



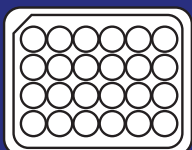
# **Formulation Development**

Deep rooted in our fundamental understanding of Protein Chemistry, our formulation expertise spans a wide range of proteins such as – chemically derivatized proteins, receptor fusion proteins, hyperglycosylated proteins, and monoclonal antibodies and fragments.

Our approach to formulation development works with the flexibility needed for a wide variety of delivery systems – Vials, Pre-filled Syringes, and Autoinjector Devices and can deliver stable Drug Product in either liquid or freeze-dried presentations.

Development is supported by a strong analytics platform through which stability and degradation profiles are evaluated and impurities are characterized.

Screening and Lead Identification



Stability and Degradation Analysis



Vial (Lyo / Liquid)



Pre-filled Syringes



Autoinjector Devices

Analytical



Leachable and Extractables, Photostability, Attribute analysis, Excipient methods

# **Formulation Development**

## Why us

Expertise in multiple recombinant protein types -  
Monoclonal antibodies, PEGylated proteins,  
Hyperglycosylated proteins, Fusion proteins

**High Concentration Low viscosity** proprietary  
formulation development

Multiple delivery platforms – **Vials, Pre-filled  
Syringe, Autoinjectors**

Cater to multiple routes of administration –  
**Intravenous, Sub-cutaneous, Intramuscular**

**Lyophilized** and **Liquid** formulation  
development

In-house characterization capability –  
High throughput screening methods, Degradation  
profiling, Photostability, Container closure studies etc.

## What we do

### Platform

Liquid | Lyophilized | Vial |  
Pre-filled Syringe |  
Autoinjector

### Stability Assessment

Real time | Stress Stability |  
Accelerated Stability |  
Hold time Stability |  
Photostability

### Development

Formulation Screening |  
Lead Optimization |  
High Concentration  
Low Viscosity Formulation

### Characterization

Leachable and Extractable |  
Drug Product Attribute  
Analysis | Excipient Attribute  
Analysis

### Protein

mAb | Fab | Fusion Protein | Cytokine | Enzyme |  
Hormone | Hyperglycosylated Proteins |  
Derivatized Proteins

**4000 SqMt.**  
of R&D Lab Space



**ALCOA+ Driven  
Quality Systems**



**200+ Research  
Scientist**



**Digital  
Infrastructure  
Supported**

ELN | Proprietary Analytics Platform

