

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 analytical method studies (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	

If you have any questions, please feel free to contact us.

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