PITON Global

EXECUTIVE WHITE PAPER · WP-66

LIFE SCIENCES REGULATORY & CLINICAL OPERATIONS · PHILIPPINES

The submission-ready standard: the executive economics of life sciences regulatory & clinical operations outsourcing to the Philippines.

An analysis of why documents processed is a volume vanity metric, how submission-readiness and GxP-grade accuracy — never processing throughput — decide the true cost of a regulatory and clinical operation once query letters, submission rejections, data-integrity findings, and rework are counted, and the vendor-selection discipline that builds a dossier that clears the health authority the first time.

AUTHORS

John Maczynski — Chief Executive Officer
Ralf Ellspermann — Chief Strategy Officer

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ABOUT THIS SERIES — VOLUME 66

Every life sciences ops proposal is priced per document processed, because volume is easy to count. This volume is about the only outcome a regulatory or clinical operation's timeline actually depends on: the deliverable — the dossier module, the clinical dataset, the safety narrative — built submission-ready, verified to source, and able to clear the health authority the first time without a query letter. The gap between processing a document and making it submission-ready is where query cycles, rejections, and data-integrity findings live. The full series lives at piton-global.com.

THE PITON-GLOBAL LEADERSHIP TEAM

About the authors

John Maczynski

Chief Executive Officer

John has bought regulatory and clinical operations capacity for three decades, and learned that the fast vendor that processes every document and builds them not-quite-submission-ready is the most expensive one a life sciences company can hire — because a dossier that draws a query letter is months added to a filing timeline, a clinical dataset with an integrity gap is an inspection finding, and every day of regulatory delay on a launch is revenue that never comes back. His standing question ignores the documents-processed report: of the deliverables you built, how many were submission-ready and cleared the authority the first time? Applied at PITON-Global, that question is what clients get on every life sciences sourcing decision — personally, with no account layer in between.

j.maczynski@piton-global.com
+1 402-598-8740

Ralf Ellspermann

Chief Strategy Officer

Ralf has spent twenty-five years running Philippine regulatory and clinical support floors, and he judges a life sciences team by its submission-readiness and data-integrity record, not its documents-per-day: whether the deliverable cleared the authority first pass and survived inspection, or drew a query and a finding. The submission contract in Section 3 codifies what he learned rebuilding teams that processed documents fast and left GxP gaps behind. He now reads life sciences providers the way he once ran them — from the query-letter log and the data-integrity audit backward.

r.ellspermann@piton-global.com
Manila, Philippines

PITON Global

ABOUT PITON-GLOBAL

PITON-Global is a buyer-side advisory practice, Manila-based since 2001, that has never operated a delivery floor or taken a placement commission. Its stock-in-trade is knowing the Philippine provider market at the operating level — 1,000+ mapped operations, re-verified continuously, including each life sciences team's real submission-readiness and data-integrity record rather than its documents-per-day headline — and converting that knowledge into a shortlist of six to ten genuinely qualified partners per engagement. Buyers from Tripadvisor, Garmin, TSYS, HealthPartners, Yetipay, Workrise, and Norman Disney & Young have run their searches through the practice.

SECTION 01

Executive summary

-57%
Fully-loaded cost per submission-ready deliverable vs. US onshore

99%+
GxP-grade accuracy on vetted teams, up from 88–94%

-64%
Reduction in query letters and submission rejections on vetted teams

6.3×
First-year ROI, reconstructed case (Section 6)

A life sciences operations engagement is bought on the price per document and paid for on the deliverables that are not submission-ready. The vendor reports thousands of documents processed at a fraction of the onshore cost; the sponsor finds the dossier modules that drew a query letter and added months to the filing, the clinical datasets with data-integrity gaps that surfaced in an inspection, the safety narratives that had to be rewritten, and a regulatory timeline slipping while the document count looked healthy. The operation hit its documents-processed number and the sponsor inherited a query backlog, an inspection exposure, and a launch date that moved. The gap between processing a document and making it submission-ready is where the real cost of cheap life sciences ops hides, because a not-quite-ready deliverable is not throughput delivered; it is a query cycle, an inspection finding, and regulatory delay on a product where every day has a price.

The Philippines — English-language, science-literate, with a deep regulatory-affairs and clinical-data talent pool trained to GxP and ICH standards — is where life sciences operations are delivered with the most submission-readiness discipline, because that pool can run the standard-conformant authoring, source verification, and inspection-ready documentation that a regulated operation demands. Five findings:

1. **Documents processed is the industry's most flattering number.** Any team can format a module and log it done. Vetted teams are measured on outcome: submission-readiness, GxP-grade accuracy, and first-pass authority acceptance. Weak providers quote a low per-document price the sponsor repays in query cycles, rejections, and inspection findings. Section 2 shows the gap.

2. **The submission-ready deliverable, not the processed document, is the product.** A deliverable that clears the authority comes from authoring to the standard, verifying every datum to source, and documenting for inspection — not from formatting to clear a queue. Teams that build submission-ready clear first pass; teams that process loosely draw queries and findings that cost far more than the document.

3. **Data integrity is the gate a single gap fails.** ALCOA+ is not a slogan: an attributable, contemporaneous, source-verifiable record is the difference between a dataset that survives inspection and one that triggers a finding, a 483, or worse. Vetted teams hold GxP-grade accuracy above 99% because the cost of the one integrity gap dwarfs every per-document efficiency.

4. **Query cycles and regulatory delay, not the per-document rate, are what cost.** A deliverable built not-quite-ready costs the query response, the resubmission, the inspection remediation, and — most of all — the months added to a filing on a product with a finite patent runway. Teams that build submission-ready protect the timeline, and that protected timeline — not the offshore rate alone — is where the case study's return is built.

5. **Contract on the submission-ready deliverable, not the processed document.** The contracting failure of life sciences ops is paying per document and hoping it clears the authority. Vetted deals price against submission-readiness floors, GxP-accuracy targets, and first-pass-acceptance standards, making the ready deliverable the team's problem, which is where it belongs.

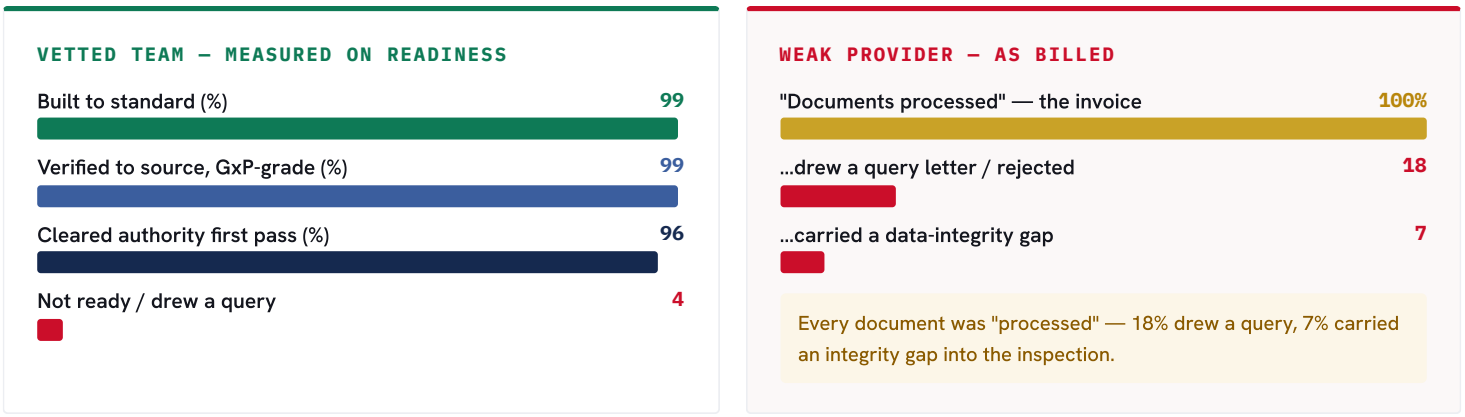
The intended reader is a VP of regulatory affairs, head of clinical operations, or COO at a pharma, biotech, or medical-device company buying ops per document and paying for it in query cycles, findings, and regulatory delay. Sections 2–4 separate the teams that build submission-ready from the teams that process documents; Sections 5–7, the method and the proof.

SECTION 02

The volume mirage: documents processed versus submission-ready deliverables

Figure 1 shows one filing's worth of deliverables two ways: as the documents-processed report a weak vendor bills, and as the submission-readiness reality the health authority's review and the inspection experience. The documents-processed number is engineered to look like output while query letters, rejections, and data-integrity findings accumulate underneath.

FIG. 1 — ONE FILING'S DELIVERABLES: SUBMISSION-READINESS QUALITY VS. REPORTED VOLUME



Left: PITON-Global engagement instrumentation, 2025–26, submission-readiness and data-integrity audited. Right: composite of pre-engagement vendor reporting reviewed in diligence.

The economics follow the readiness, not the document count. On the left, ninety-nine percent of deliverables are built to standard and verified to source, so they clear the authority first pass and survive inspection; on the right, a cheap per-document price draws a query on eighteen percent and carries an integrity gap into seven, paying in query cycles, resubmissions, and inspection findings at once. A low per-document price that is not submission-ready is not a saving; it is regulatory delay and inspection exposure, delayed and compounding on a product with a finite runway. The submission-readiness audit — build-to-standard, source verification, first-pass acceptance — is the cheapest due-diligence instrument in this paper.

SECTION 03

The submission contract: build it to standard, verify it to source, make it inspection-ready

Figure 2 lays out the three clauses of a working life sciences ops contract — the machinery a floor read verifies before any per-document price is believed.

FIG. 2 — THE SUBMISSION CONTRACT, AS OPERATED ON VETTED TEAMS

BUILD IT TO STANDARD

Every deliverable is authored to the applicable standard — eCTD structure, ICH guidelines, protocol and SAP conventions, health-authority templates — with the granular controls health authorities check, and an ambiguous requirement escalated rather than guessed. The deliverable is built right, so review finds nothing to query.

VERIFY IT TO SOURCE

Every datum, claim, and cross-reference is verified against the source record to ALCOA+ standard, with a second-person QC on anything that enters the submission, so no unverifiable figure or broken traceability reaches the authority. The record is made defensible, so it survives inspection.

MAKE IT INSPECTION-READY

The audit trail, version history, and documentation are complete and retrievable so the deliverable withstands a health-authority inspection at any time — with a readiness report the sponsor can read. Inspection-ready is the outcome the QA organization and the regulator both feel.

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THE SUBMISSION-READY DELIVERABLE

99%+ GxP-GRADE ACCURACY | CLEARS FIRST PASS | INSPECTION-READY

Deliverables are built to standard, verified to source, and inspection-ready — so query letters and rejections fall, the filing clears first pass, and every record survives inspection. The operation gets cheaper per submission-ready deliverable and protects the regulatory timeline at the same time, which is the entire promise of outsourcing life sciences ops to people who measure submission-readiness, not documents processed.

Operating parameters from PITON-Global life sciences engagements, 2025–26. Work is performed under the sponsor's quality system and SOPs; the sponsor retains regulatory ownership and sign-off.

In diligence, the contract is tested from the authority's and the inspector's side: pull processed deliverables and re-check them against the standard and the source to measure true submission-readiness; read the query-letter and rejection log; and audit data-integrity traceability against ALCOA+ — because a team that processes documents without source verification leaves the sponsor an inspection finding waiting to happen. Perhaps one team in ten survives it cleanly. Steps 3 and 5 of the framework exist to find that one before the contract does — because everything in Table 3 of Section 6 depends on submission-ready deliverables, not documents processed.

SECTION 04

Cost and performance: cost-per-submission-ready-deliverable economics and benchmarks

TABLE 1 — FULLY-LOADED COST PER SUBMISSION-READY DELIVERABLE: THREE OPERATING MODELS (2026)

OPERATING MODEL	COST / DELIVERABLE	VS. US BASELINE
US onshore in-house reg/clinical team	$430	baseline
Low-cost offshore document mill (per-doc)	$293	−32%
Vetted Manila team — submission-ready, verified	**$185**	**−57%**

Basis: PITON-Global engagement pricing 2025–26; cost per submission-ready deliverable = fully-loaded operating cost divided by deliverables built to standard, verified, and cleared first pass (queried, rejected, and integrity-gapped excluded); the document mill looks cheap per doc but query cycles, resubmissions, and inspection remediation lift its true cost per ready deliverable; US comparator fully-loaded in-house cost.

TABLE 2 — LIFE-SCIENCES-OPS BENCHMARKS, VETTED VS. BASELINE (2025–26)

METRIC	VETTED TOP TIER	BASELINE	EXECUTIVE READING
GxP-grade accuracy	**99%+**	88–94%	The only ops number the timeline follows
First-pass authority acceptance	**96%+**	78–88%	Cleared now, or a query cycle
Query letters / rejections vs. baseline	**–64%**	baseline	"Build it to standard" — held or not
Data-integrity findings (inspection)	**~0**	2–6 / filing	Survives inspection, or a 483
Deliverable cycle time vs. baseline	**–41%**	baseline	On the filing timeline, or slipping it

Source: PITON-Global life sciences engagement data 2025–26; baseline = typical pre-engagement operations billed on documents processed.

The strategic read: the document mill's –32% per doc is a false economy — query cycles, resubmissions, and inspection remediation lift its true cost per ready deliverable far above the per-document gap, and months added to a filing on a finite patent runway is a cost no rate recovers. The vetted Manila team's –57% is real because it is measured where the value is: the deliverable built to standard, verified to source, clearing first pass. Buy on documents processed and you buy the right column of Figure 1; buy on cost-per-submission-ready-deliverable and you buy submission-readiness — the same discipline every volume in this series keeps arriving at from a different door.

SECTION 05

Sourcing discipline: the 7-Step Vendor Vetting Framework, applied to life sciences ops

Life sciences diligence adds one hard requirement to every step: a per-document price is real only when the submission-readiness behind it survives a re-check of the deliverable against the standard and the source. The funnel below is representative of a 30–80-seat regulatory-and-clinical operations search.

FIG. 3 — THE 7-STEP FRAMEWORK AS A LIFE-SCIENCES-OPS FUNNEL

	STEP	WHAT IT ELIMINATES IN A LIFE-SCIENCES-OPS SEARCH	FIELD REMAINING
1	**Requirements definition**	Throughput-first scoping: fixes the GxP-accuracy floor, the first-pass-acceptance target, the query-letter ceiling, and the data-integrity standard by deliverable type and market	1,000+
2	**Market mapping**	Document mills: operations that bill document volume and treat query letters and integrity gaps as the client's problem, and generalist floors with no regulatory, clinical, or GxP depth	~40
3	**Capability screening**	Teams without the machinery: reg-affairs and clinical-data credentials, eCTD/ICH proficiency, an ALCOA+ verification workflow, and coverage across your therapeutic areas and target markets	~12
4	**Compliance & security audit**	Weak governance: GxP quality-system maturity, 21 CFR Part 11 / Annex 11 controls, PII/PHI protection, audit-trail integrity, SOC 2 scope covering the regulated stack	~7
5	**Operational diligence**	The submission re-check: re-check a sample of deliverables against the standard and the source for true readiness and integrity; read the query and rejection logs; interview on a genuinely ambiguous regulatory requirement	4–6
6	**Competitive RFP & negotiation**	Per-document pricing: finalists bid against GxP-accuracy floors, first-pass-acceptance targets, and query-letter ceilings — all carrying credits for queried, rejected, or integrity-gapped deliverables	2–3
7	**Transition & launch governance**	Cold cutover: the team calibrates against your SOPs, templates, and quality system on a sample before it owns live deliverables, with the GxP-accuracy floor certified before steady state, PITON-Global embedded buyer-side	1

Field-remaining counts represent a 30–80-seat regulatory-and-clinical operations search, PITON-Global engagements 2024–26.

The standing guarantees hold: **vendor neutrality** — PITON-Global operates no ops floors, authors no deliverables, and takes no placement economics, so the shortlist reflects audited submission-readiness performance, not inventory; **right-sizing** — teams for whom your operation is a flagship account. Six to ten genuinely qualified providers, delivered within 48–72 hours, free to the buyer, competing through a fully transparent, fair, comprehensive, and highly competitive RFP.

SECTION 06 · ANONYMIZED CASE STUDY

Re-basing the operation on submission-readiness: a 55-seat regulatory-and-clinical rebuild, reconstructed

Engagement LS-086 is a US mid-cap pharma and clinical-stage biotech — producing roughly 48,000 regulatory and clinical deliverables a year across dossier modules, clinical datasets, and safety documents — that had offshored regulatory and clinical operations to a per-document mill. The document price was excellent; the submission-readiness was not: GxP-grade accuracy sat near 90%, query letters were high and adding months to filings, an inspection had returned data-integrity observations, and a launch timeline had already slipped once. The VP of regulatory affairs wanted the arbitrage without the query cycles and the inspection exposure. Identifying details are anonymized under NDA.

SELECTION (WEEKS 0–8, SUBMISSION RE-CHECKS)

Requirements fixed a 99% GxP-accuracy floor, a 96% first-pass-acceptance target, a query-letter ceiling, and a data-integrity standard. Mapping produced 40 claimants; the machinery screen — reg/clinical credentials, eCTD/ICH proficiency, ALCOA+ verification workflow, therapeutic coverage — left 12; the GxP-quality-system and Part 11 audit left 7. Blind re-checks of each finalist's deliverables against the standard and source shortlisted 5. A Manila team won priced against submission-readiness and data integrity, with both written into the reporting spec.

TRANSITION (MONTHS 2–7, CALIBRATED FIRST)

The team calibrated against the sponsor's SOPs, templates, and quality system on a sample before owning live deliverables; the GxP-accuracy floor was certified in month 3, and the ALCOA+ verification loop ran from day one. The QA-and-verification loop fed authoring coaching continuously. By month 7 GxP-grade accuracy reached 99.2%, first-pass acceptance hit 96%, query letters fell 64%, data-integrity findings went to near zero, and cycle time dropped 41%. PITON-Global chaired the submission-readiness review board to steady state.

TABLE 3 — LS-086 FIRST-YEAR VALUE BUILD-UP (US$)

VALUE COMPONENT	YEAR 1	BASIS
Labor arbitrage on the 55-seat operation	**$1.58M**	103.1k productive hrs × ($25.30 − $10.00)
Regulatory-delay avoided (fewer query cycles)	**$1.02M**	Filing time protected on finite-runway products
Inspection & remediation exposure avoided	**$0.40M**	Data-integrity findings and 483 remediation removed
Rework & resubmission reduction	**$0.18M**	Query-response and resubmission load removed
Gross value created	**$3.18M**	
Less: engagement & transition costs	**($0.50M)**	Calibration, ALCOA+ loop build, quality-system integration; advisory fee $0 (provider-paid model)
Net value ÷ cost = first-year ROI	**6.3×**	$3.18M ÷ $0.50M

Figures rounded; readiness, query, and integrity effects audit-verified. Method in Methodology & notes.

Fifty percent arbitrage, fifty percent from avoided regulatory delay, inspection exposure, and rework — a typical split for the series, earned because the operation was re-based on submission-readiness rather than document volume. Every line traces to a diligence step: the GxP-accuracy floor to Step 1, the readiness-and-integrity pricing to Step 6, the ALCOA+ verification loop to Step 3's contract. The VP's line at the year-one review: "The document price barely moved. What moved is that filings clear first pass now — and the inspectors stopped finding things."

SECTION 07

The executive playbook: governance for the first 180 days

A life sciences ops transition succeeds when the team is measured and paid on submission-readiness and data integrity — client in command throughout.

DAYS 0–30

Define readiness, contract on it

Set the GxP-accuracy floor, the first-pass-acceptance target, the query-letter ceiling, and the data-integrity standard with regulatory and quality leadership before launch, and document the authoring standards and ALCOA+ verification workflow by deliverable type. Contract against submission-readiness and integrity — never per document alone — with floors carrying credits. Stand up the submission re-check and the data-integrity audit as the program's arbiters of truth.

DAYS 30–90

Calibrate, prove the integrity loop

Calibrate the team against your SOPs, templates, and quality system on a sample before it owns live deliverables; certify the GxP-accuracy floor and run the ALCOA+ verification loop. Switch on the QA-and-verification loop from day one. Publish the ops dashboard: GxP accuracy, first-pass acceptance, query-letter rate, data-integrity findings, cycle time.

DAYS 90–180

Own deliverables, certify steady state

Hand live deliverables to the team only after it holds the GxP-accuracy floor and first-pass-acceptance target. Review the board monthly with the query-letter and data-integrity trends on the table. Certify steady state on two months at floor including a live submission and, ideally, an inspection or audit; hand over on documented criteria; keep the submission re-check standing.

THE FIVE FAILURE MODES WE ARE HIRED TO PREVENT

Paying per document while deliverables draw query letters · formatting to a queue instead of building to the standard · skipping source verification and carrying a data-integrity gap · treating inspection-readiness as an afterthought · owning live deliverables before submission-readiness is proven. All five are settled at selection and contract.

The life sciences ops argument, in one sentence: a processed document is activity and a submission-ready deliverable is a filing that clears first pass and a record that survives inspection, and a vetted Philippine team delivers −57% cost per submission-ready deliverable with 99%+ GxP-grade accuracy, query letters cut by nearly two-thirds, and data-integrity findings near zero — for buyers who re-check submission-readiness instead of counting documents processed, and compete the finalists through a fully transparent, fair, comprehensive, and highly competitive RFP. Anyone can process a document. We make sure you buy the team that builds it submission-ready.

METHODOLOGY & NOTES

How the numbers were built

Readiness and integrity figures (Fig. 1, Table 2) derive from engagement instrumentation in PITON-Global life sciences engagements, 2025–26. GxP-grade accuracy and submission-readiness are measured by re-checking deliverables against the applicable standard and the source; first-pass acceptance, query-letter rate, data-integrity findings, and cycle time are measured against the client's pre-engagement baseline. The weak-provider column is a composite of pre-engagement vendor reporting reviewed in diligence, shown for contrast.

Cost-per-submission-ready-deliverable figures (Table 1) are fully loaded — wages, benefits and statutory charges, facilities, validated-system and technology tooling, management and QA overhead including reviewers and data-integrity specialists, and attrition-driven recruiting — divided by deliverables built to standard, verified, and cleared first pass, with queried, rejected, or integrity-gapped deliverables excluded from the denominator; US comparators reflect fully-loaded in-house cost on the same basis. A submission-ready deliverable is built to standard, verified to source, and inspection-ready.

The case study (LS-086) is anonymized under NDA; volumes and dates are generalized, figures rounded. Readiness, query, and integrity effects are audit-verified; the regulatory-delay-avoided line reflects filing time protected and is a conservative estimate. ROI = net first-year value ÷ all engagement-related client costs. PITON-Global's advisory fee is provider-paid and appears at $0 in the client cost base; neutrality safeguards are documented at piton-global.com.

Market context draws on IBPAP reporting and PITON-Global's proprietary provider mapping (1,000+ operations; submission-readiness and data-integrity performance re-verified May 2026). Work is performed under the sponsor's quality system and SOPs; the sponsor retains regulatory ownership and sign-off. This publication is not regulatory advice. Estimates and projections are PITON-Global analysis and should be cited as such. The full series is available at piton-global.com.

Would your provider's document price survive a submission-readiness audit?

Thirty minutes with John will tell you. Free to buyers, strictly vendor-neutral — a submission-readiness-verified shortlist within two to three business days.

j.maczynski@piton-global.com
+1 402-598-8740