

Contracting Laboratory Services

What you need to know!

Managing outsourced drug discovery meetings

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- Biomedical researcher at University Hospital for 18 years
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- Consulting to industry for 3 years
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Contracting Laboratory Services

What you need to know!

What will be covered

- Background
- Key decisions facing outsourcing managers
- Relationship types
- How to locate labs and consultants are identified
- Best practice principals
- Insight & anecdotes from different perspectives
(client, contractor, intermediaries & scientists)



The Big Picture

New Drug Development

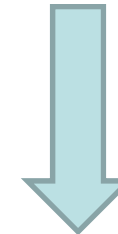
- complex
- highly regulated
- expensive
- time consuming
- time sensitive



*Constant need
for innovation &
more efficiency*

Business Imperative

more outsourcing &
external collaboration



Which labs?

Which experts?

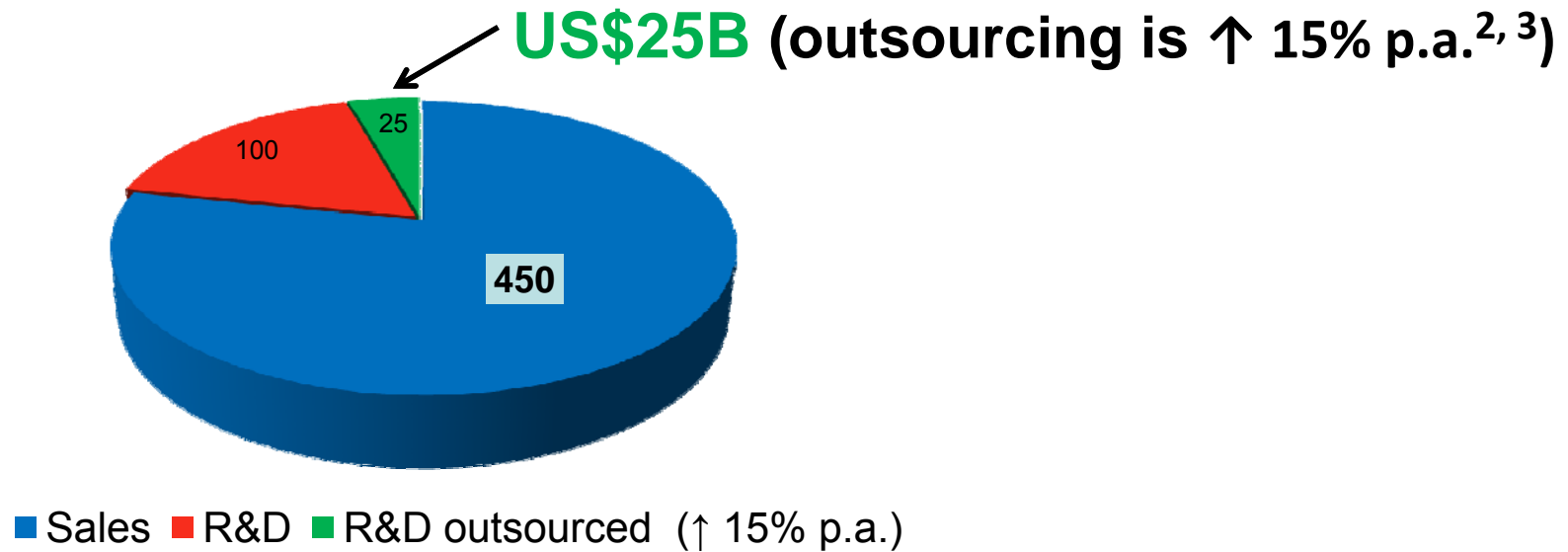
Existing Constraints

- X seekers & providers are time-poor
- X limited marketplaces for seekers & providers
- X seekers have limited filtered information
- X information gathering is expensive



R&D Outsourcing is \$25 Billion

R&D spend for Top 50 Biotech and Pharma Companies¹



References

- 1 www.pharmexec.com, May 2008
- 2 *Global outsourcing market in 2006*, Frost & Sullivan, Aug 2007
- 3 *Contract Pharma 2008 outsourcing survey*, May 2008

Key decisions faced by senior R&D managers

➤ Which new therapeutics should we develop and how exactly?



➤ Which new entities should we develop more aggressively?



➤ What is the most cost-effective and time-efficient development path likely to give us the best competitive advantage?



Contracting Laboratory Services

Where do you start?

Start with your end-goal



What type of relationship?

- ✓ Straight contract (fee-for-service)
- ✓ Collaboration
- ✓ Partnership



How to identify service providers, collaborators and partners?

Of course it depends ...

- size of company
- experience of the R&D team
- how well funded is the enterprise
- what type of company
 - biotechnology, pharmaceutical or nutraceutical
 - contract research organization (small, medium, full service)
 - generic drug manufacturers
 - specialized consultants
 - Government funded biomedical researchers



There is imperfect knowledge & information

No one has it – no individual, company or research organization



Mechanisms to identify potential service providers, collaborators and partners

- In-house staff
- Existing networks
- Use previous supplier/research group
- Engage a consultant or CRO
- Online repositories and marketplaces

e.g. Industry websites, QCTN, BayBio, Govt. databases, Pubmed, Drug Development Technology, **BioAssayLINK**, Assay Depot, GoBalto, etc ...





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Best Practice Principals

- What is your ultimate goal?
- Proof-of-concept or FDA submission?
- Quality of results?
- Confidentiality
- Achievable time-lines?
- Cost
- Track record available/visible?
- **Communication, communication,**
- **After service?**



Contract Pharma 2008 Outsourcing Survey (May 2008)

Examples of biggest complaints by customers

- Inflexibility
- Project management ownership
- Contract withdrawal - can earn more elsewhere
- Commitment to deliverables
- Communication gaps
- Quality issues
- Lack of progress updates
- Staff turnover



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