

Introduction to GMP Training – Card Sort

Teacher Key

Principle 1: Bob looks up the Standard Operating Procedure (SOP) document that describes how to properly operate the spectrophotometer.

Sewite writes a Standard Operating Procedure for using the new shaker/incubator.

Principle 2: Jalisa carefully carries out each step of the Standard Operating Procedure (SOP) for inoculating a liquid culture of bacteria.

Carlos carefully carries out each step of the Standard Operating Procedure (SOP) for using the shaker/incubator.

Principle 3: Jose writes down all of the details regarding the batch of LB (Lysogeny broth) he created in a batch record document that he signs and dates.

Jennifer finishes checking the viability of a scaled-up bacterial culture. She fills out the appropriate parts of the Upstream Process Report Batch Record and signs and dates the sections of the report she has filled out.

Principle 4: Michelle stores the batch reports from each bacterial production run in the appropriate files. This documentation demonstrates that bacterial culture is done the same way every time and that the bacterial cell line produces RFP consistently in every batch.

Junji uses the new shaker/incubator to grow multiple batches of RFP+ bacteria. He records data about each batch to verify that the new equipment works properly every time. Once he has documented that the equipment functions properly and reliably, the equipment can be used by the upstream process team.

Principle 5: The Proteins R Us company designed their new manufacturing plant so that all of the air coming into the manufacturing clean rooms is filtered for sterility.

The MegaPharma Company has installed low pore size filters on all water lines that come into their clean rooms to be sure that all water used in their biomanufacturing processes is sterile.

Principle 6: Asako and Dante carefully conduct maintenance on all equipment used in the clean rooms.

Sheila and Rosa carefully sanitize all clean room surfaces – floors, ceiling, walls, benchtops.

Principle 7: Rubin gets comprehensive training for his job as a production manager before beginning work at Proteins R Us.

Keiko and Amir have finished their aseptic technique training at Proteins R Us. Before being cleared to work in the clean room, they must demonstrate their ability to perform aseptic technique properly.

Principle 8: Jackie follows proper gowning procedures before beginning work in the clean room in order to minimize any contamination coming from herself or her clothing.

George washes his hands before gowning up to begin work in the clean room.

Principle 9: Shari tests all raw materials before releasing them for use in the biomanufacturing process.

Alberto and Yuri test the purity of the protein product they are manufacturing after every phase of the downstream purification process.

Principle 10: Hiro inspects all documentation at Proteins R Us every six months. Ruby verifies that all regulations are being followed in the manufacturing plant.

Muhammed inspects all spectrophotometers every 2 months to verify that they are performing properly.