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DEPARTMENT OF BIOMEDICAL ENGINEERING

VII Semester

OBT357 BIOTECHNOLOGY IN HEALTH CARE

UNIT- 3 VACCINOLOGY

3.9 Instruments related to monitoring of environment.

This mainly refers to **ensuring safe storage, production, and transportation of vaccines**, since vaccines are very sensitive to environmental conditions.

1. **Temperature Monitoring (Cold Chain)**

- **Digital Data Loggers (DDL):** Record continuous storage temperatures of vaccines.
- **Thermometers (Min/Max Thermometers):** Monitor storage refrigerators/freezers.
- **Infrared Thermometers:** Quick surface temperature checks.
- **Freeze Indicators / Freeze Tags:** Detect accidental freezing during transport.

2. **Humidity Monitoring**

- **Hygrometers:** Measure humidity in storage areas.
- **Humidity Data Loggers:** Track and record humidity over time (important for freeze-dried vaccines).

3. **Air Quality & Sterility Monitoring (Production Areas)**

- **HEPA Filter Monitors:** Ensure sterile cleanroom air conditions.
- **Particle Counters:** Detect airborne particulate contamination.
- **Air Samplers (Microbial Air Samplers):** Monitor microbial contamination in vaccine production facilities.

4. Water Quality Monitoring (Used in Production & Cleaning)

- **pH Meter:** Check acidity/alkalinity of purified water.
- **Conductivity Meter:** Monitor ion concentration in water systems.
- **TOC (Total Organic Carbon) Analyzer:** Detect impurities in water used for vaccine production.

5. Air Quality and Microbial Monitoring Devices

In vaccine production facilities, maintaining a sterile environment is crucial to prevent contamination. Environmental monitoring programs focus on controlling airborne microbes and particulates.

- ✓ **Air Monitoring Devices**: These portable devices measure bacterial and viral loads in the air of vaccine production laboratories. They are used to detect airborne contaminants quantitatively, ensuring cleanroom standards are met.
  - **Example**: Blood agar Petri dishes exposed for a specified time to monitor airborne microbial levels, followed by incubation and bacterial counts.
- ✓ **Laminar Flow Cabinets and Filtered Air Systems**: These provide a controlled, sterile environment for vaccine production by supplying filtered air and maintaining low microbial levels. Regular fumigation (e.g., with formalin) and ultraviolet irradiation are used to disinfect these systems.
- ✓ **Mycoplasma Detection Kits**: Rapid qPCR kits (e.g., Microstart Mycoplasma AMP) detect mycoplasma contamination in vaccine production environments within hours, ensuring compliance with international guidelines.

6. Sterilization Monitoring

- **Autoclave Indicators (Biological & Chemical):** Verify sterilization of equipment.
- **Temperature/Pressure Recorders:** Track autoclave cycles.

7. Transport & Field Monitoring

- **Vaccine Vial Monitors (VVMs):** Heat-sensitive labels on vaccine vials that change color if exposed to excessive heat.

- **Portable Cold Chain Monitors:** For transport boxes, trucks, and field distribution.

8. IoT and Blockchain-Based Monitoring Systems

Advanced technologies like the Internet of Things (IoT) and blockchain are increasingly used for real-time, transparent, and secure monitoring of vaccine storage and transport conditions.

- ❒ **IoT-Based Systems**: These systems use wireless sensors to monitor temperature, humidity, and other parameters across the vaccine cold chain (from manufacturing to administration). They provide real-time data to centralized platforms, trigger instant alerts for deviations, and support remote access for monitoring.
    - **Example**: AKCP Vaccine Transport and Storage Monitoring solution tracks vaccines from factory to end-user, using NIST-calibrated sensors and cloud-based platforms like Pharma-Mon Server for data synchronization and compliance reporting.
- ❒ **Blockchain-Based Systems**: These ensure transparency and traceability by logging environmental data (e.g., temperature, humidity) on a secure, immutable ledger. Health professionals and regulators can verify the vaccine's storage history to ensure it has not been compromised.

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