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VMC 607: VACCINOLOGY

TOPIC: SEED LOT SYSTEM

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What is seedlot system

Definition : ***A system according to which successive batches of product are prepared using the same master seed lot.***

- Master seed lot:
  - A collection of aliquots of vaccine strain microorganism which has been cultured, distributed into containers and lyophilised in a single operation and stored in such manner as to ensure uniformity and stability.
  - It shall be assigned a specific code for identification purposes.
  - It shall have been shown that upon parenteral administration , the Master seed lot is safe and able to confer immunity/protection for a duration.

- Production of biological medicinal products obtained by microbial culture, cell culture or propagation in embryos and animals should be based on a system of master and working seed lots and/or cell banks.

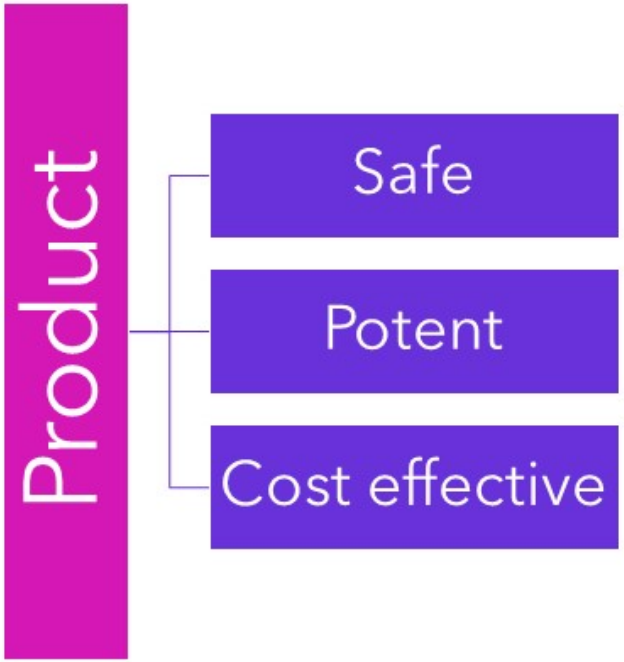
Importance of seed lot system

- To prevent the unwanted drift of properties which might ensue from repeated subcultures or multiple generations

Importance of seed lot system

1. Safe, Pure and effective products
2. valid QC test
3. compliance with cGMP
4. Continuous production
5. Good R&Ds
6. Security

Importance of seed



Principles of Seed Lot System (I)

- Manufacture of vaccine is based on a system of master and working seed lots and cell banks.
- Seed lots /cell banks are established in a suitably controlled environment
  - to protect the seed lot or the cell bank
  - to protect the personnel working with it.
- Seed lots and cell banks are characterized according to statutory guidelines
- Maintained to minimize the risks of contamination or alteration

Principles of Seed Lot System(II)

- Stability of seed lots has to be documented, including the efficiency of recovery.
- Prepared seed lot must be distributed in ampules to avoid change in characteristics of the vaccine strain and be a pathogen free, then lyophilized, to be valid for use in vaccine preparations.
  - Storage containers (hermetically sealed) are appropriate to their function clearly labeled (Barcode) , and kept at a suitable temperature.
- Storage temperatures are properly monitored.
- Deviations from set limits and any corrective actions are evaluated and documented.

Principles of Seed Lot System (III)

- Only authorized personnel under the supervision of a responsible person should handle seed lots and cell banks.
- An inventory should meticulously kept.
- A system is in place to ensure security and retrievability of seed lot or cell bank vials, without confusion or cross-contamination.
- All vials of master or working cell banks that removed from storage, are not returned.

Necessity of Seed Lot System

- Manufacturers should describe:
  - Type of banking system used.
  - Size of the cell bank
  - Container
  - Preparation
  - Storage

- 2. Manufacturers should describe their cell banking procedures.
- 3. Manufacturers should describe the procedures used to avoid microbial contamination and cross contamination by other cell types present in the laboratory. documentation system, labelling system, storage and recovery from storage (FIMS).

Principles of Seed Characterization

- Historical Record
- Identity Test
- Purity Test
- Safety Test
- Efficacy Test
- Stability Test

Kinds of Seed Banks

- Cell Bank
- Viral Bank
- Microbial bank
- Protozoal Bank

Cell Bank system

- The cell bank system consists of two tiers:
  - a master cell bank (Master cell bank established from single clone) (MCB
  - a working cell bank (WCB). should stored the MCB and WCB in two or more separate locations within the facility.
- To reduce the possibility of **phenotypic variations**, **genetic drift**, and **contamination** as much as possible, the number of passages should be minimized

Cell Bank characterization

- Identity Test
- Purity Test
- Safety Test
- Stability Test
- Tumorigenicity Test

Microbial Bank characterization

- Identity Test - morphological, cultural, biochemical, genetic and serological
- Purity Test
- Safety Test
- Stability Test

Viral Bank characterization

- Identity Test
- Purity Test
- Safety Test
- Stability Test

Facility For characterization of Seeds

- Building
- Cell culture lab
- Microbiological lab
- Immunological lab
- Molecular lab
- Animal facility
- Virological lab


Thanks