PRACTICE NOTE

Regulated-Industry Discipline, Applied to a Regulatory Inquiry Function

Responding to a regulator is a discipline before it is a subject.

Kalif Shear · Work sample · No confidential material

The hard part is not the law

What makes a regulatory response function work is not knowledge of the underlying law. The lawyers already have that, and they are better at it than any program manager will be. What the function needs is someone who can stand between an authority's question and a technical organization, hold the actual obligation steady while both sides talk past each other, and produce an answer that is complete, attributable, internally consistent with everything the company has said before, and delivered on the date it was due.

That is a process discipline, and it is domain-portable. The regulator changes. The subject matter changes. The failure modes do not. An answer that is technically true and practically misleading fails the same way in front of any authority. A deadline met by heroics rather than by system fails the moment two matters land in the same week. A position taken today that contradicts one taken two years ago is the single most expensive mistake available in either field, and it is always a records problem rather than a legal one.

01

Control mapping

Twelve controls operated under FDA regulation, each with a direct equivalent in a regulatory inquiry function.

Same control, different statute

	IN A REGULATED LABORATORY	IN A REGULATORY INQUIRY FUNCTION
Requirements traceability matrix	Every requirement mapped to the test and the evidence that satisfies it, with orphan detection running in both directions.	Every element of a request mapped to an owner, a response, and the evidence behind it. Nothing asked goes unanswered, and nothing is volunteered that no one asked for.
Scope interpretation, recorded	How an ambiguous requirement is being read for this system, written down before testing rather than argued afterward.	How the request is being read, recorded at intake. Scope disputes with a regulator are won or lost on whether your interpretation was contemporaneous or reverse-engineered.
CAPA effectiveness criteria	Acceptance thresholds defined before remediation is judged, so success is measured rather than asserted.	What a complete response looks like is agreed at intake, not negotiated at the deadline when the pressure to ship something is highest.
Change control	Changes to a validated state are reviewed, versioned, and carry a recorded rationale.	Positions are versioned the same way. When one shifts, the record shows what changed and why, which is what keeps a later filing from contradicting an earlier one.
ALCOA+ data integrity	Records are attributable, legible, contemporaneous, original, accurate, complete, consistent, enduring, and available.	The response file shows who supplied each answer, when, from what source, and what it superseded. This is what survives a follow-up request two years out.
Deviation and investigation workflow	Intake, triage, root cause, corrective action, closure, and effectiveness check, in a defined sequence with defined owners.	The lifecycle of a matter, from unified intake through triage, ownership, drafting, review, submission, and closure with lessons captured.

Same control, different statute

	IN A REGULATED LABORATORY	IN A REGULATORY INQUIRY FUNCTION
Risk-based categorization	Rigor scaled to the consequence of being wrong, rather than applied uniformly to everything.	Matters tiered by exposure and deadline. A routine information request and a matter with enforcement potential should not consume the same process.
Second-person verification	The reviewer is independent of the person who generated the result.	No response goes out reviewed only by its author. Independent review before submission catches what the drafter structurally cannot see.
Separation of duties	21 CFR 58.35(a): the quality assurance unit is separate from the personnel directing and conducting the study.	The person coordinating a response is not the person attesting to its completeness. Escalation and need-to-know boundaries are set in advance, not improvised under pressure.
Periodic review and revalidation	Validated systems and methods are re-examined on a schedule, not only when something visibly fails.	Standing positions and the response knowledge base are re-baselined on a schedule, so precedent does not quietly go stale while everyone assumes it holds.
Audit trail review	The trail is not merely enabled. It is reviewed as part of record review, and the review leaves its own evidence.	Matter history is reviewed before submission, not archived unread. Who changed what in a draft response is part of the record of that response.
Inspection readiness	The record is maintained so it holds up whenever it is read, rather than assembled ahead of an announced visit.	Trackers and evidence stay current continuously. A function that only becomes accurate once a request arrives is already behind the clock.

02

The lifecycle

Most of what goes wrong in a response function is structural rather than substantive. Each stage has a characteristic failure.

Eight stages, eight ways to lose

01 Intake

A request arrives somewhere and does not reach the function, or reaches it without the clock being started.

02 Scoping

The request is read narrowly by the responder and broadly by the regulator, and nobody discovers the mismatch until the response is rejected.

03 Decomposition

The request is forwarded verbatim to engineering, who cannot act on it because it is written in legal terms.

04 Collection

Answers arrive in inconsistent formats, at inconsistent depth, from people with different assumptions about what was asked.

05 Drafting

Technical answers are pasted in unmodified, producing a response that is accurate and unusable.

06 Review

The drafter reviews their own work, or review happens with no time left to act on what it finds.

07 Submission

The response goes out without a record of what was sent, to whom, and when.

08 Closure

The matter ends and everything learned leaves with the person who handled it.

Each failure above has a control that prevents it.

03

Decomposition

One regulator question. Nobody in the technical organization can answer it as asked, because it is not a technical question yet.

How one question becomes answerable

What the regulator asks

Describe the categories of personal data processed, the purposes of processing, and the retention applied to each.

Why engineering cannot act on it

It contains three obligations, no system boundary, no time period, and two terms that are legal constructs rather than schema fields. A well-meaning engineer will answer for the system they own and unknowingly leave the question two-thirds unanswered.

How it decomposes

For each in-scope system: enumerate stored fields carrying personal data; map each field to a documented processing purpose; state the configured retention and the mechanism enforcing it; identify fields where retention is not enforced technically, and say what governs them instead.

What comes back

Schema exports, config values, and a set of exceptions and edge cases the engineer flags because they know the system and the question surfaced something nobody asked about.

How it goes back out

Recomposed against the original three obligations, in the register the request used, with the technical artifacts as supporting evidence rather than as the answer. Exceptions surfaced deliberately, because the exception a regulator finds themselves is worth far more to them than the one you disclosed.

Deadline reliability is a system

Deadline reliability is not diligence. It is a system, and the system has four parts. The specific period is set by the instrument and the jurisdiction. The mechanics of managing it are constant.

01 Clock start

The date the clock begins is a determination, not an observation. Receipt, service, and acknowledgement are different events and may not fall on the same day. It is recorded at intake with the basis for it.

02 Internal milestones

The external deadline is not the working deadline. Draft-complete, review-complete, and approval dates are set backward from it, and those are the dates the function actually manages against.

03 Extension protocol

Whether an extension is available, who may request it, how far in advance, and what it costs in credibility. Requested early is routine. Requested late reads as a function that lost control of the matter.

04 Escalation thresholds

The point at which a slipping milestone stops being a scheduling problem and becomes a decision for counsel, defined before it happens rather than during it.

“The risk that grows fastest in a young response function is not a missed deadline. It is drift.”

Matter one describes a system in a particular way. Matter four, eighteen months later, handled by someone else, describes it differently. Neither answer is wrong in isolation. Together they are a credibility problem, and the regulator holds both.

The control is a knowledge base that captures positions rather than documents. Not what was sent, but what was asserted, on what basis, with which caveats, and what has changed since. This is the same reason a regulated laboratory keeps the rationale for a specification and not just the specification, and the same reason a filing history is reviewed before an amendment is drafted.

The six that recur

01 **Technically true, practically misleading**

The narrowest defensible reading of the question, answered precisely. It survives the first pass and produces a second request with a sharper edge and less goodwill behind it.

02 **Heroics instead of system**

One person holds the deadlines in their head and it works, until two matters overlap or that person is unavailable. Capacity failures look like individual failures and are not.

03 **Undocumented position drift**

Nobody recorded the first answer, so the fourth one contradicts it without anyone noticing until an authority does.

04 **Evidence without traceability**

A large production of documents with no mapping from request element to evidence. It reads as either disorganized or evasive, and both readings cost the same.

05 **Closure without capture**

The matter is submitted and closed, and the next one starts from zero. The function never gets faster, and precedent lives only in memory.

06 **Review as formality**

Review exists on the process map and consists of the reviewer confirming the drafter's judgment without independent access to the underlying evidence.

Same pressure, different statute.

None of these controls are specific to pharmaceuticals. They exist because a regulator can ask, years later, for an account of a decision, and because an organization that cannot produce one is treated as though it never made the decision carefully. That pressure is identical whether the subject is a release assay or a data protection inquiry.

What changes across domains is the body of law being applied, and that is the part the function already has in its counsel and its subject-matter experts. What does not change is the requirement that the answer be complete, attributable, internally consistent, and on time. That part is built, maintained, and defended by the same discipline in either field.

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