

## **The Hows and Whys of Internal Standards in Regulated Bioanalysis**

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### **Synopsis**

Internal standards are a common component of bioanalytical methods. However, for those new to the bioanalytical sphere, it may not be clear how an internal standard is selected and validated for any given analyte. This presentation will give an outline of the nature of internal standards and the selection process, and the role of the internal standard in producing robust results from a scientific perspective. In addition, the regulatory requirements for internal standards as part of method validation, in addition to expectations for internal standard use during sample analysis, will be fully outlined and discussed. This will provide a great background for QA auditors looking to understand the purpose and uses of internal standards in bioanalysis.