

Blame the Laboratory—Understanding Analytical Error

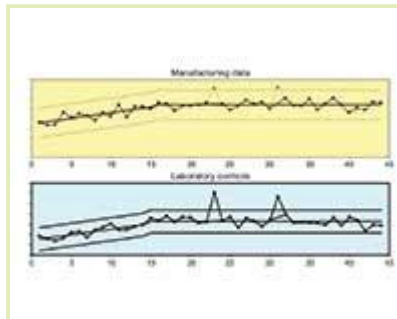


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May 21, 2013 3:14 pm EDT



Before analytical error can be reduced, it must be understood. The pharmaceutical industry has a history of confusing compliance with good quality. When outsourcing analytical tests to a vendor laboratory, not only must compliance aspects be covered in the outsourcing protocols, but also minimum standards for analytical variation must be established in advance. Validation studies and laboratory controls both suffer from the Hawthorne effect, resulting in estimates for analytical error that are lower than that which is found in routine day-to-day samples. All laboratories have an obligation to provide...

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