Summary - Equipment Cleaning Validation for Active Pharmaceutical Ingredients

A Cleaning Evaluation should be conducted, documented, and approved by the Site Quality Team & Production Team. This evaluation may be a single report or several reports and may be equipment centric or process centric and document or reference the required information. The purpose of this documentation is to justify the decisions made in developing the cleaning validation protocols. This evaluation should determine or consider for each equipment unit:

- Solubility of residues in cleaning agents (including cleaning and rinse solvents);
- Cleaning parameters and applicable ranges (e.g., concentrations, temperatures, times);
- Cleaning method (e.g., sprayball, flooding, power hosing);
- Extent of equipment disassembly;
- Potential for degradation by-products or conversion products;
- Stability of material(s) being cleaned under the proposed cleaning conditions; equipment;
- If equipment grouping is used, cleaning validation should be performed equipment within a group.

Selection of The Most Difficult To Clean Product or Process requires consideration

- Solubility of residues in cleaning agents (including cleaning and rinse solvents); cleaning operations;
- The Residue Acceptability Limit (RAL) required for cleaning;
- Cleaning history.

Rinsate Method - if a rinsate method is used as the sampling method, a measured calculated for each therapeutic product including clinical products (where dose
If a worst case limit is used for equipment producing multiple compound types (e.g.,