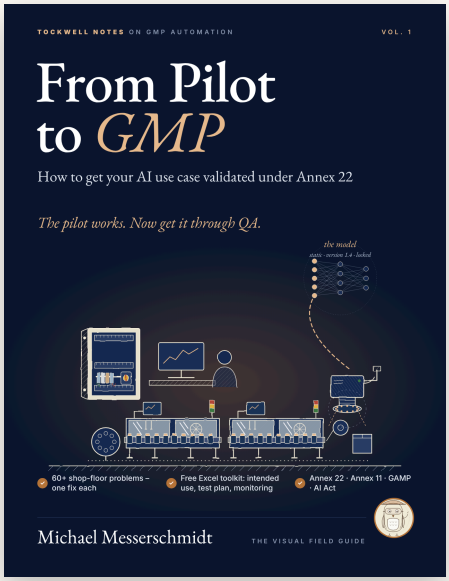
TOCKWELL NOTES ON GMP AUTOMATION · VOL. 1

Reader toolkit

From Pilot to *GMP* – all templates from the book, ready to print or to fill in on screen.



Use case canvas	Template 4.1 · p. 53
Intended use – AI model	Template 5.1 · p. 63
Data release checklist	Template 6.1 · p. 77
Configuration items checklist	Template 7.1 · p. 89
Test plan – AI model	Template 8.1 · p. 103
Monitoring plan	Fig. 9.3 · p. 113
Ready for inspection?	Fig. 14.3 · p. 161

Use the Excel file for on-screen work; print these pages for meetings and walk-throughs. Templates are general examples – adapt them to your quality system. Regulatory status as in the book (November 2026). Free for readers. © Michael Messerschmidt.

TEMPLATE 4.1 · BOOK PAGE 53

Use case canvas

No.	Field	Your entry
1	Problem and current process	
2	Proposed AI support – what the model does	
3	Decision level: inform / recommend / act	
4	GMP criticality and rationale	
5	Data sources and availability	
6	Expected value: quality, cost, time	
7	Key risks and fallback	
8	Team: process expert, QA, automation, data science	
9	Decision: go / pilot / no-go · date · signatures	

FROM THE BOOK · TYPICAL MISTAKES

✕ Decision field left empty – the idea lives on as a zombie project.

TEMPLATE 5.1 · BOOK PAGE 63

Intended use – AI model

No.	Field	Your entry
1	Model name and version	
2	Process step / equipment / product family	
3	Purpose (one sentence)	
4	Input data: type, source, format, frequency	
5	Output: classes or values, confidence score	
6	Supported decision and decision level	
7	Criticality and rationale	
8	Operating limits and relevant subgroups	
9	Out of scope and behaviour outside limits	
10	Human review: who, when, how	
11	Approval: process expert, QA · date · signature	

TEMPLATE 6.1 · BOOK PAGE 77

Data release checklist

✓	Item	Owner · date · evidence
☐	Data sources listed: system, time range, conditions	
☐	Context available: product, batch, equipment state	
☐	Subgroups from the intended use covered	
☐	Labelling instruction approved; labellers trained	
☐	Independent check of a defined share of labels	
☐	Split before development; test set locked	
☐	No overlap between sets (unit, batch, day)	
☐	Transformations documented and versioned	
☐	Data sets archived for the retention period	

FROM THE BOOK · TYPICAL MISTAKES

✕ Test set chosen after the first results looked good.

TEMPLATE 7.1 · BOOK PAGE 89

Configuration items checklist

✓	Item	Owner · date · evidence
☐	Model file and version, with checksum	
☐	Pre- and postprocessing steps with versions	
☐	Thresholds and confidence limits	
☐	Input interface definition	
☐	Output interface definition	
☐	Runtime environment and libraries with versions	
☐	Hardware: edge device, server, camera, lighting	
☐	Fallback logic and its test evidence	
☐	Access rights for deployment and configuration	

FROM THE BOOK · TYPICAL MISTAKES

✕ New camera lighting installed as “maintenance”.

TEMPLATE 8.1 · BOOK PAGE 103

Test plan – AI model

✓	Item	Owner · date · evidence
☐	Reference to intended use and model version	
☐	Acceptance criteria per subgroup	
☐	Baseline of the current process	
☐	Test data description and lock evidence	
☐	Interfaces, fallback, out-of-scope input, audit trail	
☐	Confidence thresholds and the “not sure” zone	
☐	Explainability review by process experts	
☐	Deviation handling and re-test rules	
☐	Approval: process expert, QA	

FROM THE BOOK · TYPICAL MISTAKES

✕ Criteria written after seeing the results.

TEMPLATE · FIG. 9.3 · BOOK PAGE 113

Monitoring plan

✓	Item	Owner · date · evidence
☐	Model and version in operation	
☐	Monitored metrics and frequency	
☐	Sampling plan for expert review	
☐	Warning and action limits with owners	
☐	Drift indicators for input data	
☐	Monitoring of human reviewers	
☐	Change and retraining triggers	
☐	Periodic review interval and content	
☐	Approval: process expert, QA	

FROM THE BOOK · TYPICAL MISTAKES

✕ Limits without owners – the alarm reaches nobody.

CHECKLIST · FIG. 14.3 · BOOK PAGE 161

Ready for inspection?

Seven items – within one hour

✓	Item	Owner · date · evidence
☐	Intended use, approved and current	
☐	Data sets with origin, labels and lock evidence	
☐	Acceptance criteria and test results per subgroup	
☐	Configuration: model version, thresholds, runtime	
☐	Audit trail of model decisions	
☐	Monitoring results and periodic review	
☐	Change history, including retraining	

FROM THE BOOK · TYPICAL MISTAKES

✕ Documents spread over five drives.

FROM THE BOOK · INSPECTOR ASKS

→ “Show me the documents for this AI system – and who approved them.”