

From Science to Impact – My journey into consulting in Life Sciences

How technical expertise becomes
organizational impact

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Expertise & Services

		Pre-clinical development, Clinical Phase 1 - 3	Commercial Phase 4	End-of-life	
Project Management	CMC/MSAT/ ASAT	Phase appropriate GMP	GMP Operations		
		Process Development/QbD	Manufacturing support / trouble shooting		
		Process Scale-up	PV / PPQ	Continued Process Verification	
		Analytical Dev. / AQbD / Method Qualification		Trending	
		C(D)MO Management			
		Technology Transfer (Process and Methods)			EOL Reporting
		CMC regulatory			
Interim Management	Quality	ISO / GxP			
		QA Systems			
QA Operations					
QC Methods Validation (Clinical Phase 1 Safety)					
Supplier Qualification and Audits (both internal and external audits)					
GMP Inspection Readiness					
Contract QP/RP					
Temporary Staffing	Engineering & CQV	Feasibility Studies			
		Conceptual and Basic Design			
Detailed Design Review					
Design Qualification					
Construction Management					
CQV (including CSV/CSA and Cleaning Validation)				Decommissioning	
Project Review					
Consultancy					

What people think consulting is... vs what it actually is

Consulting in Life Sciences: *More Than Giving Advice*

What I expected	What I discovered
Mostly reports	Solving operational problems, even lab work (<i>expertise</i>)
Generic pharma work	Highly technical environments (MSAT, QA, QC) with Consultancy as backup (50+ consultants)
Working from the sidelines (outsider)	Family + Embedded in project teams (project mgmt skills)
Working 100% at clients	Sometimes 3 clients, sometimes 50% & internal work
“Commercial” means sales	Commercial means creating value (<i>unload</i> client)
Lot of travelling	Surprisingly much more 50:50 & Randstad
Loose science edge	Gain network & implementation edge & novel therapies

In life sciences, innovation only creates impact when science, quality, manufacturing, regulation and people work together.

Problems consultants help solve

Unburden and accelerate

Challenge	Consultant contribution
GMP inspection readiness	Structure & risk reduction
Scaling manufacturing	Process understanding (Control Strategy)
Misalignment between teams	Communication & coordination
Tight timelines	Focus & acceleration
Complex technical decisions	Independent expertise

Example: Bringing complex manufacturing closer to patients

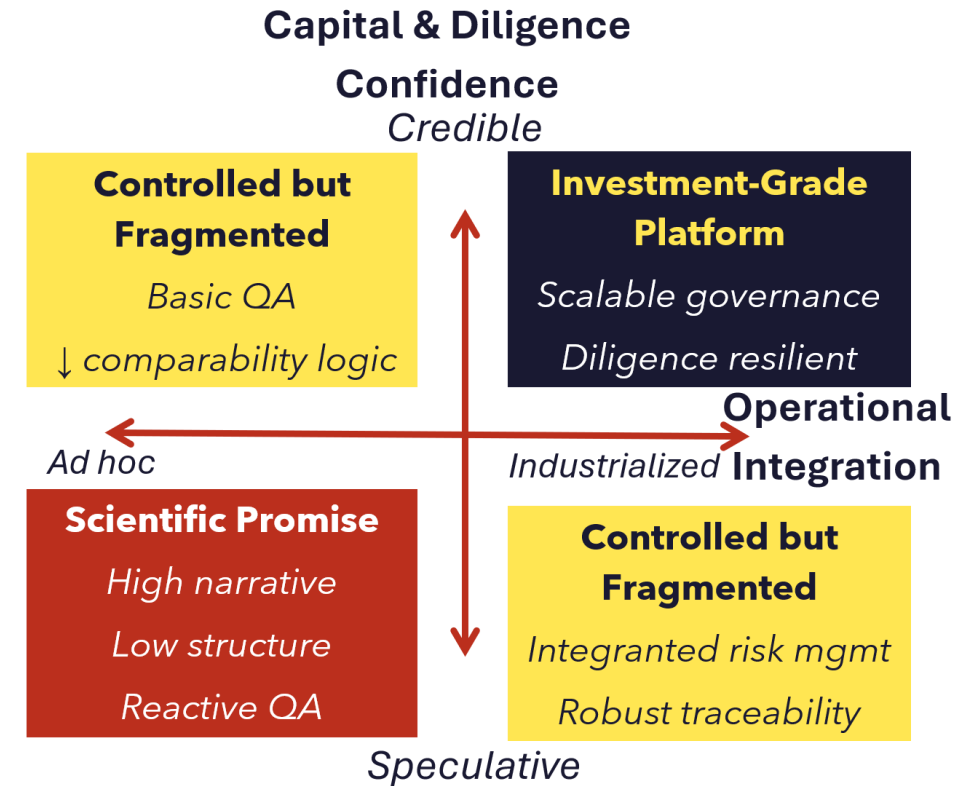
Mediator / QA support role

Challenge

- Company received FDA letter on cross contamination risk assessment.

My role

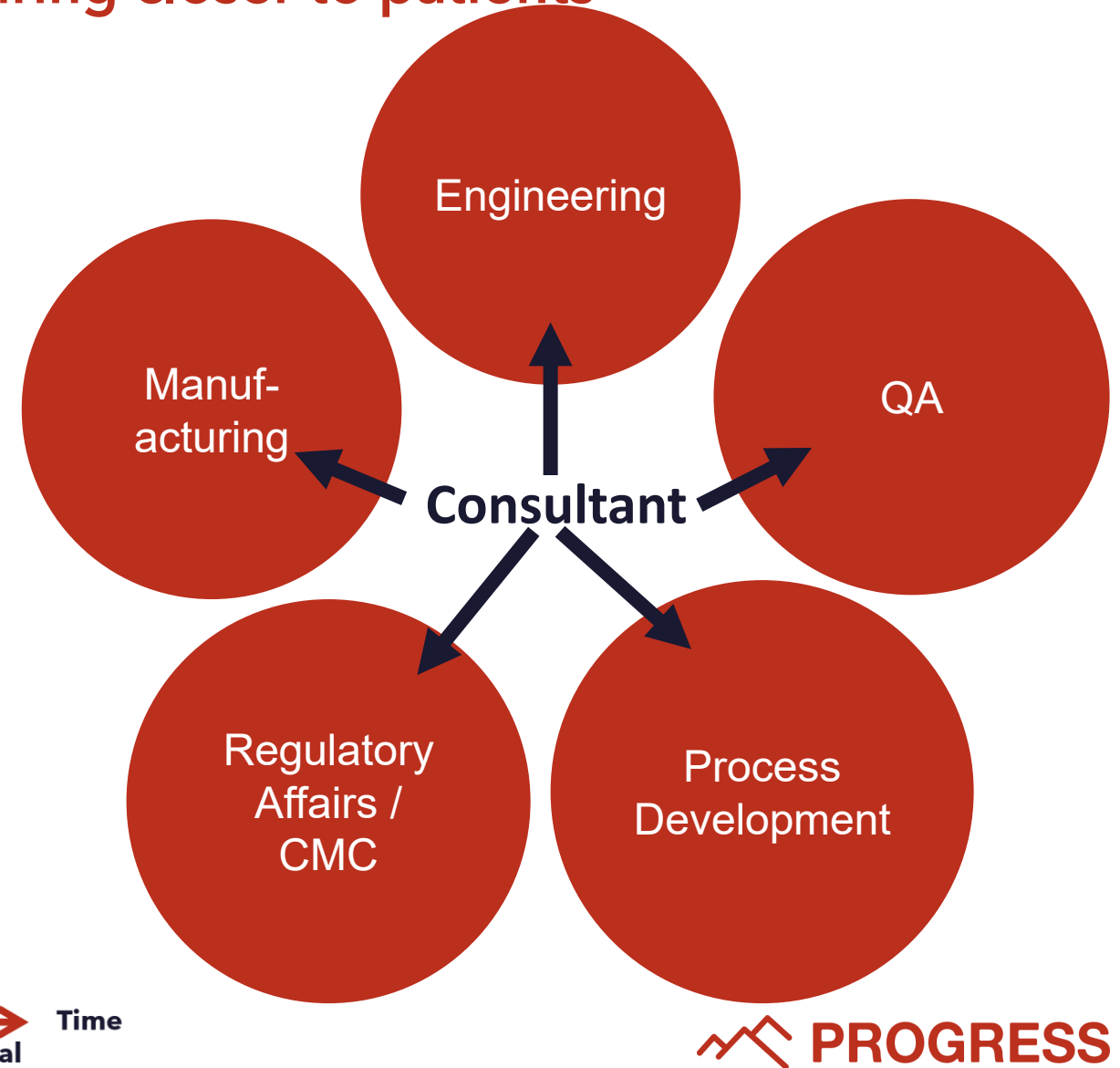
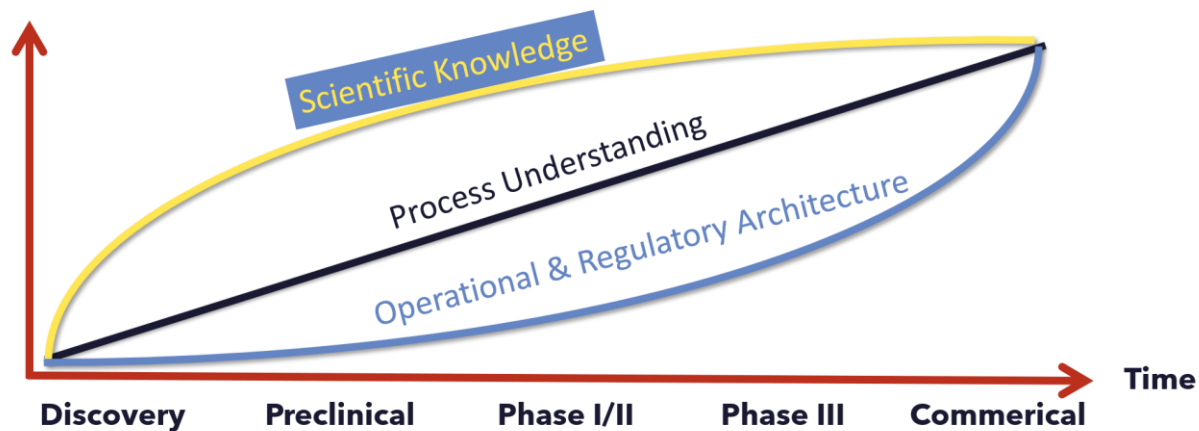
- Connecting teams (facilitate) and set up risk assessment
 - Risk assessments
 - Gemba walks (see manufacturing)
 - multi-stakeholder alignment (*company knows best*)
 - *Does the production capacity match the facility?*
 - Report writing / improvements based on Pareto chart



Example: Bringing complex manufacturing closer to patients

Role: Senior Scientist - CAR T Developer

- Write protocols for technicians & contact point
- Supplier interactions
- Extractable & Leachables (*expertise*)
- Write reports and interact with CMC, QA, Engineering
- Investigational New Drug (IND) updates
- Determine risks and Critical Quality Attributes (CQAs)



Why I enjoy consulting in Life Sciences

Variety

- Every project, company and challenge is different (from *Document Management Systems* to *Process Development*)

Learning

- Continuous exposure to new drugs (Radiopharmaceuticals, ATMPs, ADCs, vaccines), technologies (non/-adherent cell reactors; Design-of-Experiment; AI), teams (hierarchical & flat, exhausted & fun) and environments (first-in-human vs late stage)

Impact

- Helping organizations move promising therapies closer to patients (think of overcoming dogma's & cyclic events)

Collaboration

- Working with experts across science, manufacturing, quality and strategy
- Having the more *apolitical* backup at Progress

Growth

- Developing beyond a single specialization (QC, QA, MF, RA...)
- Network (Dutch ATMP Summit, DARQA, PDA, ISPE, DLS...)

Consulting allowed me to stay connected to science while growing far beyond the laboratory

Advice for students & young professionals

Stay curious beyond your specialization

- Science, manufacturing, regulation and business increasingly overlap

Learn to communicate complexity simply

- Technical expertise becomes valuable when others can act on it

Do not underestimate networking

- Communities like ISPE, PDA, conferences and industry events accelerate learning enormous

You do not need to know everything immediately

- Most growth happens on projects and through collaboration

Careers are rarely linear

- Many opportunities appear through curiosity, initiative and relationships (I have BSc Psychology)

The Life Sciences industry increasingly needs consultants who can connect disciplines, people and ideas.

**Thank you for
your attention!**

Any questions?

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