DeviceMed Article Synopsis

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MedAccred: A move towards a reduction in supplier audits?

The MedAccred program is managed by an industry group and its goal is to assure the quality of critical process manufacturing in the supply chain. The number of accreditations is starting to multiply with the first in Europe being issued to Bodycote.

In the world of medical device manufacturing, OEMs are required to oversee the critical process activities of the entirety of their supply chain. This becomes more and more difficult and costly when there are several tiers of suppliers who could be scattered all over the world. The end result is many audits which are in fact redundant because OEMs often use the same suppliers. They each have to do their own audit with the same supplier.

Administered by PRI, MedAccred has been created to address this problem and is inspired by the 25 years of success achieved by the Nadcap aerospace program. The project began in 2010 prompted by a Supply Quality Chain Director from DePuy Synthes in Ireland. Having become familiar with Nadcap he thought it would be appropriate to create a similar accreditation for medical device companies. In 2012 a roundtable brought together around 15 device makers and suppliers to officially launch the program: Abbott, Baxter Healthcare, Beckman Coulter, Boston Scientific, Brunk Industries, DePuy Synthes, GE Healthcare, Medtronic, Paragon Medical, Philips, Stryker, Symmetry Medical, Terumo Cardiovascular and Zimmer.

Today around 40 companies participate in the program which has Task Groups working initially in the areas of PCBAs, Cable and Wire Harnesses, Heat Treating, Plastics – Injection Molding, Sterilization and Welding. Other Task Groups will be created to cover a list of around 15 more potential areas of interest.

Audits which are standardized by the subscribers

The basic principle is to define audit criteria in a collaborative manner to create audits which are agreed upon by all the OEM subscribers. The audit criteria incorporate industry accepted standards and OEM requirements which are compliant with the requirements of the regulators. Focused on the process itself, the audits are conducted by auditors who are trained and approved by the industry. Accreditation is granted by the OEMs who subscribe to the program.

As it is validated by the medical device industry companies, this standardized critical process accreditation should lead to a reduction in the number of onsite audits conducted by the OEMs themselves. Something which will benefit everyone. The accreditation also provides greater visibility

of the supply chain through all tiers and sub-tiers involved in critical processes who are working under the regulatory guidelines (FDA, ISO 13485, MDD, etc). Finally it will also improve the flowdown of requirements from the OEMs to the suppliers at lower levels of the supply chain.

The MedAccred program seeks to have regular communication with the FDA and in July 2015 it received a positive reaction with the FDA encouraging the program to continue its development. Dialogue should soon begin with other global regulatory agencies.

The number of accreditations grows

It was the American company Solar Atmosphere who got the ball rolling at the beginning of 2015 by obtaining the first accreditation from MedAccred for Heat Treating. Last month they also became the first company to achieve a reaccreditation (the initial accreditation is based on a 12 month cycle). Solar Atmospheres increased the scope of their accreditation to include Hardness Testing.

In January 2016 it was the turn of the Costa Rican site of the UK company Synergy Health to gain the first accreditation for Sterilization. The American company Global Technologies followed in February with the first accreditation for Cable and Wire Harnesses.

Last month Bodycote joined this group of pioneers with the first accreditation in Europe for the critical processes taking place in its UK site in Derby. This facility conducts Heat Treating as well as HIP (Hot Isostatic Pressing) for the European orthopedic implants market and other device manufacturers.

Other companies such as the American Sanmina group (PCBAs) and Hansen-Balk (Heat Treating) have conducted audits and are working towards accreditation. Other companies such as MTD Micro Molding and BMP Medical have participated in pilot audits which will be used to validate the audit criteria for Plastics Injection Molding and are likely to eventually result in accreditations.