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Process validation and critical regulatory requirements in manufacturing of inactivated veterinary vaccines

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Process validation is the most critical regulatory requirement for licensed biopharmaceuticals and vaccine facilities. It is also considered as an economic issue through understanding and controlling any process and subsequently minimizing the processes failures. The Process Design (PD), Process Qualification (PQ) and continued Process Verification (PV) are the main three stages for an industry for process validation. It was defined as the collection and evaluation of data, from the process design stage throughout production, to establish a scientific evidence that a process is consistently delivering high-quality products and in accordance with the principles of Good Manufacturing Practice (GMP). The challenges of vaccine production process are not limited to its complicated details which may change the validity of the process but also the cross-process that still the biggest challenge. Therefore, process validation in biopharmaceutical industries has the high priority especially vaccine production. In conclusion, continuous monitoring and validation of inactivated veterinary vaccines have the great impact on defects, nonconformance decreasing and processes improvement. Also, the critical parameters of process validation of inactivated veterinary vaccine manufacturing are highlighted.

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