

Regulatory considerations when developing biological products. Report of the Center for Biologics Evaluation and Research.

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The Center for Biologics Evaluation and Research, whose regulatory authority includes monoclonal antibodies, cytokines, vaccines, toxins and somatic cellular therapies, communicates to sponsors issues for consideration in the development of biological products through the publication of "Points to Consider" and "Guideline" documents. This paper summarizes the available "Points to Consider" and "Guideline" documents and outlines recommendations from these documents for characterizing the cells used to produce biological products.