Control Strategy for Vaccine

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Control strategy is applied to assure the vaccine product quality and to ensure that the vaccine is manufactured to meet the expectations defined in the quality targeted product profile (QTPP). It reflects the level of process understanding of the critical quality attributes (CQAs) and how the critical process parameters (CPPs) and material attributes influence these CQAs and should be controlled. The strategy covers characterization of vaccine antigen and final product during development, establishment of scientifically sound specifications of the vaccine antigen, intermediates, and vaccine products, raw material control, manufacturing process validation, in process control and stability studies. Characterization data includes physico-chemical properties, biological activity, immunological properties, microbiological properties, purity and impurities of both antigen and the final product. Specifications are established to confirm antigen and vaccine product quality; they include the list of tests, analytical procedures, references of analytical procedures, and appropriate acceptance criteria. Specifications are linked to the entire development and manufacturing process, preclinical and clinical studies, stability study data, and analytical procedures. In-process monitoring and testing are performed at critical decision making process steps and at other steps where data is used to confirm consistency of the process during production of either the vaccine antigen or the final product. They are linked to the critical process parameters and the acceptable limits should be appropriately defined. Raw materials including cells, seeds, excipients, other biological materials, and chromatography resin should be controlled. Manufacturing processes should be validated to ensure process robustness to produce consistent product quality. Stability studies shall be executed as a part of the overall control strategy.

Keywords (5 keywords): Control strategy; Vaccine; Critical quality attributes; Critical process parameters; Quality targeted product profile (QTPP).
The related SDG (Optional): None