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Intrinsic Compliance: A Model for Process Validation Optimisation



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INTRINSIC COMPLIANCE This paper defines intrinsic compliance as a design technique applied to manufacturing systems and processes to ensure maximum alignment, connectivity and compatibility between process requirements and system capabilities across the 3-Stage PV Lifecycle. The technique is based on the identification of process:facility pairings and the sharing of risk-based datasets assigned at the point of process definition. Intrinsic compliance does not relate to GMP compliance in the procedural sense. **SET THEORY** Set theory, familiar from schooldays, is the primary basis of this paper. The...

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