The Veeda Newsletter

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FDA

FDA Issues Revised ICH Risk-Benefit Submission Guidance

The FDA issued a revised version of its ICH-developed guidance on completing the clinical overview section of the Common Technical Document, including more details on risk-benefit submissions.The guidance, known as M4E(R2), lists what sponsors should consider when describing risks and benefits, but does not specify a particular industry approach for completing assessments.

Read More: http://www.fdanews.com/articles/182804-fda-issues-revised-ich-risk-benefit-submission-guidance

FDA Publishes Over 30 New and Revised Product-Specific Draft Guidance

The new guidance include recommendations for developing generics for aspirin and its combination with the heartburn medication Prilosec (omeprazole) — in addition to therapies for schizophrenia, epilepsy and colorectal cancer, as well as antibiotics and a topical corticosteroid. They also include antivirals and combinations for HIV and hepatitis C.

Read More: http://www.fdanews.com/articles/182631-fda-publishes-over-30-new-and-revised-product-specific-draft-guidances

Drug maker Cited for GMP, Quality Issues

A PET finished dose manufacturer in Ohio was cited by the FDA after investigators witnessed numerous cGMP violations and potential quality problems on a January site visit.An IBA Molecular North America facility in Oakwood Village, Ohio, a radiopharmaceuticals maker that also does business as Zevacor Pharma, was not adhering to its own quality plans and procedures, according to the FDA.

Read More: http://www.fdanews.com/articles/182712-drugmaker-cited-for-gmp-quality-issues

EMA Adopts Five Product-Specific Bioequivalence Guidances

The guidances include recommendations for Gilead's elvitegravir antiviral, both alone and as a fixed-dose combination with cobicistat, emtricitabine and tenofovir under the brand name Stribild. The EMA recommends single-dose, crossover studies in healthy volunteers — one for the combination, but two for elvitegravir alone, at 85 and 150 mg strengths.

Read More: http://www.fdanews.com/articles/182594-ema-adopts-five-product-specific-bioequivalence-guidances