



MODULE MANUAL

Physical boundaries, standards and model validation

Turn a calculated result into a traceable engineering statement

DOCUMENT BASIS

Product workflows, visible results, review criteria, evidence boundaries and controlled handover.

M07-EN-4.2 | RELEASE 4.2

6 OCTOBER 2026



Document control

One controlled basis for public product guidance.

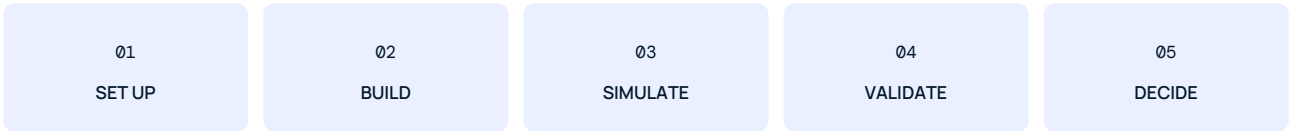
FIELD	VALUE
Document ID	M07-EN-4.2
Release	4.2
Reviewed	6 October 2026
Audience	Model Owner, Reviewer, QA, Process Safety, MSAT, Regulatory
Purpose	Is the result sufficiently supported for its intended use, and which gaps block the decision?
Owner	Acatian Product and Engineering

APPLICABILITY LIMIT

This manual explains the product workflow and the evidence needed to interpret its outputs. It does not replace qualified engineering judgement, customer quality systems, safety review, equipment-vendor data or validation for a regulated intended use.

Scope and use

Use the navigation path, input register, visible-result description, review criteria and handover record together. A screen or exported number without its model version, basis, unit, evidence status and limitations is not a controlled engineering result.

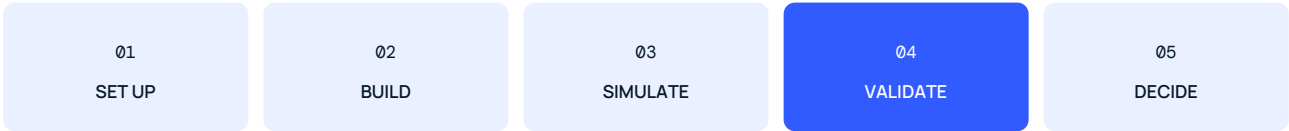


LANGUAGE

This document is written consistently in English. Product navigation names remain as displayed in the interface.

Physical boundaries, standards and model validation

Turn a calculated result into a traceable engineering statement



ENGINEERING DECISION	PATH IN ACATIAN
Is the result sufficiently supported for its intended use, and which gaps block the decision?	Validate > Boundaries + AI / Standards / Readiness / Engineering review
PRIMARY USERS	PERMITTED MATURITY
Model Owner, Reviewer, QA, Process Safety, MSAT, Regulatory	Screening, Calibrated, Validated or Not decision-ready - always evidence based

START WITH THE DECISION

Validation connects intended use, data, equations, numerics, physical boundaries, comparison evidence and approval. Acatian exposes the state but does not replace technical or regulatory approval.

Expected artifacts

ARTIFACT	RECIPIENT
Module result package	Engineering reviewer
Readiness register	Model owner
Controlled version	Project team

Prepare the model

INPUT	WHY IT MATTERS	READY WHEN
Intended use	Defines acceptance criteria and required evidence.	Decision, population, scale and risk are explicit.
Physical boundaries	Limits working volume, oxygen, temperature, shear, ammonium and lactate.	Boundary, unit, source, action and range are documented.
Validation dataset	Tests prediction outside calibration.	An independent dataset and comparison plan exist.
Standards and requirements	Connects engineering, GMP, safety and project requirements.	Applicability, version, owner and evidence are recorded.
Approval roles	Establishes independent review and controlled approval.	Author, reviewer and approver are separated.

Preflight check

CHECK	Confirm the correct project, branch and controlled version
CHECK	Verify units, provenance and permissions
CHECK	Save a restore point before a decision-relevant change
CHECK	Keep blocking gaps visible

Workflow

01

Define validation plan

Document intended use, risk, datasets, metrics and tolerances.

VISIBLE RESULT: The plan is versioned before results are inspected.

02

Verify numerics

Assess closure, solver, convergence, discretisation and reproducibility.

VISIBLE RESULT: Numerical health has no unexplained blocker.

03

Verify physics

Evaluate process, equipment and quality bounds against trajectories.

VISIBLE RESULT: Violations include time, magnitude and action.

04

Compare data

Compare prediction and measurement with residuals, bias and intervals.

VISIBLE RESULT: Pass/fail is traceable for every criterion.

05

Map standards

Map applicable requirements to model, data, operation and documents.

VISIBLE RESULT: The matrix shows evidence or gap.

06

Set maturity

Select Screening, Calibrated, Validated or Not decision-ready by evidence gates.

VISIBLE RESULT: State, rationale, reviewer and date are stored.

07

Approve or reject

Close findings and sign a controlled version.

VISIBLE RESULT: Audit trail and residual uncertainty are complete.

Review the result

CRITERION	PASS CONDITION	IF IT FAILS
Scope and structure	The documented criterion is satisfied and supported by traceable evidence.	Correct the model or keep the output Not decision-ready.
Units and balances	The documented criterion is satisfied and supported by traceable evidence.	Correct the model or keep the output Not decision-ready.
Evidence and uncertainty	The documented criterion is satisfied and supported by traceable evidence.	Correct the model or keep the output Not decision-ready.
Reproducibility	The documented criterion is satisfied and supported by traceable evidence.	Correct the model or keep the output Not decision-ready.
Review state	The documented criterion is satisfied and supported by traceable evidence.	Correct the model or keep the output Not decision-ready.

APPLICABILITY LIMIT

Acatian organises evidence and tests; qualified people and approved company processes own regulated, safety and investment approval.

Troubleshooting

OBSERVATION	LIKELY CAUSE	CORRECTION
The result looks plausible but cannot be explained	Inputs, units, model version or evidence are missing.	Open the relevant register, restore traceability and rerun.
A change affects unexpected outputs	Dependencies or imported mappings were not reviewed.	Inspect the change plan and before/after diff; undo if required.
The module appears complete but readiness is low	Required industrial evidence is still missing.	Assign the visible gaps and keep maturity at Screening or Not decision-ready.

Controlled handover

ARTIFACT	RECIPIENT	MUST CONTAIN
Module result package	Engineering reviewer	Inputs, calculations, results, units, intervals, maturity
Readiness register	Model owner	Gap, required work, owner, due date, intended use
Controlled version	Project team	Branch, version, change note, reviewer and restore point

Completion check

CHECK	The active project, branch, version and intended use are visible.
CHECK	Inputs carry units, provenance, review state and uncertainty where relevant.
CHECK	Blocking model, physical, numerical and evidence gaps are closed or assigned.
CHECK	The result maturity matches the available evidence.
CHECK	The output package opens correctly and includes its limitations.

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