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BIONEEDS

# Biotherapeutic Process Development Solutions

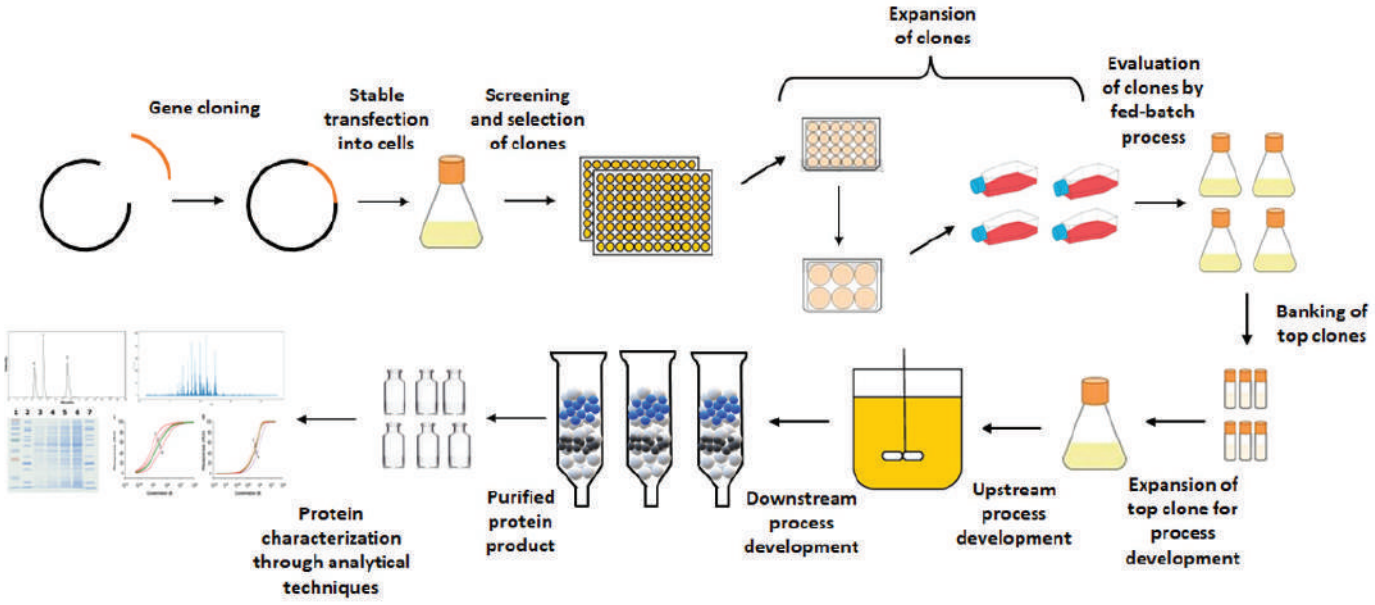
## Overview

The process development at Biopharma Division of Veeda is equipped for expression and purification of heterologous proteins in microbial and mammalian cells (CHO; HEK) for therapeutic and non-therapeutic proteins with process development and scale-up at 2 L and 5 L bioreactors. The cell line development is supported by analytical and assay biology departments for evaluation of critical qualities, enhancing the early development of cell substrates for biosimilars and other biologics.

Process development area has separate labs for handling different activities with clean room for cell line development and upstream processes in a GLP and GMP compliance ways.

**Cell Line Development**

**Process Development**




# Cell line Development

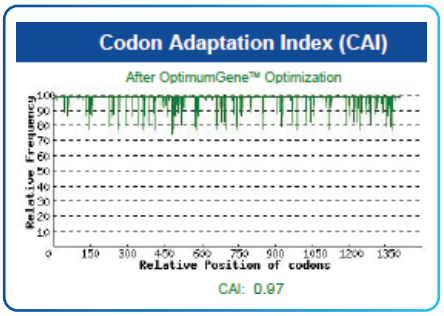
Microbial and Mammalian Cell Lines

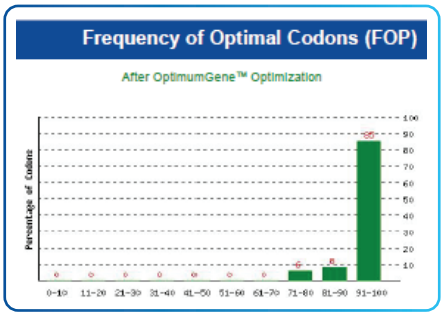
Microbial

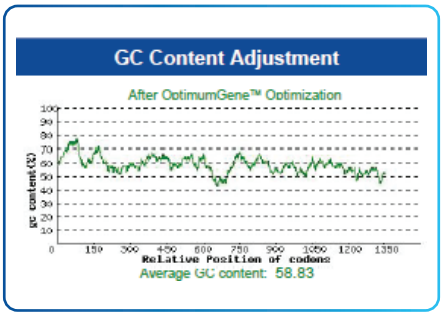
- Cloning and expression of recombinant heterologous proteins
- Protein expression optimization (media, feed, inducer conc., induction time)
- Protein purification and characterization by SDS-PAGE and Western blotting
- Host cell characterization (Purity, strain identification and plasmid copy numbers

Mammalian

- Cloning, expression and purification of recombinant heterologous proteins
- Cell line development for biosimilars and biologics
- Protein purification process development
- RCB preparation and characterization (purity, sterility and stability)



### Stable Pool Creation

- Vector Design
- Host Selection
- Stable Transfection

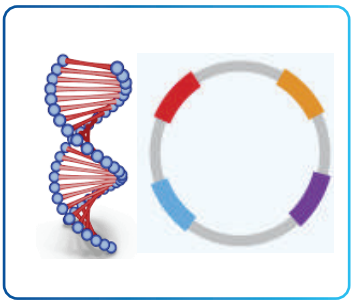
### Single Cell Cloning

- Single Cell Isolation
- RCB

### Growth & Expansion

- Static / Fed-batch Expansion
- Cell Banking

### Banking of Top Clones

# Process Development

Mammalian

### Process development & Optimization (10/30/500 mL)

- Bioreactor suitability
- Media/feed screening
- Feeding strategy
- Process parameters
- (pH, temperature, dO2, dCO2, pressure, agitation)

### Process scale-up at 2L /5L scale

- Feeding strategies
- Aeration strategies
- PH
- Material generation

### Harvest clarification

- Centrifugation
- Filtration

### Centrifugation Filtration

- Affinity chromatography
- Ion-exchange chromatography
- Size exclusion chromatography
- Hydrophobic interaction chromatography
- Filtration
- Concentration

### Cell Line / Clone Selection

- Protein sequence verification
- Sequence variants characterization
- Post-translational modification (PTM) analysis
- Glycosylation analysis
- de novo sequencing

### Upstream

- Harvest titers
- Identity
- Purity
- Glycosylation analysis
- Post-translational modification analysis

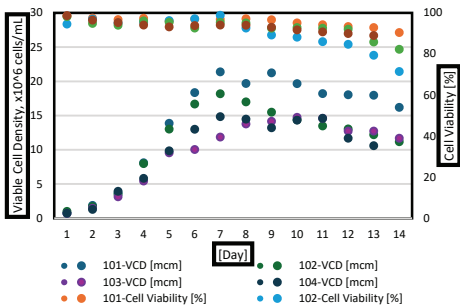
### Downstream

- Size and charge variants
- Refolding efficiency
- Identity
- Purity
- Heterogeneity
- Impurity characterization
- N-/O-glycans
- Residuals
- Potency

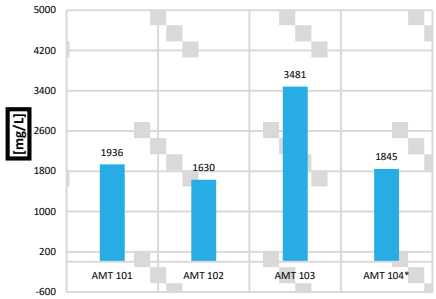
# In-house Development Data

Monoclonal Antibodies

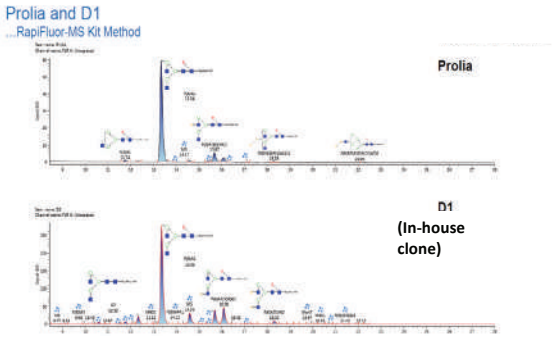
### Growth Profiles of in-house mAb Clones in 2L Bioreactor Studies



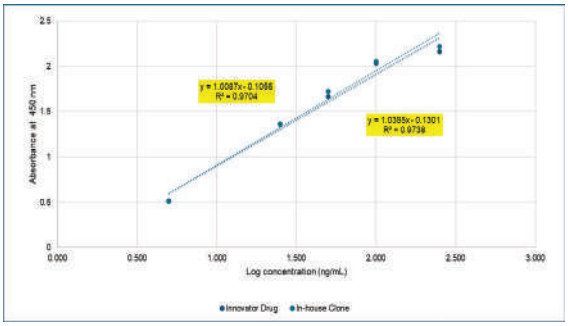

### Productivity of in-house mAb Clones in 2L Bioreactor Studies




### Glycosylation profile of innovator and in-house clone




### Ligand binding evaluation




# State-of-the-Art Process Technologies

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