ATMOSPHERES RECEIVES FIRST REACCREDITATION FROM MEDACCRED

Solar Atmospheres, Inc. has become the first company to receive MedAccred critical process reaccreditation. The Pennsylvania based Heat Treating company expanded its scope of accreditation for Heat Treating to include Hardness Testing and Metallography & Microindentation Hardness.

In early 2015 Solar Atmospheres was the first company to achieve a MedAccred critical process accreditation globally. An initial accreditation from MedAccred is valid for 12 months after which time a company receives a

reaccreditation audit which includes the verification of the corrective actions from any non-conformances found in their previous audit.

The successful completion of the reaccreditation audit means that Solar Atmospheres has now demonstrated their ability to consistently uphold the high standards required to maintain the accreditation over an extended period of time. Ed Engelhard, Vice President of Corporate Quality explains why MedAccred is so important in terms of their overall approach to quality: "The company really takes pride in being on the cutting edge of heat treatment activity, and active involvement in MedAccred was seen as an extension of that. You want the customer experience to be unremarkable, and by extension, safe. That's our goal. I see safety and quality as inextricably linked and that's the intrinsic value of a program like MedAccred for the industry."



Image of the Solar Atmospheres clean room furnace provided by Solar Atmospheres

MDT MAGAZINE EDITORIAL HIGHLIGHTS MEDACCRED AS TOP INDUSTRY TREND

MedAccred was identified as one of the top three trends for device designers by Lee Goldberg, the new editor of Medical Design Technology magazine, in his March 2016 editorial. Mr Goldberg learned about MedAccred after spending three days walking the floor of the MD&M West show in Anaheim, February 2016 where MedAccred had a strong presence. The editor identifies three trends from the show highlighting MedAccred an important example of, "companies beginning to take a proactive approach to regulatory requirements."

Links to the full editorial are available on the MedAccred News page of the MedAccred website.

HOW DID MEDACCRED START?

The concept for the program was first put forward by today's MedAccred speaker at Implants 2016, Simon Adam, Senior Director, Supplier Quality for DePuy Synthes from Cork, Ireland. In his own words, Simon explains what inspired him:



"While on a benchmarking visit to an aerospace company in 2010 the Nadcap program came up for discussion. It struck me as something that could be highly beneficial for medical devices, as both industries have many similarities, both are highly regulated, safety critical, and in many cases, the supplier base and technologies have a lot of commonality.

After the benchmarking visit was over, I researched Nadcap further to learn more. My research cemented the concept in my mind for the medical device industry and I reached out to the organization that administers Nadcap for the aerospace industry,

to see if there was any opportunity to develop a similar system for medical devices."

Thanks to Simon's vision, a series of initial meetings culminated in an industry roundtable in Chicago, USA in December of 2012 where a critical mass of key industry stakeholders agreed to formally establish MedAccred. Since then, the program has evolved into a fully functioning industry managed supply chain accreditation program for the medical devices industry.

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.MEDACCRED.ORG

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.