Roundtable Session 2 – Table 7 –

Managing/Leveraging CMOs and CTOs for Lifecycle Success

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Abstract:

Contract manufacturing organizations (CMOs) and contract testing organizations (CTOs) are vital to the pharmaceutical industry, especially during the clinical and commercial phases of product lifecycles. CMOs provide a diverse array of services that facilitate the production and development of products across various sectors, with a strong emphasis on pharmaceuticals, biotechnology, and consumer goods. These services generally encompass:

- Product Development
- Drug Substance and Drug Product Manufacturing
- Quality Control and Assurance
- Packaging and Labeling
- Regulatory Support
- Supply Chain Management
- Technology Transfer
- Customized Solutions

By harnessing the expertise and resources of CMOs and CTOs, companies can concentrate on their core competencies while ensuring high-quality production and adherence to industry standards.
To effectively manage and utilize CMOs and CTOs for optimal success, pharmaceutical companies should evaluate their offerings, available capacity, and the capabilities of service providers throughout the product lifecycle. A thorough due diligence process is essential to assess their capabilities, quality standards, regulatory compliance, and historical performance. This evaluation aids in forming strategic partnerships that align with the specific requirements of the product. Additionally, it is crucial to establish flexible and scalable solutions that can adapt to evolving demands throughout the product lifecycle, including timely responses to market dynamics. By implementing robust strategies for the selection of CMOs and CTOs, pharmaceutical companies can ensure effective management and leverage their services, ultimately enhancing the success of their clinical and commercial product lifecycle.

Discussion Questions:

Strategic Alignment

- What challenges do CMOs and CTOs face in aligning their strategies, and how can these be overcome?
- How can organizations foster a culture of collaboration between CMOs and CTOs to ensure ongoing strategic alignment?

- How can feedback loops between CMOs and CTOs be established to continuously refine and align strategies?
- How can the integration of emerging technologies impact the strategic alignment between CMOs/CTOs and sponsor companies?

Roles and Responsibilities

- In what ways can the responsibilities of CMOs/CTOs overlap with sponsor companies, and how should these overlaps be managed?
- How can pharmaceutical companies ensure clear communication and delineation of responsibilities between CMOs and CTOs?

Quality Control and Assurance

- What are the key components of a robust quality assurance process that CMOs and CTOs should implement?
- How can feedback from clients and stakeholders be integrated into the quality assurance processes of CMOs and CTOs?

Regulatory Considerations

- How can leveraging regulatory support from CMOs and CTOs improve operational efficiency?
- What strategies can CMOs and CTOs implement to stay ahead of regulatory changes?
- How can technology be utilized by CMOs and CTOs to streamline regulatory compliance processes?

Notes:

For simplification CRO, CDO, CMO, CTO are all subsumed under the term contract organization (CO).

In general, it is recommended to be clear regarding scope of work and aligned on paths/extend of communication between both parties from the beginning. Both sides should review proposals/contracts/agreements carefully and align on potential roeadblocks (e.g., quality expectations) early on.

Ideally there are project managers on both sides that support a joint project continuously and from beginning to the end, also in case of phase transitions. Knowledge management and its conservation throughout the entire product lifecycle is key and often becomes an issue if not ensured properly. However, this expectation is often not realistic due to involved staff changing positions over time or in case no project management organization is established, which is often the case for smaller sponsors or COs. Here external PM services can help and are leveraged by some companies, particularly smaller ones.

Project management is typically the first level contact between parties, depending on the respective topic project managers may then involve other functions (e.g., subject matter experts) if necessary. However, issues may arise if functions beyond project management are not involved in a timely manner or if one partner refuses to involve additional functions. This involvement, particular of subject matter experts, at the right point in time can help clear roadblocks or even prevent them, and therefore should also be aligned on from the beginning between parties to facilitate a smooth and functional collaboration.

Some attendees have seen parties having established a dedicated code of conduct for external collaboration (or parts of their general code of conduct related to external collaboration). Establishing such a behavioral standard can help to ensure mutual understanding of the different perspectives of involved parties.

Roles & responsibilities of either party should be clarified as detailed as possible to avoid misinterpretation (e.g.: facility-related -> CO, product/molecule related -> sponsor). However, since the QAA is often based on a template is typically not elaborated in enough detail. It is therefore recommended to include important details (e.g., data management, level of detail for reporting, periodic review, and further) explicitly in the QAA or a suitable and binding associated document.

One detail that has been discussed exemplarily is the importance of periodic review of data for trending. However, especially small CO may not have enough capacity for a full periodic review. In such cases it may be required to completely take over the periodic review activities by the sponsor, which in turn requires facilitation by the CO, e.g., by providing the relevant raw data. Some sponsors will also request raw data for further evaluations or trending, according to participants raw data availability frequently becomes a roadblock because it has not been agreed or defined previously. Data exchange via shared platforms (e.g., joint LIMS systems) using previously agreed data standards can help where this approach is feasible.

Some CO also provide support with regulatory documentation (up to full IND authoring service as part of contract). The level of involvement and detail of the deliverable should be clarified early on (e.g., what happens in case of authority questions or requests, how to handle inspections). However, completely relying on a CO for an IND usually does not work since the authoring process is complex and typically requires product knowledge beyond what a CO can provide.

In any case it is essential to have due diligence regarding skills and knowledge, but even more so what is lacking or only a weak/not yet elaborated skill. Some CO promise a completely final package with "red bow" that includes every aspect that needs to be considered. In reality, however, this is rarely the case and is almost impossible to achieve due the by default limited insights into all aspects of a drug development program on the side of a CO.

It was the general agreement amongst all roundtable participants that mutual respect and recognition of both skills and specific challenges on either side (sponsor and CO) is essential for successful collaboration.