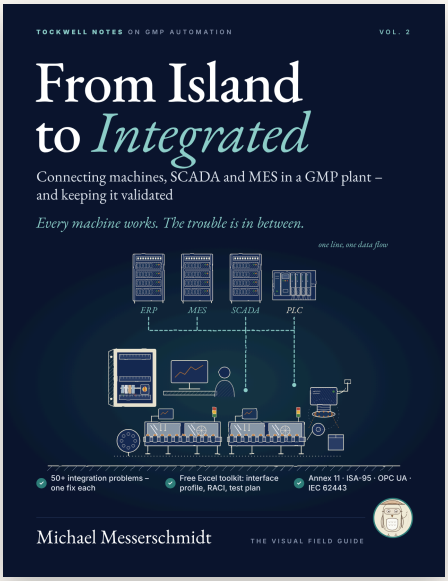
TOCKWELL NOTES ON GMP AUTOMATION · VOL. 2

Reader toolkit

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



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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 · FIG. 3.1 · BOOK PAGE 35

Interface requirement in five lines

Fill in for every interface

✓	Item	Owner · date · evidence
☐	Standard: e.g. OPC UA with a defined data model	
☐	Data: points, units, update rates, direction	
☐	Failure: buffering, alarm and safe state if the link drops	
☐	Context: user, timestamp and reason travel with the value	
☐	Tests: who tests what – supplier, integrator, plant	

FROM THE BOOK · TYPICAL MISTAKES

✕ “Connect to SCADA” as the only requirement – every supplier reads it differently.

TEMPLATE · FIG. 3.2 · BOOK PAGE 37

Who does what, per interface

Example roles – adapt to your plant

Interface	Specify	Build	Test	Operate
Filler ↔ SCADA	Plant A	Builder R	Integr. R	Plant A
SCADA ↔ MES	Plant A	Integr. R	Integr. R	Plant A
MES ↔ ERP	IT A	MES R	IT R	IT A
Line controller	Plant A	Integr. R	Integr. R	Plant A
Time source	IT A	IT R	IT R	IT A
Your rows				

FROM THE BOOK · HOW TO USE IT

→ One A per interface and step – never two.
→ R can be a supplier; A stays with the plant or IT.
→ Review the matrix whenever a supplier changes.

FROM THE BOOK · TYPICAL MISTAKES

✕ “Supplier” as the owner – the contract ends, the interface stays.
✕ Nobody owns the time source – yet every audit trail depends on it.

TEMPLATE · FIG. 7.2 · BOOK PAGE 69

Who leads which master data

Typical allocation – adapt to your plant

Master data	Leading system	Receives
Materials · bills of material	ERP	MES, LIMS
Master recipe	MES	SCADA, PLC
Specifications · limits	LIMS or MES	the other, SCADA
Equipment · units	MES / asset system	SCADA, ERP
Users · roles	directory	all systems
Your rows		

FROM THE BOOK · RULE

→ Changes happen only in the leading system; every other system receives.
→ Every received change has a version and an effective date.

FROM THE BOOK · TYPICAL MISTAKES

✕ Material updated in ERP – MES runs the old version for a week.
✕ Specifications maintained in two systems by two departments.

TEMPLATE · FIG. 8.3 · BOOK PAGE 81

Interface profile

One page per interface

Field	Content
Systems · direction	SCADA → MES, events and values
Standard · version	OPC UA, companion spec, version
Data	points, units, rates – list attached
GMP relevance	records carried, ALCOA+ assessment
Failure behaviour	buffer, alarm, recovery
Owner (A)	named role
Tests · evidence	test IDs, date, result
Change history	version, date, change no.
Your rows	

FROM THE BOOK · TYPICAL MISTAKES

✕ The profile written for the FAT and never updated.

TEMPLATE · FIG. 12.3 · BOOK PAGE 115

Test plan – interfaces

Example rows

Interface	Test type	BY	Evidence
Filler ↔ SCADA	interface + failure	Integrator	protocol IT-01
SCADA ↔ MES	interface + failure	Integrator	protocol IT-02
Sensor → eBR	end-to-end	Plant + QA	protocol E2E-01
MES ↔ ERP	interface	IT	protocol IT-05
All	regression set	Plant	standard set R-01
Your rows			

FROM THE BOOK · IN PRACTICE

→ Supplier protocols become evidence in your plan – they do not replace it.

FROM THE BOOK · TYPICAL MISTAKES

✕ Five suppliers, five binders, no overview.
✕ Interface tests nobody owns because each supplier tested only his side.

FROM THE BOOK · INSPECTOR ASKS

→ “Show me where the test of this data flow is.”

TEMPLATE · FIG. 13.2 · BOOK PAGE 121

Line baseline

Example rows

System	Version	Config	Backup · restore test
PLC filler	FW 4.2	proj. v17	weekly · tested Q2
HMI filler	SW 7.1	v12	weekly · tested Q2
SCADA server	SW 8.0 SP2	v31	daily · tested Q3
MES	R 2025.1	v9	daily · tested Q3
Firewall line	OS 10.4	rules v6	on change · tested Q1
Your rows			

FROM THE BOOK · IN PRACTICE

→ One list for the line: every element, version, configuration and backup.

FROM THE BOOK · TYPICAL MISTAKES

✕ Backups that were never restored.
✕ The firewall forgotten in the baseline.

FROM THE BOOK · INSPECTOR ASKS

→ “Which configuration is the validated one – and can you restore it?”