Summary - Non-Sterile API Manufacturing Area Environmental Control

For each API product, a risk-based assessment of environmental control requirements should be performed, documented, and approved by the Site Quality and Production Teams.

The risk assessment may be conducted on a product or facility-centric basis. This risk assessment should include consideration of at least the following:

- Type of API manufactured (e.g., small molecule API via chemical synthesis or classical fermentation);
- For APIs produced by chemical synthesis or classical fermentation, the risk assessment should be conducted to include the step where the API molecule is formed and on each of the subsequent step(s) of manufacture, including an evaluation on whether or not there is further purification of the API;

Final API steps include where the API molecule is formed and any subsequent manufacturing steps where there is no further purification of the API. The environmental control strategy for these areas should include consideration of the following:

- Design of the applicable API areas to meet the criteria for the drug product manufacturing area where the API is first exposed in drug product manufacturing [e.g., design of these API areas to meet the comparable ISO 14644 Non-Viable Particulate levels];
- Temperature and humidity requirements, where specified for the product;
- Potential for microbial contamination from the environment, if critical to product quality;
- Pressure Differentials between adjacent areas to avoid contamination of the API product;

Read More