

Question 4c:
Does the FDA agree with the
process phases and batches
for the Comparability Study?

| Process Phase | Number of DP Batches | Use | Comments |
|---------------|----------------------|---------------|--|
| (b) (4) | (b) (4) | Clinical | Representative of the original manufacturing process |
| (b) (4)-PPQ1 | | Original BLA | Assessment of the changes from (b) (4) through PPQ1 was performed and documented in Appendix G (QAR-013.01) of the meeting package |
| Post-PPQ1 | | Late clinical | DP manufactured with the most recent process improvements prior to commercialization |
| PPQ2 | | Commercial | |