The Veeda Newsletter

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483 Roundup: FDA Cites Firms Over Complaint Handling, Other Deficiencies

The FDA cited device manufacturer US Vascular for a wide range of deficiencies, including inadequate procedures for handling complaints. Following an April inspection of the firm's Beaverton, Ore., facility, the FDA issued a Form 483 with 14 observations. Inspectors found at least six complaints the firm failed to evaluate to see if they required further investigation or reporting to the FDA as an MDR.

Read More:http://www.fdanews.com/articles/182261-roundup-fda-cites-firms-over-complaint-handling-other-deficiencies

FDA's Generic Drugs Office Passes Last Year's Record for ANDAs Received.

Two-thirds of the way through fiscal year 2017, the FDA has received at least 877 ANDAs, passing fiscal 2016's total of 852 and beating fiscal 2015's total by more than 330 applications.For fiscal 2017, the agency has totaled 477 approvals so far, 119 of them tentatively, while issuing 1,124 complete response letters.

Read More:http://www.fdanews.com/articles/182367-fdas-generic-drugs-office-passes-last-years-record-for-andas-received

FDA Publishes Case Studies on Biomarker Qualification

The FDA highlighted two fictional case studies it published on the role biomarker qualification plays in drug development — as part of a reorganization of the agency's biomarker materials — to help drugmakers understand the validation studies necessary to support qualification, the collaborative efforts involved and the potential benefits.

Read More:http://www.fdanews.com/articles/182308-fda-publishes-case-studies-on-biomarker-qualification

FDA Updates Q&As on Clinical Trials to Evaluate Potential Heart Rhythm Risks

The FDA published a set of revisions to an ICH supplement, answering industry questions on the evaluation of certain drugs' potential to produce abnormal heart rhythms.

The question-and-answer document — stemming from the ICH's E14 guideline on clinically measuring QT prolongation, first adopted by the FDA in 2005 — includes updates on new technologies, late-stage monitoring and clinical study design for special cases, as well as combination products and large, targeted proteins, including monoclonal antibodies.

Read More:http://www.fdanews.com/articles/182273-fda-updates-qas-on-clinical-trials-to-evaluate-potential-heart-rhythm-risks