

.crft AI-NATIVE PRODUCT BUILD

Regulatory Submission Accelerator

THE SITUATION

Submission prep is months of assembling, cross-referencing and reformatting documents that already exist somewhere. Your most qualified reviewers spend that time checking formatting instead of judging science, and every delay moves the filing date.

THE SOLUTION

AI drafts, cross-references, and validates submissions against FDA and EMA requirements, compressing months of document prep into weeks. Qualified reviewers approve; the AI does the heavy lifting, with traceability throughout.

01 HOW CRFT WORKS

01

Validate the core workflow in a short prototype sprint

02

Build the production-grade, owned system end-to-end

03

Hand off source, credentials, docs, and a 90–day roadmap

02 WHY IT MATTERS

- Months of prep compressed to weeks
- Validated against FDA/EMA requirements
- Full traceability for inspection readiness
- Reviewers approve; AI does the drafting

> *CRFT engineers the document intelligence pipeline from ingestion to submission-ready output.*

03 FOUR WAYS TO BUILD AN AI SYSTEM — AND HOW THEY COMPARE

	BUILD IN-HOUSE	DEV SHOP	AI SAAS TOOL	CONSULTING	CRFT
Time to first value How long before it changes a number.	◔	◑	●	◔	◕
ROI guarantee Who carries the risk if it underperforms.	○	◔	◔	○	●
On-the-ground integration Whether it fits your stack, data and workflow.	◕	◑	◔	◔	●
Gets smarter with use Whether run 50 beats run 1.	◔	◔	◔	○	●
Tells you where to start Scored opportunities, not a debate.	◔	◔	◑	◑	●
Change management Roles, trust and adoption designed in.	◑	○	◔	◑	●
You own it outright Code, prompts and data in your accounts.	●	●	○	◔	●

04 LIFE SCIENCES — THE OPPORTUNITY IN NUMBERS

50–65%[1]
faster regulatory filing timelines at leading pharma

5
highest-value AI use cases mapped per function

3×[2]
target ROI within 90 days

1. McKinsey, 2025 — filings delivered 8–12 weeks after database lock
2. AWSM LABS CRFT engagement guarantee — 3× ROI on the build fee by day 90, or we keep working at no charge

Explore this for Life Sciences.

A short scoping conversation, then a costed plan with the ROI stated up front — not a proposal deck.

awsmlabs.ai/industries/life-science