

101g Implementation of 3 Consecutive Continuous Reactions in the Pilot Plant for Gmp Production of Api

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A three stage continuous reactor system has been scaled-up for use in the pilot plant to produce an Active Pharmaceutical Ingredient (API) under GMP conditions. The three continuous stages include two liquid-liquid phase reactions (one plug flow and one stirred tank) and a gas-liquid oxidation reaction (trickle bed reactor). The pilot plant implementation includes numbering up of the lab oxidation reactor. In-line IR monitoring was used to expedite startup of two metered feed streams. Steady-state operation was demonstrated for over 72 hours. Advantages of continuous operation in terms of safety, quality and economics will be evaluated. Equipment selection, process layout and utility requirements will also be examined. The process proved to be robust with respect to planned and unplanned process changes. Knowledge gained from the first implementation was applied to two subsequent implementations with several modest alterations yielding improved performance. Further scale-up and optimization will be discussed.