3.04 Producing a Pharmaceutical or Biopharmaceutical  
Handout for PowerPoint

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<th>Process development</th>
<th>Description</th>
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</table>
| **Synthesis**       | -Preparing the materials  
                     -Mixing and measuring chemicals and reagents |                           |
| **Purification**    | -Separating the desired product from the residue or by-product  
                     -End result, bulk product |                           |
| **Formulation**     | -Solid  
                     -Liquid  
                     -Gel  
                     -Cream  
                     -Aerosol  
                     -Mixes the active ingredient with other substances needed in the final form |                           |
| **Final dosage form preparation** | -Formulated preparation is made into its final form and placed into containers  
Container are labeled and packaged |                           |

**Quality**

| Quality control | Employees sample and test both the raw materials and the product during many stages of the manufacturing process |                           |
| Quality assurance | Ensures product quality by setting up and checking Standard Operating Procedures (SOP) |                           |

**5 Rules of Quality**

1- Understand customer needs  
2- Say what you do  
   (write down procedures)  
3- Do what you say(follow Procedures)  
4- Prove it (keep records)  
5- Improve it
3.04 Prototype Assessment Items

Note: These items illustrate the types of items used in the item bank for this objective. All items have been written to match the cognitive process of the understand verb in the objective. Questions require students to interpret, summarize or explain concepts of biotechnology research and development. These exact questions will not be used on the secured test, but questions in similar formats will be used.

These assessment items may be used as prototypes by teachers and students to generate similar items to comprise formative assessments for your classroom. This strategy is especially helpful during the field test year when classroom item banks are not available. Results of formative assessment should be used to diagnose levels of mastery, determine if re-teaching is needed, and guide further instruction.

1. A research biotechnologist is able to decrease the likelihood of an epidemic among herd animals. This is an example of which application of biotechnology?
   a. Agricultural application
   b. Chemical application
   c. Environmental application
   d. Medical application
   Answer: A

2. Research East is developing a new treatment for hypercholesterolemia. There are 270 participants in the trials. What type of study are these participants engaged in?
   a. Adverse reactions
   b. Confirmation
   c. Laboratory
   d. Safety
   Answer: D