



Using readily understandable Atomic Elements as a prototype, the paper recommends that Manufacturing Elements be equally integral, with mandatory Relational Data and Risk Flags acting as the basis of the PV lifecycle and its Process:Facility handshakes. This is a far more datacentric and transparent approach than the current reliance on URS vs IOQ traceability matrices etc. Similar commitments can be made on behalf of other aspects of manufacture, e.g. [QTPP:Batch], [CMA:CofA], [CQA:CofA], [UnitOp:System], [IPC:Sample], [CPV:Ctrl.Chart], [Assay:Analyser].