Formula 1

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Formula 2

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Formula 3

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Detailed Explanation

ASME V&V 40 establishes a foundational philosophy distinguishing verification (‘Did we build the model right?’) from validation (‘Did we build the right model?’), emphasizing credibility assessment over binary pass/fail judgments. The Digital Twin Validation Protocol Template operationalizes this philosophy by requiring explicit articulation of the ‘context of use’—including decision objectives, required accuracy thresholds, operational boundaries, and risk tolerance—before any V&V activity begins. This context anchors all subsequent evidence generation, such as experimental data comparison, sensitivity analysis, and uncertainty propagation, ensuring relevance and defensibility. The protocol mandates traceability across four key artifacts: (1) the digital twin’s purpose statement and decision impact; (2) the physical system’s characterization and measurement uncertainty; (3) the computational model’s assumptions, discretization choices, and software verification status; and (4) the validation metrics and their statistical interpretation. In practice, it supports regulatory engagement, audit readiness, and cross-disciplinary alignment—especially in high-consequence domains like pharmaceutical manufacturing, power generation, and chemical process safety—where digital twins inform real-time control, predictive maintenance, or regulatory submissions.

Key Components

#	Component
1	Context-of-Use Statement
2	Evidence Traceability Matrix
3	Uncertainty Quantification Plan
4	Validation Metric Specification
5	Credibility Assessment Summary

Applications

#	Application
1	Regulatory submission support for FDA/EMA digital twin-based process validation
2	Operational qualification of digital twins in industrial IoT platforms
3	Audit-ready documentation for ISO 55000 or IEC 62443-compliant asset management systems

Related Concepts

#	Concept
1	Computational Model Credibility
2	Process Simulation Verification
3	Digital Twin Lifecycle Management
4	Uncertainty Quantification (UQ)
5	Model-Based Systems Engineering (MBSE)

Tags

digital-twin, verification-and-validation, ASME-VV40, process-simulation, uncertainty-quantification