Clinica

EU medtech notified bodies face code compliance audits

30 December 2013

Vibha Sharma

The association of EU medtech notified bodies, Team-NB, has completed an audit – the first of its kind – to check whether its member companies are following the association's code of conduct. Though no enforcement deficiencies were found in the first round of audits that was completed on 16 December, the audits will continue in 2014 and beyond to keep medical device notified bodies on their toes.

TEAM-NB's code of conduct prescribes standards for various issues, including the minimum time a notified body should spend on auditing medical device companies, conducting unannounced inspections of device companies, sampling of Class IIa and IIb medical device technical files, performing design examinations, verifying products manufactured in accordance with the In Vitro Diagnostics Directive and subcontracting issues.

Compliance with the code became mandatory on 1 January 2013. The code was last revised in April, when more details on the enforcement of the code were agreed upon, Team-NB director Françoise Schlemmer told *Clinica*'s sister publication *Scrip Regulatory Affairs*.

After the enforcement framework and rules were decided, the association hired a team of auditors. As per the initial schedule, the auditing team intends to audit every member company once over a three-year period. The association currently has 29 members, which means around 10 companies will be audited every year. Compliance with the code is compulsory for TEAM-NB members; failure to comply would result in the errant company being dismissed from the association's membership.