Table 55: Tech Transfer from R&D into Commercial Manufacturing: The Initial Risk Assessment

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SCOPE:
Risk assessment is an important tool during biologics drug development, and is an integral part when filing a BLA. It becomes even more necessary as companies consider breakthrough designation, wherein the CMC development may not go through the traditional phases. In this roundtable, we will discuss some aspects of how risk assessment is done when exploring fast track development.

QUESTIONS FOR DISCUSSION:

1. How many companies do a formal risk assessment in various phases of development?

2. Does this risk assessment differ when considering a breakthrough designation?

3. If a formal and complete risk assessment is not done, what other practices (e.g. gap analysis) are considered?

4. What feedback, if any, can be shared from interaction with regulators?