

Gene Therapy 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 Gene Therapy Assessment Task List.

	Name of Gene Therapy:		
	Therapeutic Application/Intended Use:		
	Proposed Clinical Regimen/Route of Administration:		
Task Completed (Y or N) Details			
1.	Development of Therapy Completed (see Attachment A)		
2.	Vector?		
3.	Characterization Completed?		
4.	Pilot Batch(es) Manufactured		
5.	Final Product Formulation Established?		
6.	Filling Process Established?		
7.	Filled Product Release Criteria?		
8.	Filled Product Stability?		

Gene Therapy Assessment Task List (continued)

	Task	Completed (Y or N)	Details
9.	Immunogenicity Method Development		
10.	Immunogenicity Study		
11.	Toxicity Study		
12.	Biodistribution Study		
13.	Integration 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		

Attachment A
Gene Therapy Manufacture and Characterization Information

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