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Upgradation of Punjab veterinary vaccine institute, Ludhiana as per GMP norms

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Punjab Veterinary Vaccine Institute, Ludhiana is an integral part of Department of Animal Husbandry, Government of Punjab which was established in 1973 at Ludhiana. The institute has the distinction to supply veterinary vaccines and diagnostic products throughout the state of Punjab as well as other states of India. Considering the regulatory guidelines of WHO and Drug Controller of India, Punjab Veterinary Vaccine Institute is proposed to be upgraded to meet the requirements of GMP. The department decided to establish three wings of Vaccine Institute, (I) Animal House, (II) Bacterial vaccine Production Wing, (III) Quality Control Laboratory, on the lines of GMP requirements for quality vaccines. All maps were developed in respect of shell structure, partitions within the cell structure, keeping in mind classification of clean room, material and manpower movement, temperature, AHU zoning, supply and return air as well as other parameters required to meet GMP norms. As per schedule M, which basically relates to the premises, quality control and production areas are developed independently of each other. Testing of Veterinary Vaccines includes physicochemical, biological and microbiological analysis for which separate laboratories have been established. Quality control is a crucial part of GMP practices that involves taking of samples during the process of vaccine/antigen production. The present map design has been developed keeping in mind the further expansion of production as well as testing of bacterial and viral veterinary vaccines and different diagnostic products.

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Readiness for regulatory inspection and audits

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It is very usual and common for any pharmaceutical industry to get regulatory inspections may be in manufacturing or in a CRO. Regulatory inspections guide us to make our systems more robust and the presented talk will discuss about: Inspections of majorly two types: (1) Triggered by projects submitted majorly from USFDA, EU/ UKMHRA, WHO, and (2) To assess the system and facility which is been applied for the facility approval to conduct the trials and analysis. For example: ANVISA, MOH Turkey, DCGI. Key problems extracted from various warning letter issued in bio-analytical investigators from where the problems can be anticipated in our labs too. Importance of having corrective and preventive actions so that there are no discrepancies in industrial scenario. For example, Falsified laboratory records with respect to employee time/date records that are inconsistent and/or falsified; Analytical Procedure (AP) raw data sheets; Manipulation of samples - FDA has determined that a firm manipulated test samples in order to meet predetermined acceptance criteria. How we can modulate our routine practice to be prepared for the inspections without any hiccups and last minute rush. Need for maintenance of all calibration and qualification records, access control records, attendance of staff. Any deviations occurred should be addressed properly. Focus on routine activities to bring the system and facility in line to regulatory requirements so that we can bring down the non-compliances drastically. Gap analysis, and RACI/ 6 Sigma like tools, Regular IQA focus on the closure of the same. System department to more focus on SOP, Protocol compliance.

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