

## Monoclonal Antibody Assessment Task List

The task list is designed to identify what work has already been initiated or completed and to identify what work still needs to be completed in order to create a successful development plan. Please indicate if the following tasks have been initiated and/or completed. If any reports or summaries are available please send those along with the completed Monoclonal Assessment Task List.

	Name of Monoclonal Antibody:		
	Therapeutic Application/Intended Use:		
	Proposed Clinical Regimen/Route of Administration:		
Task			
		Completed (Y or N)	Details
1.	Master Cell Bank and/or working cell bank available?		
2.	Characterization Completed?		
	Structure defined		
	Immunologic properties		
	Antigenic specificity		
	Complement binding		
	Reactivity/cytotoxicity		
3.	Pilot Batch(es) Manufactured?		
	Methods established?		
	Batch records available?		
4.	Drug Substance Characterized?		
	Storage Conditions determined?		
	Stability established?		
	Criteria for release defined?		

5.	Final Product Formulation Established?		
6.	Filling Process Established?		
7.	Filled Product Release Criteria?		
8.	Filled Product Stability?		
9.	Immunogenicity Method Development		
10.	Immunogenicity Study conducted?		
11.	Toxicity Study conducted?		
12.	Biodistribution Study		
14.	Pre-IND meeting w/FDA		
15.	cGMP Clinical Trial Materials (CTM) Manufacture		
16.	IND Compilation and Submission		
17.	Additional Comments or Work Performed		
18.	Patents, Publications, Technical Reports or Literature References		

**Monoclonal Antibody  
Manufacture and Characterization Information**

Amount of Test Article Available (ml)	
Concentration	
Vehicle or Diluent Components	
Potency Determination Method(s)	
Storage Conditions	
Stability under storage and conditions of use	
MSDS Completed?	
Certificate of Analysis available?	