

# STRATUM MEDICAL

The Four Stages From Drug Substance to Finished Drug Product

## STAGE 1

Formulation  
Forced Degradation  
Impurity Profile

### Tasks

- 1.1 Establish Analytical Method
- 1.2 Establish Solubility Profile
- 1.3 Forced Degradation
- 1.4 Sterile Filtration Feasibility
- 1.5 Formulation Optimization
- 1.6 Solid Formulation

## STAGE 2

Engineering Run  
Specifications  
Stability

- 2.1 Engineering Run and Lyophilization Cycle
- 2.2 Release Testing and Specifications
- 2.3 Stability Study
- 2.4 Qualification of Test Method
- 2.5 Technology Transfer

## STAGE 3

Production  
Release  
Clinical Material

- 3.1 Clinical Supply Manufacturing
- 3.2 Release of Finished Product
- 3.3 Labeling, Packaging and Shipping
- 3.4 Toxicology Material
- 3.5 Drug Substance Standard

## STAGE 4

Regulatory  
CMC  
IND

- 4.1 Chemical and Manufacturing Control (CMC)
- 4.2 Stability Program
- 4.3 Investigational New Drug Application (IND)

*A Leader in Peptide Formulation Development*