

Part 11 & IP Gap Map

Date: _____
Firm: _____

A working artifact from your 30-minute diagnostic session

Two different questions, run together. Questions 1–2 are about protecting your IP. Questions 3–4 are about what 21 CFR Part 11 asks you to produce. Part 11 governs electronic records and signatures — it says nothing about where a file is hosted, so we label which half is which rather than dressing the first two up as regulatory findings.

1 The Gap Map · answer in your own words during the briefing

"I'm not sure" is a real answer to several of these, and a useful one.

QUESTION	SCOPE	WHAT A GOOD ANSWER LOOKS LIKE	YOUR ANSWER / THE GAP
Q1 The second copy — which regulated files sit outside your systems of record?	IP <i>Not a Part 11 matter</i>	A real answer about where the copies went — mailboxes, SharePoint, OneDrive, shared drives — or a clear-eyed "we could not produce that list."	_____ _____
Q2 The external hop — how many CROs and CDMOs, through how many mechanisms?	Part 11 <i>§11.30 open systems</i>	You can name the mechanisms and say, per partner, whether their audit trail arrives with the data or has to be chased.	_____ _____
Q3 Evidence you can produce — who accessed a record, and has it changed?	Part 11 <i>§11.10(d), §11.10(e)</i>	A named system, a real production time, and an honest account of which half of the question it cannot answer.	_____ _____
Q4 Signature and identity — cryptographically bound to a person, or a typed name?	Part 11 <i>§11.50, §11.70, §11.300</i>	You know which e-signature tier you are on and what it includes. At the major vendors Part 11 sits behind an enterprise agreement.	_____ _____

2 Where You Land · mark the one closest to your four answers

All three are useful. Only one of them is a project.

☐ Documented
FURTHER ALONG THAN YOU THOUGHT

Systems of record are tight and external exchange is already governed. The map itself becomes evidence for a partner audit or an investor's diligence questionnaire.

☐ Sequencing
ONE PROJECT, NOT TWO

The exposure work and the Part 11 work are the same work. Teams that treat them separately buy the controls twice — once to close the exposure, again at submission prep.

☐ Dated gap
A REAL GAP WITH A DATE

There is a gap and a submission or partner audit on the calendar. The map becomes a scoped list with a sequence and a this-quarter / next-quarter call.

3 Decisions

Submission or partner audit date driving this:

Which gaps are tooling, and which are process:

Is our exposure work and our Part 11 work one project or two:
