PROJECT MANAGEMENT

Personalized and constant support through complete project lifecycle

- **Initial project assessment** with client
- **Proactive dedicated Project Managers** as interface between client and internal project team
- **Dynamic project team** including the appropriate internal experts
- **Specific project management tools** for identifying and establishing detailed formal client needs
- **Recognized flexibility and strong anticipation skills** on the overall project requirements
- **Adaptability** to project and client constraints

YOUR + ONE STOP FILL & FINISH PARTNER

CLINICAL MANUFACTURING
Scale-up
Technology transfer
Preclinical supply
GMP process optimization
GMP clinical batches
Release analytics
Clinical packaging
Stability studies
GMP storage
CLINICAL DISTRIBUTION

COMMERCIAL MANUFACTURING
Tech transfer
Process validation
GMP commercial batches
Release analytics
Secondary packaging
Serialization
On-going stability studies
GMP storage
DISTRIBUTION

BACCINEX

your + fill & finish expert

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- **ONE STOP CDMO FOR STERILE LIQUID AND LYOPHILIZED DRUG PRODUCT UNDER GMP**
- **CLINICAL MANUFACTURING PROJECT MANAGEMENT** from DP development and batch manufacturing to clinical centers supply will be enhanced by the value of our long term expertise
- **COMMERCIAL PRODUCT** from process transfer and manufacturing to Finished Product delivery secured by a robust and long-term relationship

CLINICAL DP MANUFACTURING

1 INITIAL PROJECT ASSESSMENT

- Feasibility Assessment And Support
- Technical Feasibility
- Regulatory Feasibility
- Budgetary And Timely Feasibility

2 DEVELOPMENT

- Manufacturing Process Development
- Formulation Development Support
- Freeze-Drying Cycle Development

3 PRECLINICAL MATERIAL

- Tox Study Material
- Stability Samples Manufacturing
- Indicative Stability Study

4 CLINICAL MANUFACTURING – PHASE I, PHASE II & PHASE III

- Process Alignement with GMP
- Pilot batch
- Scale Up
- GMP manufacturing
- Secondary Packaging
- Randomized Labeling
- Clinical Kit Preparation
- GMP Storage
- Controlled Temperature Shipment

5 COMMERCIAL MANUFACTURING

SPECIFIC STRENGTHS

- **Utmost flexibility** related to timelines and technical solutions
- **Strong project management** system for a proactive follow-up all project steps
- **Technical and GMP regulatory support** related to the clinical project
- **Extensive expertise in management of limited quantity of valuable API**
- **About 50 different clinical manufacturing projects** managed per year
- **Standard aseptic process simulations** available
- **No minimum batch size**

COMMERCIAL MANUFACTURING

CAPABILITIES	
Aseptic fill-finish	•
Terminal sterilization	•
Liquid filling	•
Lyophilization	•
Complex formulations	•
Peptides	•
Biological products	•
Controlled substances	•
Small molecules	•
Sterile suspensions	•
Ophthalmic	•
Placebos / Diluents	•
Vials	•

DEVELOPMENT SERVICES

- Freeze-drying cycle development
- Manufacturing process development and transfer
- Formulation development support
- Filter/material compatibility
- Client specific development upon request

ANALYTICAL SERVICES

In-house Physico-chemical and microbiological GMP laboratory

- HPLC-UV (assay, purity)
- UPLC-UV
- sub-visible particle counting
- osmolality
- residual humidity by Karl Fischer (volumetric / coulometric)
- spectrophotometry UV-Vis
- spectrophotometry IR
- pH
- visible particles
- SDS - Page
- thin layer chromatography
- potentiometry
- viscosity
- TOC
- sterility testing under isolator
- endotoxins by kinetic turbidimetry
- bioburden testing
- specific germs contamination

METHODS VALIDATION / VERIFICATION

- ✓ HPLC/UPLC
- ✓ sterility test
- ✓ endotoxin test
- ✓ bioburden test

STABILITY STUDIES

- Long term stability storage under ICH conditions
- Analytical testing at different stability points