Unblock CMC.
Recover launch runway.

CMC has become biopharma's strategic chokepoint — and how a scientist-centered, data-continuous architecture can reduce cycle times by up to 40%.

Zifo

Science Led. People Driven. Technology Centered.

Technology Centered.

Zifo Provides Global Scientific Digital Solutions - Empowering Science with Data for AI

Lab Informatics | Clinical Development | Bio Informatics | Data Sciences | Scientific Cloud Computing



GLOBAL COMPANY

Offices in:

Canada
USA
France
Germany
Ireland
Spain
Switzerland
UK
China
Japan
India
Singapore
South Korea
Mexico

14



SECURE

Established in 2008, fastest growing company since 2012 (Deloitte)

12



TEAM

90% of our team comes from a scientific background

2500+



PEOPLE CENTRIC

5 times Best Company to Work For by the Great Place to Work® Institute; Trust index of 80%+

80%+



CUSTOMERS

Experience with customers from the pharmaceutical, biotechnology, FMCG, food and chemical industries

200+



PARTNERS

Our partners rely on Zifo to extend their scalability, subject-matter expertise and regional reach

90+



QUALITY FOCUS

ISO 9001 and 27001 certified

Regularly audited by Pharma, Biotech and med device companies

125+

Science Led. People Driven. Technology Centered.

Focus Areas



Scientific service provider

Enterprise Scientific Service Provider of choice for Life Sciences Companies from Instruments to Insights

Data for AI

Empowering Science with Data for AI

Lab DATA ecosystem as a service

Move from App centric approach to Data Centric Approach

Gen AI, AGENTIC AI, SLM, AI/ML

AI offering across horizons

Reimagine services

Reimagine all our services in the new world

Science-first architecture, not generic IT transformation.

Zifo bridges scientific workflows, informatics, data, AI and regulatory reality.

1

SCIENCE LED

CMC domain fluency, Process development
Analytical & Quality context

2

PEOPLE DRIVEN

Scientist-centered UX, Change adoption, Operational empathy

3

TECHNOLOGY CENTERED

FAIR data foundation, AI-ready Architecture, Workflow orchestration

The Zifo promise: We will help you remove the blockade between early science and commercial viability.

Discovery accelerated but CMC did not follow

Billions flowed into AI discovery and global manufacturing — the bridge between them is still narrow, fragmented and manual.



Discovery

Fast, computational, high-throughput

Every therapy must pass through this point before it reaches patients.

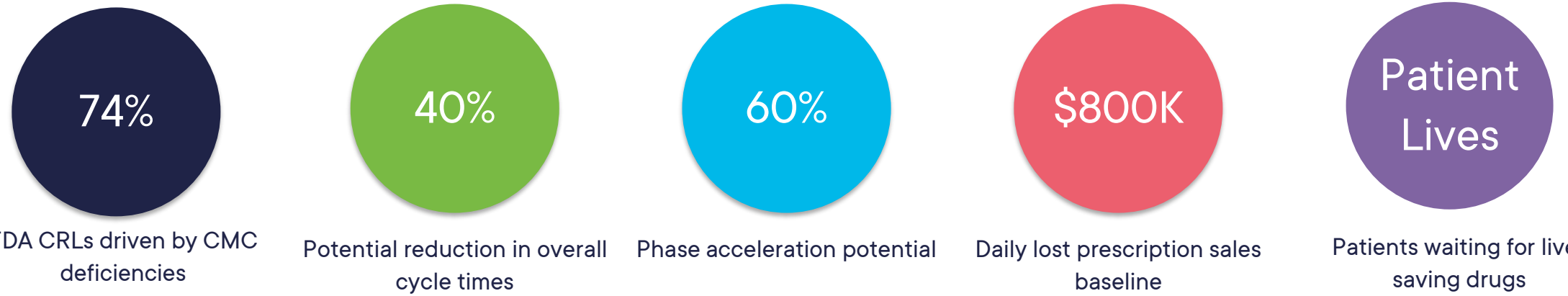
Commercial scale

Bigger footprint, bigger value at stake

The market problem is not “slow CMC teams.” It is architecture: siloed data, analog evidence and brittle handoffs.

The CMC blockade is now an enterprise-value problem.

Delay is no longer administration. It is lost launch runway, stranded science and slower patient access.



CMC modernization belongs in the boardroom because launch velocity, regulatory readiness and enterprise value now depend on it.

Therapeutics changed. Legacy CMC hasn't

Small molecules were comparatively predictable. Biologics and CGTs turn process variability into product risk.

Synthetic chemistry

Predictable. Linear. More forgiving.

- Finite variables
- Scale-up by volume ratio
- Broader environmental tolerance
- Excipients largely inert
- Process supports the product

Complex biologics & CGT

Living systems. Non-linear. Hyper-sensitive.

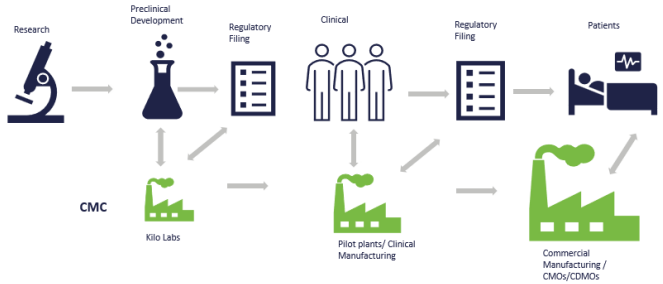
- Hundreds/thousands of connected parameters
- Scale-up changes biology and physics
- Shear, oxygen, humidity, kinetics matter
- Excipients may introduce safety risk
- The process is the product

Modern modality complexity makes CMC data continuity a must-have — not a nice-to-have.

CMC friction concentrates where evidence, teams and systems split.

The everyday experience is not one linear process; it is a chain of interfaces, PDFs, spreadsheets, instruments and local workarounds.

Mission is to make discoveries become manufacturable, compliant, and available to patients at scale.



CMC is more than making a product - proving the product with Data

CMC - Hurdles

- Advanced Modalities
- Regulatory Expectations
- Data Silos
- Global Partner Network
- Manual Reporting



DATA SILOS

MANUAL REPORTING

TRIBAL HANDOFFS

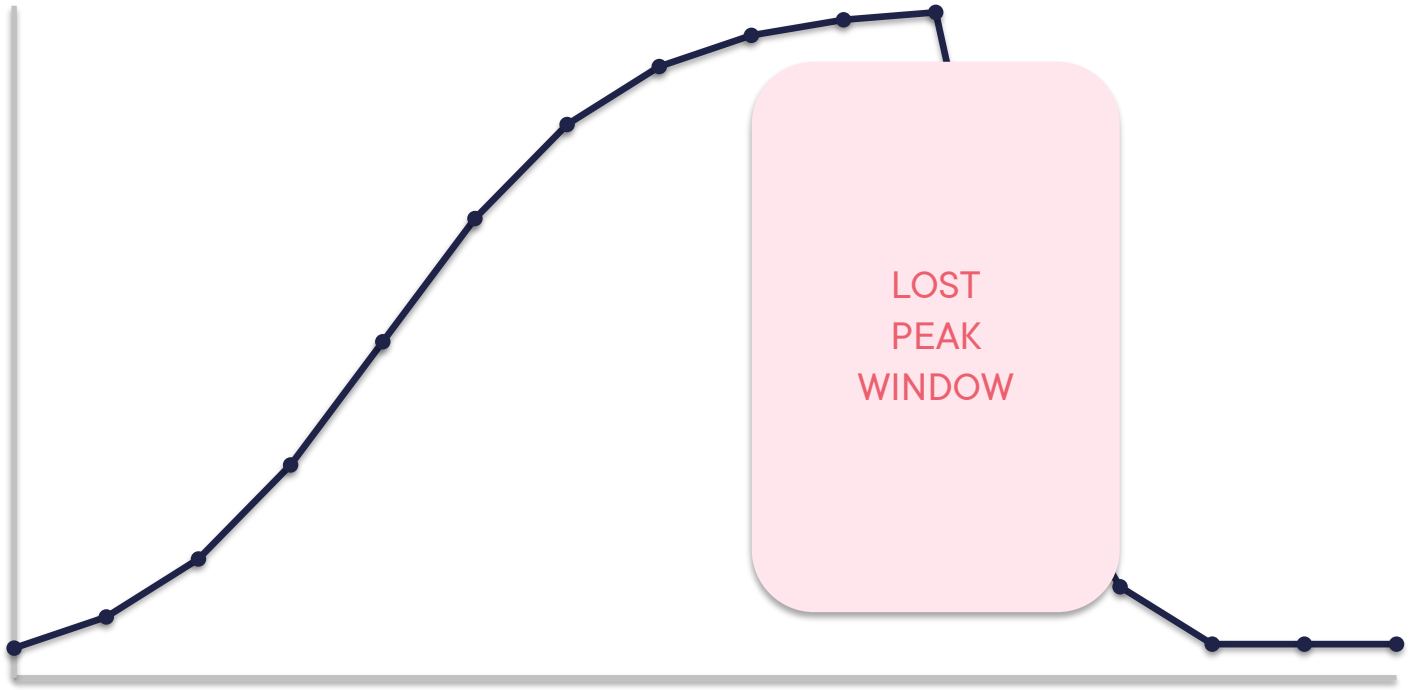
REGULATORY FRICTION

TECH TRANSFER

The “blockade” is a system-of-systems problem — not a single software gap.

A launch delay does not shift revenue. It removes it.

Patent expiry is a fixed cliff; CMC delay truncates peak commercial potential and vaporizes asset value.



$800K

Estimated value of a lost or delayed prescription-sales day

- Submission delay → lost exclusivity runway
- Late tech-transfer friction → idle capacity
- Re-validation loops → unplanned cost
- Patient access slows when scale-up stalls

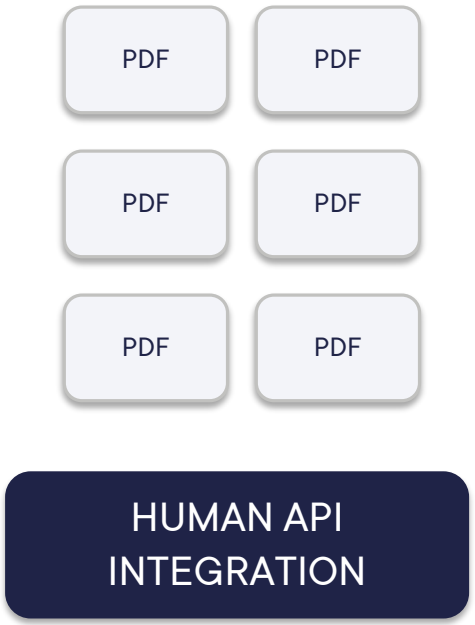
Your best scientists are becoming data janitors.

The paper's strongest practitioner hook: CMC talent is too often trapped in cleanup, reconciliation and evidence assembly.

30–40%

of PhD-level scientist time can be consumed by data cleanup

- Extracting numbers from disconnected instruments
- Matching sample IDs across spreadsheets and systems
- Reconstructing context from PDFs and handwritten records
- Formatting evidence for regulatory review



The fastest way to increase CMC capacity is to give scientists their science time back

Stop digitizing dysfunction.

Point solutions make broken workflows prettier. CMC acceleration needs a total architectural reversal.



Key moves to scientific driven CMC.

A repeatable architecture for converting CMC from administrative bottleneck to competitive advantage.

Revolutionise DMTA

Context continuity across every loop

Orchestrate scientist UX

One hub, modular components

Scale scientific intelligence

Scientific Language Models

Liberate trapped evidence

Batch records, CoAs, PDFs, reports

Connect data choke points

Instruments, ELN, LIMS, inventory

Handoff by design

Continuous tech transfer

The suggested order: evidence → data foundation → workflow → intelligence → transfer velocity.

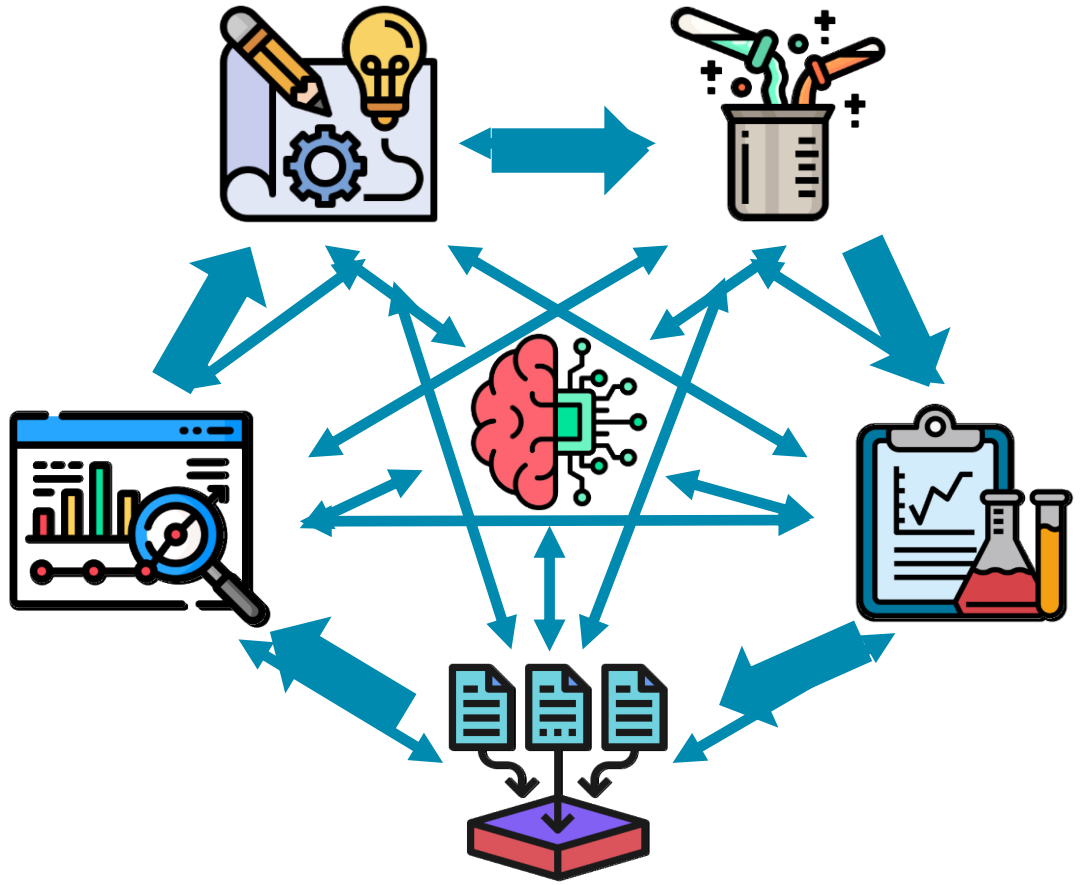
Break the DMTA doom loop.

DMTA should be a continuous learning system — not a sequence of blind handoffs.

LEGACY DMTA

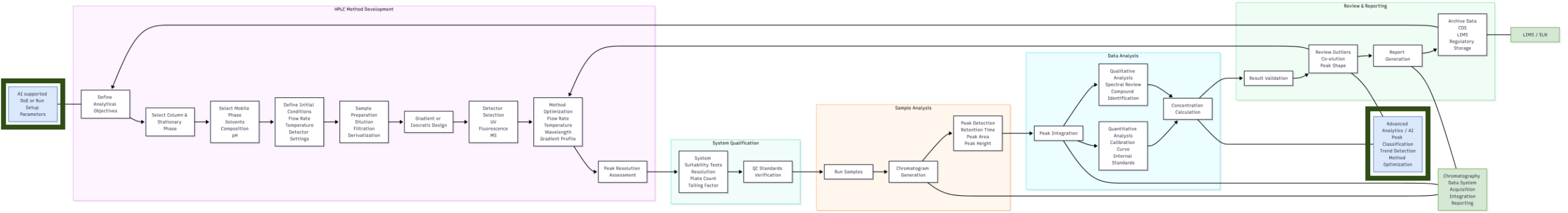
Design → Make → Test → Analyze

Every arrow leaks context.
Every handoff creates waiting.
Every system forces reconstruction.



Reimagined DMTA: scientists navigate the loop as biology demands — with context already retrievable.

HPLC as an example



High level view showing:

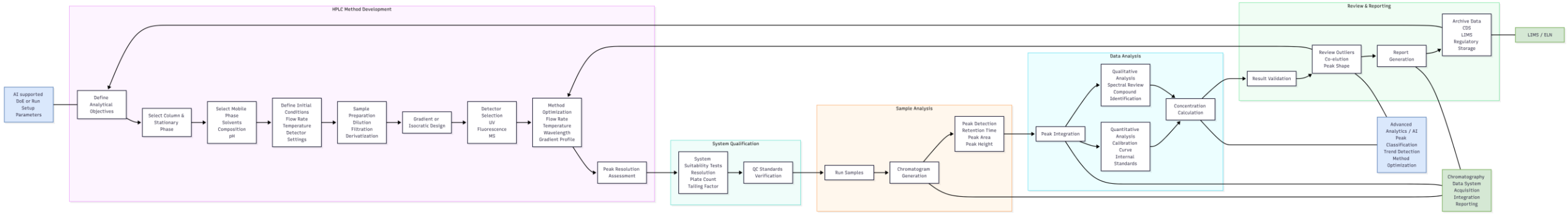
- HPLC Method Development
- Sample Analysis
- Data Analysis
- Quality & Compliance

Opportunities to Transform

- Before Run: Automated/AI supported DoE
- During Run: Automated/AI supported Anomaly Detection
- After Run: AI Assisted peak identification, Knowledge reuse across methods

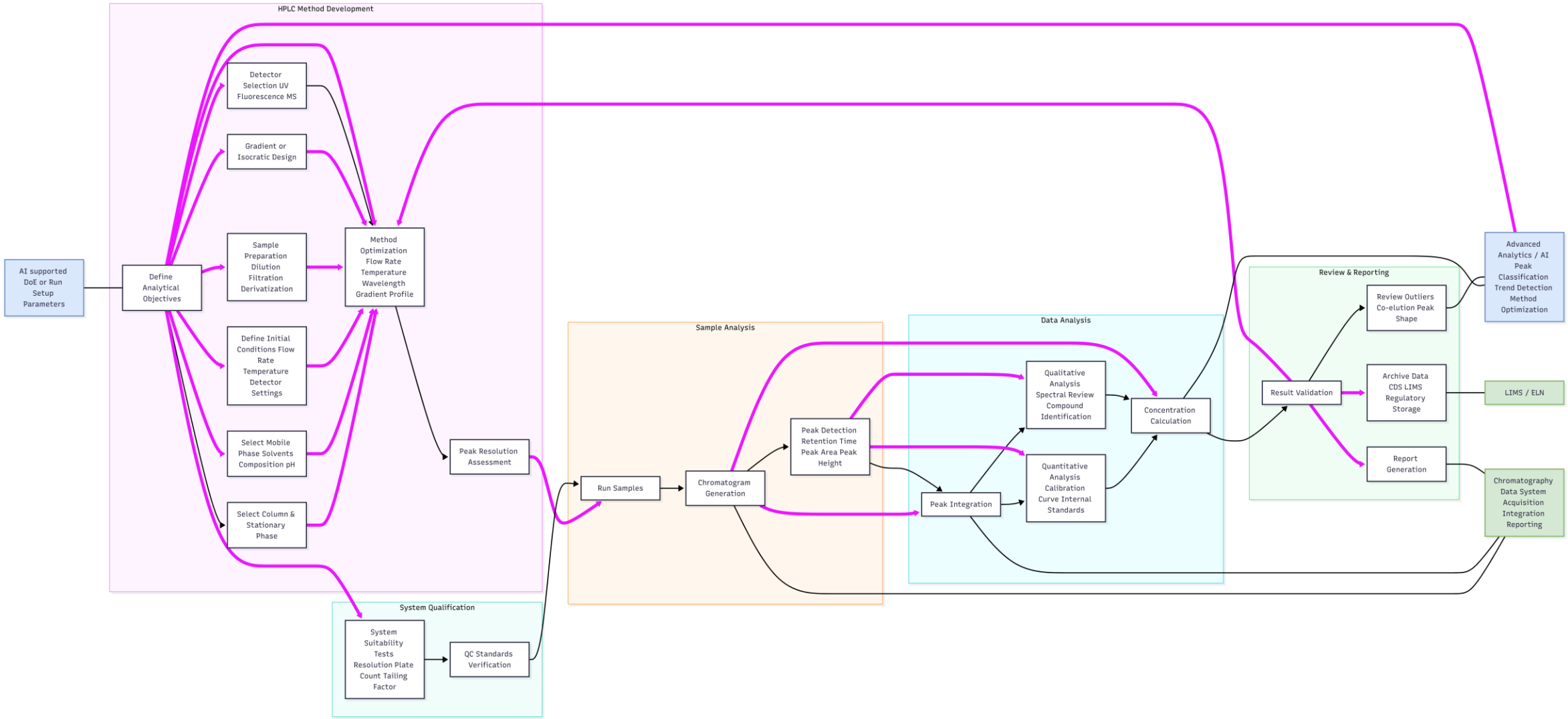
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HPLC as an example



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HPLC as an example



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HPLC – Scientific Insight and Reasoning

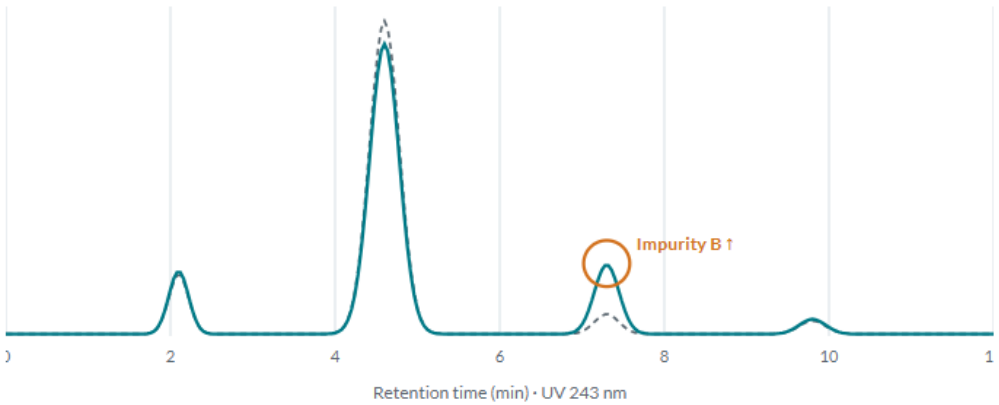
Chroma Assist
HPLC run setup & analysis

Complete

Run complete 15.0 / 15.0 min

The run is complete. I found a significant change compared to the reference standard.

Chromatogram



PEAK	RT	REFERENCE	SAMPLE	Δ
Solvent front	2.10	–	–	
Paracetamol	4.60	99.1%	97.6%	−1.5%
Impurity B (4-aminophenol)	**7.30**	**0.06%**	**0.21%**	**+250%**
Impurity C	9.80	0.04%	0.05%	+25%

LIKELY CAUSE

Oxidative degradation — **87%** confidence

Impurity B increased 3.5× and is a known oxidation product of paracetamol. Two contributing factors were identified:

- **Extended storage** — 6 months at ambient conditions — **High impact**
- **Elevated column temperature** — 40 °C accelerates on-column oxidation — **Medium impact**

RECOMMENDATION

Reduce storage duration and repeat with optimised conditions

Limit sample storage to under 30 days at 2–8 °C, protected from light, before analysis. Then repeat the analysis:

1. Prepare fresh sample from a lot stored < 30 days, or retest the current lot alongside it.
2. Lower the column temperature from **40 °C → 25 °C**.
3. Degas mobile phase with helium and use amber vials to minimise oxygen and light exposure.
4. Keep autosampler tray at 4 °C and inject within 4 h of preparation.
5. Run reference standard and blank before and after the sample to confirm system suitability.

NEXT STEP

Create a new setup from these recommendations?

I can rebuild the method with a shorter storage window, a 25 °C column and light/oxygen control, then run it against this sample.

Yes, create the new setup | No, keep current results

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HPLC – Scientific Insight and Reasoning

Yes — build a new setup from those recommendations.

Done. I've rebuilt the method around the recommendations — cooler column, fresh sample, and light/oxygen control.

Optimised method setup

SAMPLE
Paracetamol 500 mg — fresh lot (< 30 days) + Lot PX-2291

COLUMN
C18. 150 × 4.6 mm. 5 µm

MOBILE PHASE
A: 0.1% H_3PO_4 in water, helium-deg
Acetonitrile

FLOW RATE
1.0 mL/min

INJECTION
10 µL · amber vial, autosampler 4 °C

RUN TIME
15 min

Start run

NEXT STEP

Start a new setup?

This sample is cleared. Set up another run — I'll keep OPT-25 available as a starting point.

Yes, create a new setup

NEXT STEP

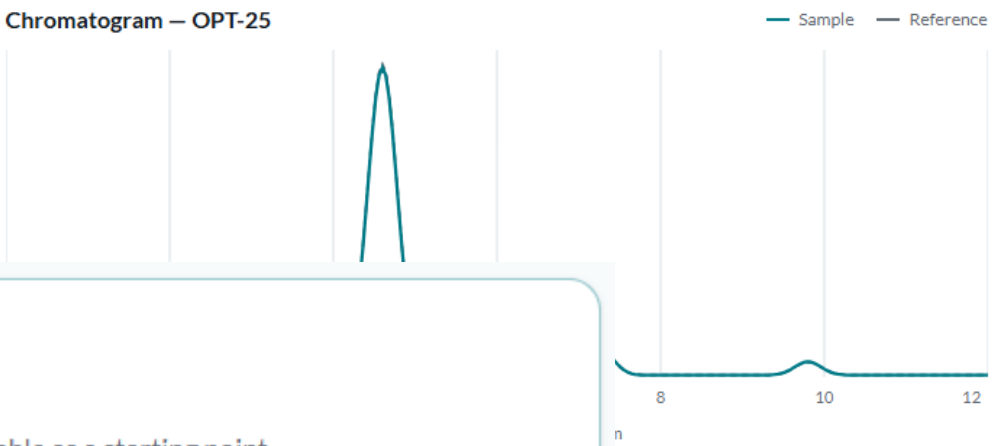
Should I execute this run?

The method is queued on the instrument. Start it now, or save it and run it later.

Run it now | **Save for later**

Optimised run complete. Impurity B is back in line with the reference — the degradation was avoidable.

Chromatogram — OPT-25



			ENCE	SAMPLE	Δ
				–	
				99.0%	−0.1%
Impurity B (4-aminophenol)	7.30	0.06%		0.07%	+17%
Impurity C	9.80	0.04%		0.04%	0%

VERDICT

Within specification

94% confidence

Impurity B fell from 0.21% to 0.07% (limit 0.10%) once the column ran at 25 °C and the sample came from a lot under 30 days old. Oxidative degradation is confirmed as the cause of the earlier result.

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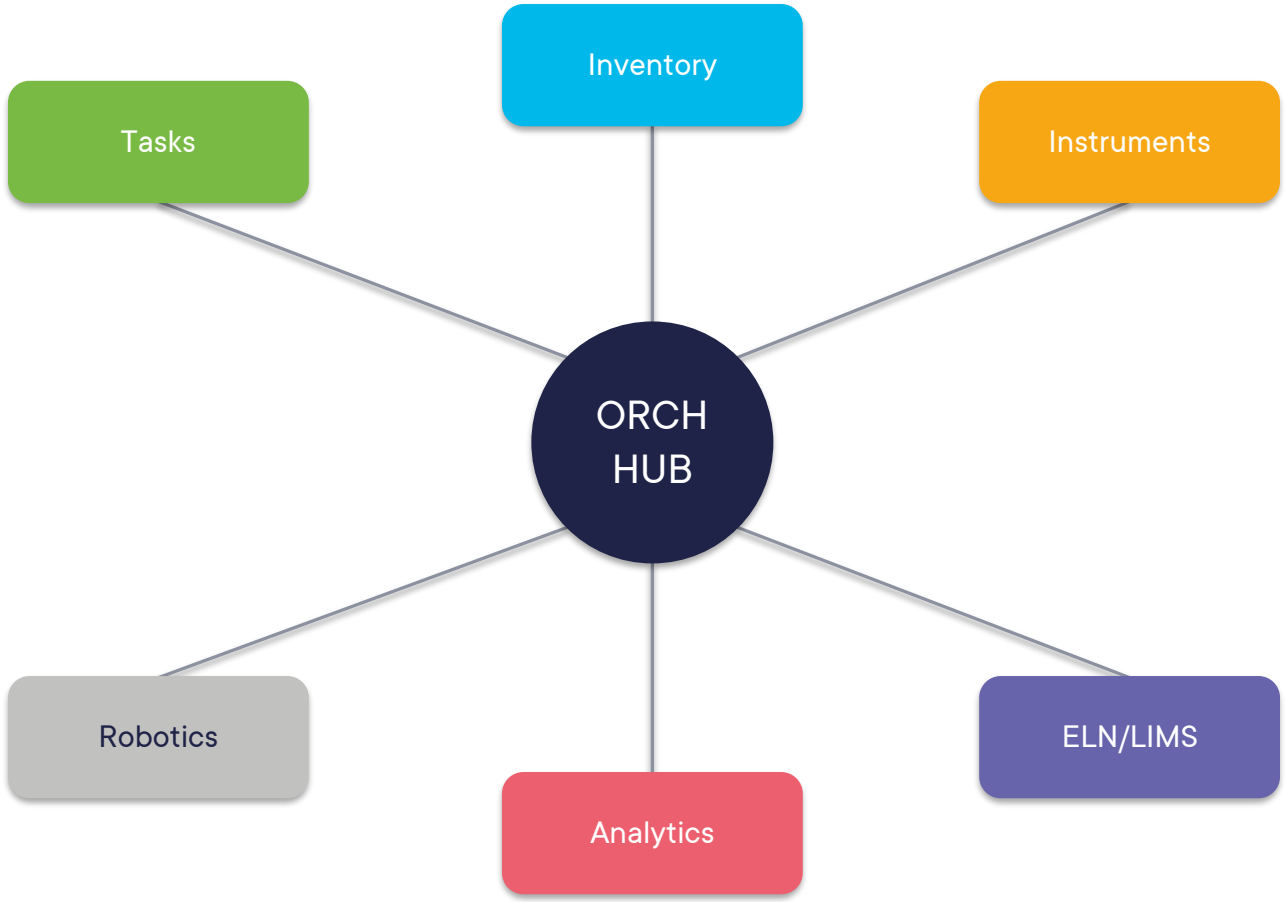
The system should adapt to the scientist.

Reimagine the lab around a central orchestration layer, not around vendor-specific interfaces.

Scientists run science.

The architecture structures the data continuum in the background.

- Tasks surface automatically
- Context travels with samples
- Instrument telemetry streams inward
- FAIR data flows outward
- Insights return in workflow



Generic LLMs draft text. Scientific Language Models change experiments.

In CMC, the target is contextual intelligence trained on proprietary process data.

GENERIC LLM

✓ Summarizes public literature
✓ Drafts administrative text
✓ Structures basic content

✗ Cannot safely predict proprietary biological outcomes

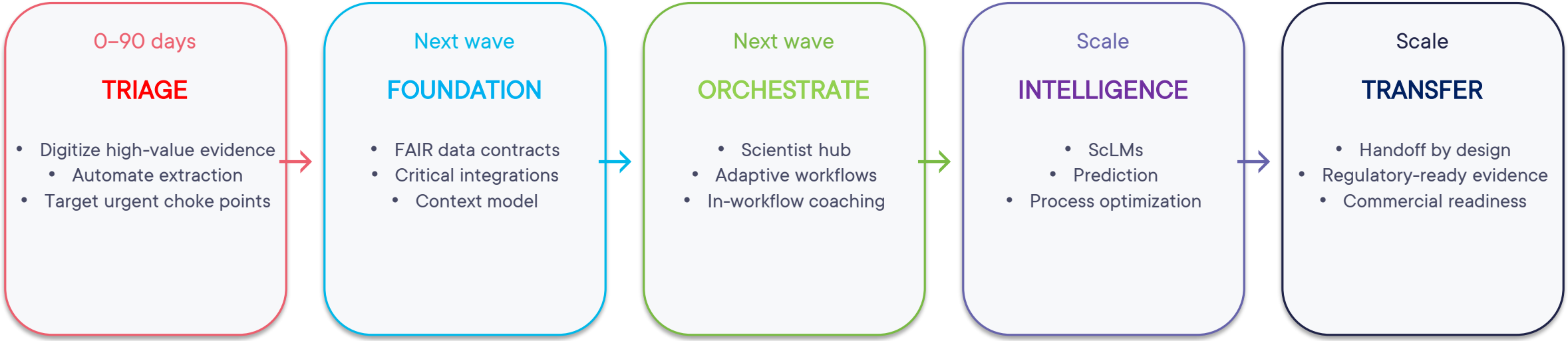
SCIENTIFIC LANGUAGE MODEL

✓ Trained on enterprise CMC data
✓ Understands modality/process context
✓ Recommends parameters
✓ Reduces failed physical experiments

Move from AI that writes about science to AI that helps scientists make better process decisions

Triage to transformation without waiting for a digital utopia.

Use lighthouse projects to stop the bleeding now while building the architecture for compounding gains.



Zifo Message to CMC community: “Stop the bleeding today. Build the scientific data continuum that compounds tomorrow.”

THE CLOSING ARGUMENT

CMC is no longer the back office of science.

It is the new battleground for launch velocity.

✗ **The market question is not** “Do we need another CMC system?”

✓ **The right question is:** “Where is our launch runway leaking — and what data architecture will recover it?”

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