High Force Research

The HFR GMP Journey

R & D Quality Level		Traceable Quality Level	GMP Quality Level		
Development	**Optimisation**	**Traceable Manufacture**	**GMP Preparation**	**GMP Manufacture**	**Post GMP Manufacture**
Typically 3-6 weeks	Typically 2-3 months	Typically 1-3 months	Typically 1 - 3 months	Varies	Ongoing
Production method transfer/development	Define Production Methods and route assignment	Qualify suppliers/contractors before start	ICH validation of key analytical methods	Production reported on batch production record	Store in secure qualified and monitored facilities
Testing using general methods/methods provided	Develop key analytical methods	Agree the technical agreement before start	Formally define specifications	Analyse in process controls	Despatch by qualified cold chain shipment
	Qualify reference markers	Formally define all analytical methods	Formally define production methods	Investigate deviations and out of specifications	ICH stability study
	Partially validate key tests/ informal stress test	Production reported on blank production records	Preparation of Technical agreement	Analysis reported on certificates of analysis	Stress test study
	Develop remaining analytical methods	Test API in full	Preparation of master production records	Create TSE statement for API	
	Develop purification methods		Raw material order, log in, and analysis	Create campaign report	
	Prepare, qualify and dispense reference		Equipment order, log in, qualification and maint.	Create certificate of GMP Compliance	
	Informal stability study				