Table 8: Contractors and In-licensing: Working Effectively Across Companies

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<th>Session 1: Facilitator: Megan Ward, Bayer</th>
<th>Session 2: Facilitator: Houjun Yang, Johnson &amp; Johnson</th>
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<td>Scribe: Ian Meemaduma, Biogen</td>
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SCOPE:
When a product development is largely outsourced to a contract research organization, or a product is in-licensed from another company, there are frequent challenges facing the compound development team due to the differences of the company’s operational philosophies, cultures, practices, organizational structures, platforms, technical experiences, regulatory exposures, etc. To overcome these challenges and have a successful compound development program, it requires strategic thinking, good planning, flawless execution, scientific excellence, open communication, and team work. This roundtable discussion is to share best practices and lessons learned across companies.

QUESTIONS FOR DISCUSSION:
1. What should be included in a contract/license/quality agreement to ensure high quality results for the project?
2. How can we effectively overcome operational, cultural, and other differences between companies?
3. How can we create strategic partnership between companies (other than one-time business deal and/or service-based relationship)?
4. What type of governance should be in place?
5. How can we address risks/gaps effectively?

DISCUSSION NOTES:
Day 1
Question 1: What should be included in a contract/license/quality agreement to ensure high quality results for the project?
- Expectations and deliverables need to be clearly defined upfront
  - e.g. have very specific deliverables, such as itemized list of documents expected such as raw data, detailed and summary reports, detailed test procedures, number of batches, number of QC test sites, etc.
- Clear understanding of roles and responsibilities of both parties
  - A ‘RACI’ table in agreement could prove effective in defining this
- Agreements should have provisions to accommodate change orders, scope extensions etc.
  - Ideally some high-level description on contingency measures/scenario planning is useful
- Seek cross-functional input into quality agreements beyond just QA
  - Where appropriate, multi-functional signature page should be introduced to encourage this
- Individual agreements shouldn’t be developed in isolation
  - e.g. Quality Agreement should connect to Master Service Agreement (MSA)
- Areas of confidentiality, intellectual property rights etc. need to be incorporated
Question 2: How can we effectively overcome operational, cultural, and other differences between companies?

- A F2F kick-off (KO) meeting allows team leads to share expectations on frequency of interactions, mode of communication (email, skype, phone etc.) and when to escalate
  - Participation by the right people is critical
- Joint training for both parties
- Effective succession planning
  - If there are personnel changes, commitments and responsibilities should be transferred to the team lead until a functional team member is identified
- Introducing joint development milestones and business objectives
- It should be agreed that any information going outside of the sub-teams should be agreed by both parties before being shared to a larger audience

Question 3: How can we create strategic partnership between companies (other than one-time business deal and/or service-based relationship)?

- Use of regular check-ins to create a ‘high-touch’ environment
- Activities that are collaborative rather than transactional with full transparency and a data-driven core
- KPIs or scorecards to allow two-way monitoring of partnership

Question 4: What type of governance should be in place?

- Formation of a joint technical/project team (which is separate from the business aspect) composed of functional groups (analytics/USP/DSP/DP/QA/RA.PM etc.)
  - At least one member from each company
- Clear understanding of the resources allocated to support outlined project
  - Will there be a project KO meeting; how many meetings and who is expected to attend etc.
- Alliance management team to support business aspect
- Joint steering Committee - for escalation issues

Question 5: How can we address risks/gaps effectively?

- Protocol/recipe driven processes help mitigation
- Mechanisms for transparency - communication plans put in place along with appropriate governance and escalation processes
  - define how to manage when things go “sideways”

Day 2:

1. What should be included in a control / license / quality agreement to ensure high quality results for the project?

  - Key Performance Indicators: what constitutes success
  - Roles and Responsibilities, including in case of investigations, escalation process and conflict resolution
  - Plan of activities and deliverables, including knowledge and tech transfer activities
  - Communication plan including regular meetings between SMEs and governance or steering committees and what would trigger an ad-hoc meeting
2. **How can we effectively overcome operational, cultural and other differences between companies?**

- Importance of face-to-face meetings, especially at the start of the project. There would generally be one between the sponsors or steering committee, but they are also critical for the governance team and the SMEs
- We should never forget that we deal with people, be respectful, listen and sympathise – whichever side of the fence we are
- Limit assumptions to the minimum, don’t be afraid to go in to the finest details – all organizations work differently, even the same word may not mean the same thing.
- For the best results a couple of roles are critical:
  - Project managers from the Contract Organization
  - SME in contracting activities from Contracting Organization – this person would be versed in the technical field and would have worked on a project that would have been contracted out themselves, and would be able to understand the relationships that need to be established between the two organization
- Training of the SMEs in a contracted relationship is also essential – understanding of the contract and what is acceptable, what is not on both sides

3. **How can we create strategic partnership between companies?**

- Ensure that there is technical compatibility between the 2 organizations as well as business compatibility – from the start
- If the same organizations work in partnership on different projects, it is important to have an overseeing committee – could be the governance or steering committee. This identifies trends in the relationship but also can lead to recommendation of best practices
- Do not change things too much: try to limit the number of Contract Organizations or customers you work with. If people can be maintained in their role, this is an advantage. Turnover of personnel is almost always damaging.

4. **What type of governance should be in place?**

One size does not fit all: create governance that both companies are comfortable with and which will facilitate delivery of the projects

5. **How can we address risks / gaps effectively?**

- As a contracting organization, you should know what is appropriate for contracting out and what should remain within your complete control or what you would be better contract in, i.e. get contractors within your organization. Decision trees may be useful.
- Have a plan B – if the relationship does not work, have another potential partner in mind or ensure that your own organization could potentially bring the activity back in-house.