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BUILDING QUALITY NOVEL FORMATS AND DEVELOPMENT PROCESSES

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There has been an explosion of interest in bispecific or multi-specific bio therapeutic formats. Monospecific antibodies remain the foundation for most bispecific formats. However, monospecific strategies cannot be directly translated into the discovery and development of bispecific antibodies. Bispecifics present unique challenges especially for efficient and consistent assembly/production processes and analytical methods to ensure high quality drug products. Improvements in selection of bispecific combinations/architecture, yield and efficiency and common analytical issues and resolutions will be discussed. Applying improved methods learned from Fab-arm exchange bispecifics and alternative scaffold-antibody fusions, we have established a foundation of knowledge that enables accelerated development.