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CHALLENGES AND THEIR RESOLUTIONS DURING PROCESS DEVELOPMENT AND TECH TRANSFER OF A LATE STAGE BISPECIFIC ANTIBODY PRODUCT

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During the Phase III process development and tech transfer of a bispecific antibody project in Sanofi, many technical and logistical challenges were encountered for this cross-site collaboration project. In particular, Phase III process development and tech transfer involves three different sites as sending and receiving units located in different continents using different scales of equipment. Due to this constraint, additional considerations are required to address gaps between different small scale models prior to scale-up in order to de-risk the challenges that we may encounter during process transfer. Particularly, computational fluid dynamics (CFD) modeling and first principles calculation are used not only to support scale-up but also to bridge the difference between the small-scale models. In addition to this logistical challenge, the team also systematically addressed some technical challenges in order to close several major manufacturability gaps between the Phase I/II and the Phase III processes. This poster summarizes our approach to resolve each of these challenges in order to collaboratively accomplish a successful tech transfer.