

Explicit Microsoft Excel Methods For Computerized System Validation



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To combat CSV non-compliance, established here are cost and time effective explicit methods to verify and validate Microsoft Excel Workbooks – designed to meet standards set by Australian regulatory bodies: The Therapeutic Goods Administration (TGA) and Pharmaceutical Inspection Co-operation Scheme (PIC/S). INTRODUCTION The Good Manufacturing Practice (GMP) environment in Australia is rapidly expanding with more companies manufacturing pharmaceutical compounds, biological interventions, and medical devices (1). In Australia GMP standards are set by the Therapeutic Goods Administration...

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