

Roundtable Session 2 - Table 10 - Best Practices in CMC Decision-Making (Clinical Phase) by Applying Inclusive Principles in Team Build

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TPP: Being inclusive in TPP Design.

- Emphasize the fit for purpose design, which should require wide and diverse function.
- Example: Clinical strategy for dosing kept changing, communication with CMC was limited. The thinking process was product can always be diluted or concentrated. When CMC developers finally got involved, the concentration was so low, concentration was not possible. Trial got delayed.
- Example 2: Tox material: CMC and non Clin, how much material needs to be made? What is the quality?
- CMC shouldn't be expected to make anything happen.

Inclusive CMC function:

- How to ensure best relationship within the functions?
- Making sure CMC principles are included in the clinical design and vice versa, include a clinical representative in the CMC team.
- Early CMC lead is vital to make sure CMC is involved before the candidate selection. CMC tech lead is important. Early CMC lead has to have an overarching structure to be informed in the late stage manufacturing experiences to make sure CMC strategy is viable.
- Well defined core structure, early on.

Knowledge Management

How to apply **knowledge management** system effectively?

Has to be a stage gate approach for implementation/growth of:

- **System**
 - Objective documentation to store legacy understanding.
 - CMC program manager team -> Extremely good minutes, which is documented in a searchable
 - Decision Logs are a must.
- **Personnel**
 - Employee retention
 - Succession planning

Change Management

- Understanding who does what in documenting changes? For example: is the change management done by CDMO versus sponsor.
- How does a sponsor have visibility into changes in quality agreement, raw material changes between a vendor and CDMO? It is important to ensure clear communication of changes are included in the quality agreement. External facing team structure is crucial to ensure clear communication.
- Proper due diligence is a must in ensuring best selection of CDMO.

- Balancing COGS with the expected quality is critical for CDMO selection and a part of the CMC decision making. This is challenging for a new company starting the effort.

Internal decision making within a CMC team:

- Pre reads with data
- Include the right people to be able to assess data to determine impact to change.