BLUE stream LABORATORIES

THE CRITICAL PATH: Finding Solutions

	DISCOVERY	RESEARCH	DEVELOPMENT	PRECLINICAL	IND SUBMISSION (CMC)	Phase I	Phase II	Phase III	BLA SUBMISSION	COMMERCIAL PRODUCT
DISCOVERY SUPPORT										
2D Gel Protein Separation & Identification										
Protein / Peptide Structural Characterization										
Protein / Peptide Sequence Determination										
Immuno-based Activity Screening										
DEVELOPMENT & LOT RELEASE SUPPORT										
Structural Characterization										
Reference Standard Characterization										
Method Development & qualification										
Method Validation										
Stability Testing										
Formulation Services										
Purity Testing										
Bioactivity / Efficacy Testing										
GMP Lot-release Testing										
PROCESS / MANUFACTURING SUPPORT										
Process Equivalency (Comparability) Studies										
Impurity Determination										
Residual Determination										
Cleaning Validation										
Raw Material Release Testing										
Process Development Consulting & Services										
REGULATORY SUPPORT SERVICES										
Product Development Consultation										
CMC Consultation										
Phase-specific Compliance Consultation										
Commercial Lot-release Program Consultation										

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