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## **FDA Audits Amarex HQ - All is Good!**

### **FDA GCP Audit of Amarex**

This past week the US FDA conducted a GCP audit of Amarex Clinical Research headquarters in Germantown MD. The result of the audit was 'no findings' and no '483s'. The FDA auditor complimented Amarex's SOPs, documentation, and the helpfulness and thoroughness of the Amarex employees that assisted with the audit.

The FDA performs audits as part of their medical product approval process. This audit was due diligence for a pending FDA Marketing Approval for the product of an Amarex client. The audit involved an overall systems audit of Amarex and examined Amarex's SOPs, documentation practices, personnel training, and facility design.

Dr. Mukesh Kumar, VP of Amarex Regulatory Affairs, said "this audit demonstrates the high quality performance applied to Amarex managed clinical trials. This is our second 'clean bill of health' FDA audit in the past five years."

Amarex is a global Contract Research Organization (CRO) that provides complete clinical product development services to bioscience companies to achieve FDA approval for their new medical products. General Service categories include: 1) product development plan creation, 2) pre-clinical and clinical trial conduct, 3) applications to the FDA for marketing approval of new or improved medical products.

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