

Summary - Clean/Pure Steam System Commissioning and Qualification Sampling Plans

This document recommends sampling locations, frequencies, and testing activities associated with the commissioning and qualification of new installations or major revisions of Clean /Pure Steam Systems (e.g. the addition of new subloops or other system wide retrofitting).

Clean Steam is defined to be steam that does not contain any additives (e.g., boiler additives), is used where the steam and/or condensate have direct contact with product, and the steam condensate meets USP/EP WFI requirements. In addition, clean steam that is used for sterilization applications of “porous loads” for international manufacturing also should meet the requirements of European Standard EN 285. The USP states that “Pure Steam [Clean] is prepared from suitably pre-treated source water analogously to either the pre-treatment used for Purified Water or Water for Injection”.

Qualification is an adjunct to commissioning and serves to provide documented evidence with oversight by Quality Assurance personnel that a clean steam system will consistently produce the appropriate quality of steam to end users in accordance with regulatory expectations.

A Clean Steam quality attribute may be defined as critical based upon the need to meet specific quality requirements where the quality is not enhanced further by additional downstream operating steps. For example, conductivity is a critical attribute that is measured at the outlet of a Clean Steam Generation System (e.g., condensate outlet of the clean steam generator) for verifying the results meet necessary steam quality requirements. Sampling the conductivity at this point would occur both during commissioning and qualification activities. For details regarding the design of a condensate collection apparatus for testing, refer to European Standard EN 285 – Sterilization-Steam Sterilizers – Large Sterilizers.

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