

## Biotech 2E: Manufacturing Technology: Formulation, Filling, Packaging

| <u>Topic</u>  | <u>Typical Activity</u>                                       |
|---|---|
| Formulation/Fill  | Formulate a bulk<br>Aseptic filling<br>GMP regulations        |
| Drug Delivery   |   |
| Lyophilization  | Critical Steps/Off site tour<br>Analysis of melt back samples |
| Packaging/Labeling  | Tour  |
| Role of FDA in Facility and<br>Product License Inspection | FDA Audit   |