Observation 1:

Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

Specifically, your firm's large batch media fill consists of (b) (4) vials however your firm routinely produces sterile (b) (4) drug products with batch sizes greater than (b) (4). Examples include but are not limited to the following:

- (b) (4) (lidocaine) which has a batch volume of (b) (4) and is packaged in (b) (4) 10 ml vials
- Methylcobalamin 1000 MCG/ML which has a batch volume of (b) (4) and is packaged in (b) (4) 10 ml vials

Observation 2:

Hazardous drugs were produced without providing adequate containment, segregation, and/or cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination.

Specifically, hormone and non-hormone drug products are prepared and processed in the same rooms (sterile prep area & clean room) using the same equipment (b) (4) & LAFH). Also, there are no change over cleaning procedures in place to prevent cross-contamination.