

## Checklist for Cost of Goods Calculations

### Production Levels

- Expression levels
- Working volume
- Harvest losses
- Purification yields

### Manufacturing costs

- Upstream Bioreactor
  - Time in plant
  - Raw materials
  - Components
  - Equipment
  - Labor
  - Overhead
  - Sample testing
  - Waste disposal
  - Success rate
- Downstream Purification
  - Time in plant
  - Raw materials
  - Components
  - Equipment
  - Labor
  - Overhead
  - Resin cycling
  - Sample testing
  - Waste disposal
  - Success rate
- Fill and Finish
  - Line size
  - # of batches
  - Sample testing
  - Success rate



Manufacturing costs are based on:

- Direct costs – labor, materials
- Indirect costs – labor, materials
- Facility overhead
- Bioreactor size
- Opportunity costs – excess capacity
- Amortized capital expense for facility and equipment

Manufacturing costs can be further refined based on:

- Product demand
- Dose requirements
- Vial size
- Single versus multi-dose vials
- Amount per vial
- Concentration of drug product
- Overage per vial
- Wastage per vial
- Liquid v lyophilized
- Shelf life of product
- Route of delivery
- Bioavailability

Contract manufacturing negotiating points:

- Long term “take or pay” commitment
- Use of secondary or back-up manufacturer
- Scheduling
- Campaigning
- Minimum/maximum requirements
- Flexibility
- Allowed adjustments to demand forecast
- Price per batch v Price per gram/unit
- Competitive price quotes

See also: [Determining the Cost of Manufacturing a Biologic Product](#)