Althea introduces a new, state-of-the-art prefilled syringe line. We can provide batch sizes from 100 to over 100,000 syringes for all phases of clinical development through commercial launch and supply. Our product development scientists and regulatory team work with our customers to create a smooth transition from vials to syringes, if needed, evaluating possible interactions between the product, silicone oils, piston and syringe.

**Manufacturing Capacity**
- Line speeds up to 13,000/hour
- Batch sizes over 100,000 syringes
- Syringe sizes of 0.5 to 20 mL
- Commercial capacity: 30+ million units annually
- Clinical batches
- Stability and registration batches
- Labeling and packaging

**Technical Capabilities**
- Peristaltic and rotary piston pumping systems
- Non-destructive, in-process weight checks
- Real-time fill volume measurement and recording
- Vacuum filling
- Vacuum and mechanical piston placement
- Nitrogen overlay
- Restricted Access Barrier System (RABS)
- Continuous environmental monitoring

**Complementary Services**
- Syringe force testing
  - Break away
  - Gliding
- Protein aggregation analysis
- Analytical methods
  - Development
  - Transfer
- Protein Characterization
- Formulation Development
  - Liquid
  - Lyophilized
- Stability Testing
Althea’s Product Development Services

Stability Testing and Formulation Development

Stability Testing and Storage
- ICH compliant protocols
- Method transfer and optimization
- Long-term stability studies
- Accelerated stability studies
- ICH storage conditions

Formulation Development
- Solution formulations
- Lyophilized formulations
- Lyophilization cycle development
- Sustained release formulations
- High concentration formulations

PD and Scale-Up
- Strain selection and development
- Fermentation optimization
- Product recovery
- Yield optimization
- Downstream process optimization

cGMP Manufacturing
- 30L, 100L (x2), 1000L fermentors
- microfluidizer
- Delta V system with Finesse TrueBio
- Homogenizers
- 1,000L single use mixer
- Continuous centrifuge
- 75 LPM TFF System
- 1, 3, 6, 10, and 25 mm Chromatography

cGMP Protein & Plasmid Production

Manufacturing Capacity
- Line speeds up to 13,000/hour
- Batch sizes over 100,000 syringes
- Syringe sizes of 0.5 to 20 mL
- Commercial capacity:
  - 30+ million units annually
  - Clinical batches
  - Stability and registration batches
  - Labeling and packaging

Technical Capabilities
- Peristaltic and rotary piston pumping systems
- Non-destructive, in-process weight checks
- Real-time fill volume measurement and recording
- Vacuum filling
- Vacuum and mechanical piston placement
- Nitrogen overlay
- Restricted Access Barrier System (RABS)
- Continuous environmental monitoring

cGMP Syringe Filling

Capacity and Dosage Forms
- Parenteral products
- Lyophilized products
- Viscous products
- Suspension products
- Complex formulations
  - Liposomes
  - Adjuvants
  - Crystallized proteins
- Clinical batches from 100 to 30,000+
- Commercial batches > 100,000
- Vial sizes from 0.5 mL to 100 mL

Technical Capabilities
- Complex formulation processes
- Peristaltic & rotary piston pumping
- Nitrogen overlay
- High speed vial labeling
- Continuous environmental monitoring

cGMP Vial Filling

Product Development

Protein Analytic Capabilities
- Method development
  - Qualification
  - Validation
- Product characterization
- Reference standard qualification
- Comparability studies
- Stability indicating assays
- Product release testing

Protein Analytical Tools
- Primary structure analysis
- Secondary & tertiary structure analysis
- Carbohydrate analysis
- Immunohistochemistry
- Purity profiles, variant purification & identification
- Aggregation analysis
- Conjugated protein analysis
- Particulate analysis