



## Preclinical Development

Product Characterization

Assay development & qualification  
-identity  
-strength  
-purity  
-potency  
-safety

Process Development  
Drug Substance  
-fermentation  
-cell culture  
-purification

Product Development  
Drug Product  
-preformulation  
-formulation  
-lyophilization development



## Tox & CMC Support

Tox manufacture  
Drug Substance  
-fermentation  
-cell culture  
-purification  
Drug Product  
-fill/finish  
-lyophilization

QC Testing  
-identity  
-strength  
-purity  
-potency  
-safety

Product Characterization

Additional Assay Development and Qualification

Additional Process Development



## Phase I

IND Submission  
-CMC

Raw Material Testing

Drug Substance  
Manufacture  
-fermentation  
-cell culture  
-purification

Drug Product  
Manufacture  
-fill/finish  
-lyophilization

QC & stability testing  
-identity  
-strength  
-purity  
-potency  
-safety

Product Characterization

Additional Assay Development and Qualification

Additional Process Development



## Phase II

Raw Material Testing

Drug Substance  
Manufacture  
-fermentation  
-cell culture  
-purification

Drug Product  
Manufacture  
-fill/finish  
-lyophilization

QC & stability testing  
-identity  
-strength  
-purity  
-potency  
-safety

Product Characterization

Additional Assay Development and Qualification

Additional Process Development



## Phase III

NDA/BLA  
-CMC

QC & stability testing  
-identity  
-strength  
-purity  
-potency  
-safety

Method Validation

Process Validation (Testing Support)  
-viral clearance  
-residuals



## NDA/ Commercial

QC & stability testing  
-identity  
-strength  
-purity  
-potency  
-safety

Revalidation of Process (Testing Support)

Revalidation of Test Methods

Reformulation



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