BIOSIMILAR			INNOVATIVE BIOPHARMACEUTICAL		
TASK	YEAR	SPECIFIC ACTION / TESTS	TASK	YEAR	SPECIFIC ACTION / TESTS
Define Target	0	• Create project plan based on Quality by Design (QbD) • Characterize originator • Develop Bioassays • Risk Assessment (Critical Quality Attribute (CQA) evaluation) • Evaluate facility, cost of goods etc.	Define Target	0	• Create project plan based on Quality by Design (QbD) • Characterize originator • Develop Bioassays • Risk Assessment (Critical Quality Attribute (CQA) evaluation) • Evaluate facility, cost of goods etc.
Product Characterization	1	• Assay verification • Assay development/optimization • Potency assay • Biophysical/ Bioanalytical characterization • Stability Study • Drug Substance (DS)/Drug Product (DP) formulation and Container Closure Assessment • Assess Product quality, safety and efficacy	Proof of Concept, Cell Line, Cell Culture and Purification Development	1	• Design of Experiment (DOE) • Perform Proof of Concept (POC) study • Media Optimization • Cell growth Kinetic Evaluation • Clone development/selection • Stability studies • Cell Expansion • Purification • Quality Testing of Purified Product (safety, efficacy, purity and identity etc) • Product Formulation and container closure assessment
Cell Line Development		• Design of Experiment (DOE) (Multivariant Analysis) • Media Optimization • Cell growth Kinetic Evaluation • Clone development/selection • Stability studies • Cell Expansion • Purification • Testing (Bioanalytical/biophysical characterization) • Creation of Research and Master Cell Bank (RCB, MCB)	Phase I Manufacture	2	• Engineering Runs (non- GMP) • Tox study • Animal study • Human Safety and Efficacy Study • Product Characterization and assay qualification
Full Process Development (PD)	2 – 3	• DOE/PAT (Process Analytical Technology) based PD • Testing (biophysical/Bioanalytical characterization) • PD for Upstream and Downstream • Stability Studies • Additional assay development • Animal Studies • Formulation and Container closure assessment	Phase II Manufacture	3	• Manufacture for Phase II trials • Continue Product Characterization
Phase I Manufacture	3	• Tox studies • Manufacture for Phase I trials	Phase I Manufacture	4	• Validation of Assays and processes • Completion of 3 Conformance lots
Characterization & Compatibility	4	• Refine CQA definitions • Establish bioactivity correlations. • Testing- Bioanalytics (Glycans, post translational modification analysis, mass spec, peptide mapping, N-terminal sequencing, AA analysis, extinction coefficient, chromatographic profiling etc) • Initiate Phase I studies	GMP Manufacture (Phase III)	5 – 7	• Initiation of Phase III Study • BLA Filing
Process Validation and Monitoring	5 – 6	• Assay Validation • Process Validation and testing • Process Monitoring			
GMP Manufacture (Phase III)	6 – 7	• Manufacture of 3 conformance lots			