

Word documents that *trend themselves*.

The wet ink no instrument ever sees, captured as
data the moment it is written.

Vincent Garcia
Co-founder

A talk about problem reframing — a framework for finding a better problem to solve. Three examples first, then what it revealed about paper in GxP.

The Nursing Home

Residents with dementia can wander off and not find their way back. For decades the solution was to lock them in.

The Nursing Home

A German nursing home left the doors open and built a fake bus stop outside. Residents sit and wait for a bus that never comes, until a nurse says “the bus is running late — come in for a cup of tea”.

A wide-angle shot of the interior of a Eurostar train car. The car is filled with passengers seated in blue upholstered seats. Some passengers are looking at their phones, while others are sleeping. Overhead luggage racks are filled with bags and suitcases. The train is moving, as evidenced by the blurred view through the windows. The lighting is bright and even.

Eurostar's AU\$ 12B

London - Paris

Eurostar spent AU\$12 billion on new track to cut the London–Paris journey by 45 minutes.

Eurostar's AU\$ 0.1B

London - Paris

For a fraction of that cost you could hire famous comedians and serve unlimited champagne - and make the journey so good that passengers would beg for the train to be slowed down.

Framework: Problem Reframing

Tenants are complaining that the lift is slow and they're annoyed because that they have to wait.

More or Faster Lifts

Make the wait less annoying



The problem you name decides the solution — almost every building chose the mirror.

Are we solving the right problems?

Do we have a paper problem? Or an Ink Problem

Idea one for reframing: question the problem itself. Perhaps we don't have a paper problem, we have an ink problem — we only print because entering data in Microsoft Word isn't compliant.

If something is not working, try the opposite

Digital (with) Transformation vs Digital Without Transformation

Idea two: if something isn't working, try the opposite. Digital transformation is hard - so what about digital **without** transformation? Keep the documents you already have, and follow the same rules.

The opposite of a good idea, can also be a good idea

Paper-less vs Paper-like

Idea three: the opposite of a good idea can also be a good idea. Paper-less is a great idea. Its opposite is paper-like — software that mimics the paper page people already know.

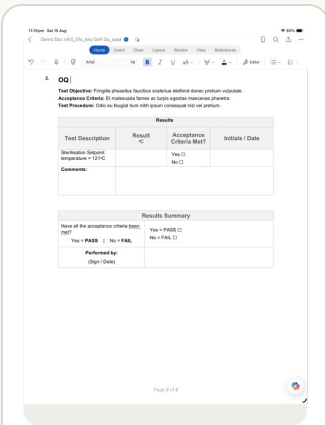
What is the most stupid thing that *you* do at work?

Jason Clarke (Minds at Work), at PharmOut Forum 2019

I spent two years on that question. Then one day I finished a validation protocol in Word, was about to press print, and it clicked: our documents are already digital, and we print them only to enter data. We have a data entry problem.

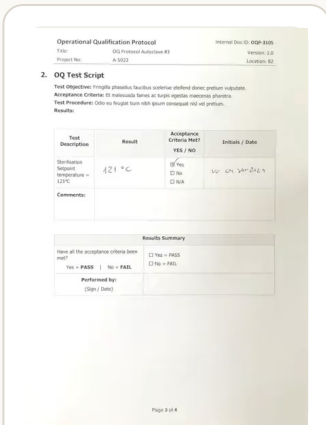
Every GxP document follows the same five stages.

The path is universal. The same for forms, batch records, protocols, CAPAs...



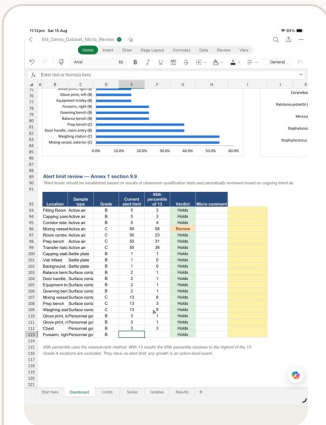
01

Draft



02

Enter Data



03

Excel



04

Scan



05

Archive

- Signatures
- Text
- Attachments

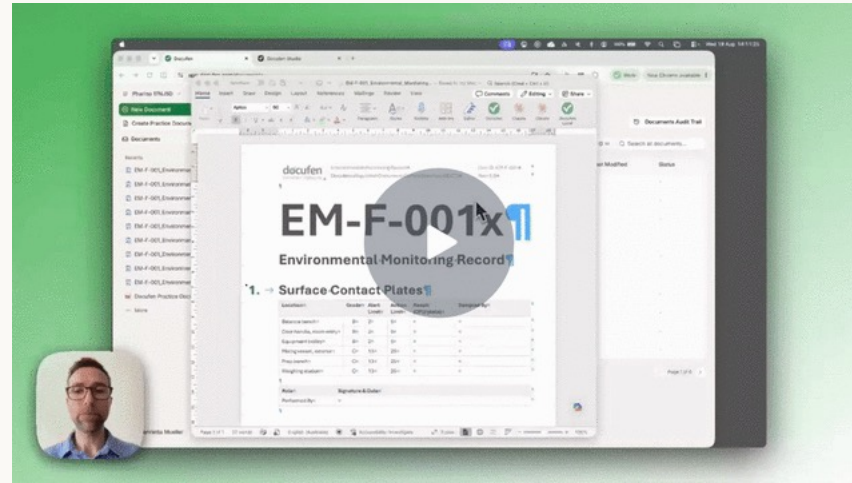
Signatures, text and attachments are the same in every document type.
Make those entries compliantly digital and stages 03–05 disappear.

Demo

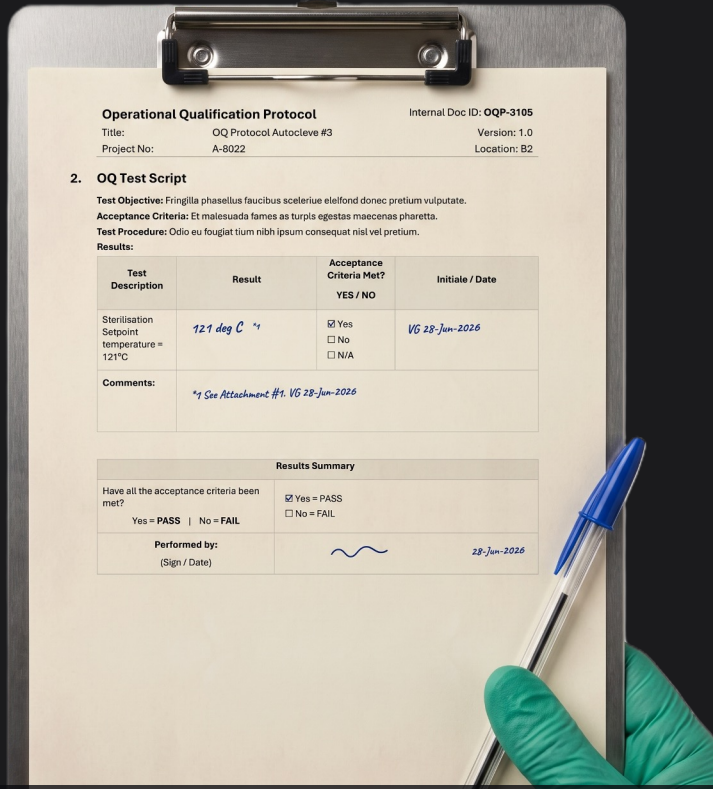
The same document, never printed

[Watch Video – Part 2](#)

<https://docufen.com/capsig>



Before



Operational Qualification Protocol Internal Doc ID: OQP-3105

Title: OQ Protocol Autoclave #3 Version: 1.0
Project No: A-8022 Location: B2

2. OQ Test Script

Test Objective: Fringilla phasellus faucibus scelerisque eleifend donec pretium vulputate.
Acceptance Criteria: Et malesuada fames ac turpis egestas maecenas pharetra.
Test Procedure: Odio eu fouglat tium nibh ipsum consequat nisl vel pretium.
Results:

Test Description	Result	Acceptance Criteria Met? YES / NO	Initiale / Date
Sterilisation Setpoint temperature = 121°C	121 deg C	☒ Yes ☐ No ☐ N/A	VG 28-Jun-2026
Comments:	*y See Attachment #1. VG 28-Jun-2026		

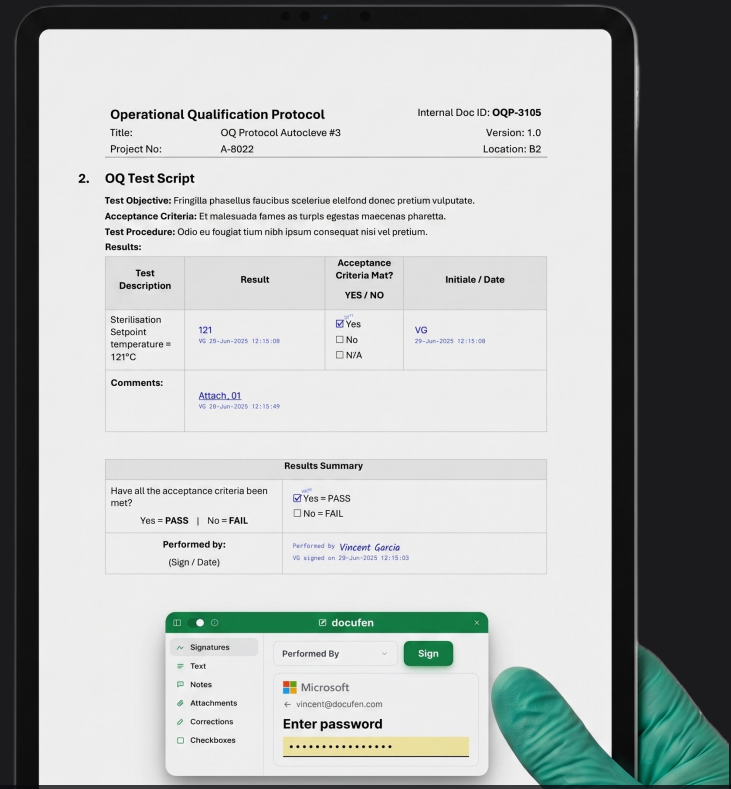
Results Summary

Have all the acceptance criteria been met?
Yes = PASS | No = FAIL

☒ Yes = PASS
☐ No = FAIL

Performed by: (Sign / Date)  28-Jun-2026

After



Operational Qualification Protocol Internal Doc ID: OQP-3105

Title: OQ Protocol Autoclave #3 Version: 1.0
Project No: A-8022 Location: B2

2. OQ Test Script

Test Objective: Fringilla phasellus faucibus scelerisque eleifend donec pretium vulputate.
Acceptance Criteria: Et malesuada fames ac turpis egestas maecenas pharetra.
Test Procedure: Odio eu fouglat tium nibh ipsum consequat nisl vel pretium.
Results:

Test Description	Result	Acceptance Criteria Met? YES / NO	Initiale / Date
Sterilisation Setpoint temperature = 121°C	121 VG 28-Jun-2025 12:15:08	☒ Yes ☐ No ☐ N/A	VG 28-Jun-2025 12:15:08
Comments:	Attach_01 VG 28-Jun-2025 12:15:49		

Results Summary

Have all the acceptance criteria been met?
Yes = PASS | No = FAIL

☒ Yes = PASS
☐ No = FAIL

Performed by: (Sign / Date) Performed by: Vincent Garcia
VG signed on 28-Jun-2025 12:15:03

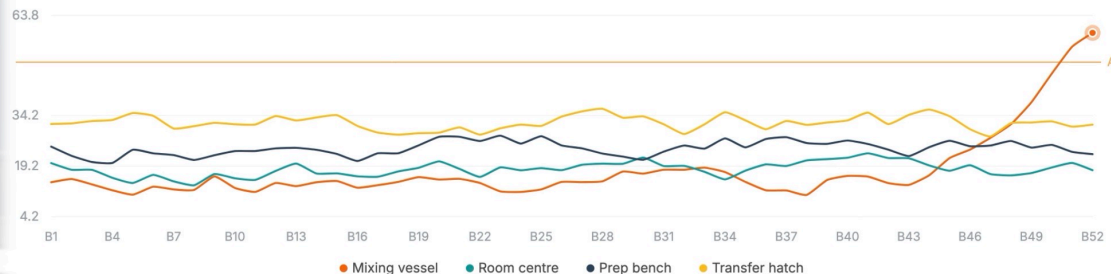
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Signatures
Text
Notes
Attachments
Corrections
Checkboxes

Performed By: Microsoft
vincent@docufen.com
Enter password
.....

Thought one: digital paper. Imagine the Word documents you already have, exactly as they are, filled in digitally - the familiar paper process kept intact, with zero pages printed. One site in Australia has already done it.

All 4 sampling locations across 52 batches



Thought two: every data entry becomes a sensor. If every entry on site, from every GxP document type, were available in real time, you could trend it — combining EM charts with, say, a staff entry–exit logbook. Connecting those dots improves product quality and lowers risk to patients.

What is the most stupid thing that *you* do at work?

Mine was entering data on paper, onto documents that were already digital.

Keep the wisdom. Change the ink.

Your documents. Your rules. Your review. Only the substrate changes.

What this is

Digital ink and trending for any GxP record.

Not continuous Grade A monitoring. That's a sensor stream, and Annex 1 asks for it there.

Vincent Garcia

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*Scan for the
demo and a one-
pager*

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and your time goes to patients, not paperwork.