Timeline - GMP development

For a new peptide the usual development timeline will be:

Process	Duration	Description
1. Production of API		
1.1 Non-GMP Process (lab scale)	3 months	Our R&D/QC will carry out process development work and corresponding **a**nalytical method **s**tudies (AS), then, carry out lab scale production to assess the feasibility to scale up, in this stage, we will get some non-GMP product
1.2 Scale up (3-4 batches)	3 months	We will scale up the developed production process to check the process robustness in our R&D plant. We will also start and finish the AS method validation work. In this stage, we will get pilot scale product, and we will have a full specifications of the product
1.3 Process validation in GMP factory (3 batches)	2 months	Our R&D will carry out three validation batch runs. Scale to be discussed with the client. As this stage, **we can get more** than 100 gram peptide per batch.
1.4 Stability studies; development and pre-validation of AS method; preparation of the working standard	6 months	Our QA/QC will carry out stability studies out of the validation batch materials based on the pre-approved stability testing protocol. We will also start and finish the AS method validation work. A preliminary stability study on the scale-up material will also be carried out. And, we will prepare the working standard.
1.5 Impurities study	3 months	Including impurity identification, characterization and preparation:
2. DMF Document Preparation	1 month	Our QA will prepare the whole DMF documentations for API.
Total Time Required	**18 months**	