

# Establishing Successful External Partnerships for Small Molecule Purification & Analysis

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*Kahuna  
Scientific  
Consulting*

- customer view
- pharmaceuticals discovery research
- 7 years with external full parallel chemistry partners to Pfizer(global)
- 2 years external purification-analysis partners to Pfizer(Groton)
- 1 year external compound stability study to Pfizer(global)
- <1 year consulting to service providers

## Capacity

- consistent high chemistry demands
- periodic shortfalls(peak submissions, staff decrease)

## Capability(expertise, technology)

- chemistry based(chiral, physical properties, etc)
- volume/quantity
- speed

## Workflow Efficiency

- external full chemistry process

➤ *Most organizations can benefit from external partnerships*

- Identify analytical support gaps where outsourcing can have a direct or indirect positive impact
- Consider internal partnerships first
- Develop plan that identifies intended benefit & cost
- Gain internal support
- Identify potential partners and ask them for preliminary information and gauge interest.
- Evaluate your potential partners
- Establish relationship with preferred partners
- Monitor deliverables and make necessary adjustments

- Are there new analytical support needs that your group is not able to cover?
- Is the volume of support needed periodically or consistently beyond your capacity?
- Does your team have sufficient scientific and technical opportunities to advance the lab/group capability?
- Can you efficiently scale your work for volume or quantity and not take a hit elsewhere?
- Are highly repetitive experiments or tasks causing team member burn-out?

- Is there another analytical chemistry group that can provide periodic support.
- Can a new or improved open access support model achieve additional support.
- Are there workflow components that can be shared with upstream or downstream groups in your process flow.

# Human Development

- Define work function(s) to outsource?
- Reconcile your team's vs external partner's roles
- What are the logistical sample & data requirements?
- Specify sample 'quality' & deliverables criteria
- Establish problem solving process...*pre-emptive preferred*
- Plan to seamlessly integrate external work into your environment
- Achieve chemistry customer satisfaction.

- What is a reasonable price...your cost + ?
- What does it cost for you to perform the work?
- For multiple sample qualification step processes breakdown the cost sections around decision points
- Are you willing to commit to a minimum level of work or spend?
- Work with an internal finance and procurement colleague

per Sample	Plate/Vial Prep	Pre-Prep Analysis	Prep	Evap	Weighing	Reformat Dup	QC	Data	Shippi
	1	5	10	720	2	2	5		
Cost (\$)*	0.03	0.45	0.90		0.04	0.06	0.45		
es									
ents	0.15	0.14	3.50			0.45	0.14		
ns(inj)		0.30	6.00				0.30		
tubes			0.20						
oval(liquid)	0.04	0.07	1.65			0.04	0.07		
oval(solid)		0.10	0.86				0.10		
	0.22	1.06	13.11		0.04	0.55	1.06		
per Run	Anal. Plate	Pre-Prep Analysis	Prep	Evap	Weighing	Reformat Dup	QC	Data	Shippi
								120	
Cost per				21.60					
es									
per run	9.00					9.00			
110/hr**	110.00	55.00	110.00	55.00	55.00	110.00	55.00	220.00	
	119.00	55.00	110.00	76.60	55.00	119.00	55.00	220.00	100

- Management team endorsement of strategy & budget
- Include analytical colleagues & customer base on outsourcing idea early
- Enlist chemists & analysts to participate in evaluation and testing phases with potential partners.
- Be prepared to frequently present, discuss, and answer questions about the external partnerships

- Use colleagues, instrument manufacturers, and competitive intelligence to find potential external partners.
- Determine if you need partnerships close to you
- Do not count out foreign partners if work deliverables allow
- Can you tag-team with another group that already has an external partnership established?
- Probe potential partners for capability and interest that matches your need....*be clear.*
- Be wary of companies that promise future capability
- Understand that successful partners have clients and must balance your needs with other workloads.

- Communicate exact work to be outsourced...state your sample & data requirements
- Ask for proposal that defines solving your work problem.....*face to face visit at your facility is a plus*
- Review their process, technology, and deliverables proposal
- Ask technical & scientific questions...*pose hypothetical problem and ask for their solution*
- Identify at least one analyst who has problem solving skills
- Be flexible as many approaches can solve the work problem.
- Perform site visit to see facilities, equipment, & staff....*check for safety & insurance level*
- Does it seem to be a good work match and are you comfortable with them
- Get cost estimate and type of business relationships preferred
- Strongly consider having  $>1$  partner

- Agree on cost & business terms within signed contract
- Involve analyst group and customer base in establishing partner workflow
- Finalize parameters for selecting samples for outsourcing...*set partner up for success as it is your own success*
- Design trial runs
  - set data transfer content, file format, & mechanism
  - agree to problem solving mechanism
  - reiterate quality expectation and share any requirement docs
- Execute trial experiments with partner
  - first trial is a simple sample set to test process and data integration
  - second trial is a duplicate sample set to confirm success and quality
- Kickoff partnership

- Examine samples and associated data early & often
- If data is uploaded to larger informatics system check for integrity of data retention and viewing from that system.
- Communicate with partner on success & any issues
- Following startup period spot check key parameters in deliverables to confirm quality & integrity
- Monitor staff time commitment to the partnership
- Don't forget that the external work is yours to defend & explain
- Also make sure payment is promptly made to partner

Full Chemistry External Partnerships

- Full chemistry partnerships include synthesis, purification, & analysis workflows
- Focus is on synthetic chemistry
- Initial startup often has purification & analysis function not well established
- Product deliverables from an analytical quality perspective not well defined

# Chemistry Partnerships

- Be involved in full chemistry team technical meetings
- Start periodic analyst subgroup technical meetings to review status and potential problems
- Establish standards for quality deliverables
- Provide mechanism for problem troubleshooting & resolution
- If possible perform partner site visit to understand process, instrumentation, & staffing expertise
- Use instrument manufacturer's strengths to bolster partner team

# Final Thoughts

To reiterate external partnerships can

- expand your capacity
- give you new capability
- open up time opportunities to explore new technologies/methodologies

Partnerships benefit your chemistry customer base and your analytical team

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