

Clarification on the Qualification of Manufacturing Sites

Each Manufacturing Site:

1. Will undergo a manufacturing site visit.
2. Will provide the completed batch records to the CMC Monitoring Committee (for review and approval) of three (3) batches of islets using the process defined in the CIT Master Production Batch record. These three lots;
 1. Must be produced using the Serva enzyme
 2. Must be produced using either the Protide or Mediatech solutions
 3. Must have a minimum yield of 250,000 IEQs for a research grade pancreas and 300,000 IEQs for a clinical grade pancreas post culture that meet product release criteria
3. Will receive a notification letter from the NIH Project Manager informing the sites “Effective (**insert date**) transplants for the CIT protocols may begin.”