

# INSPECTION OF MANUFACTURING UNITS

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**What is Inspection?**

# Inspection

- Examine
- Look at carefully
- Scrutinize
- Critically examine
- Officially



# Audit

- What is audit ?
  - Examination of account
- What is an account?
  - Maintenance of chronological record, capturing all aspects of activities



# When to Inspect?

# Types of Inspection

- Grant
- Renewal
- Statutory
- Investigation
  - NSQ
  - Complaint

# Process of Inspection

- Preparation
- Inspection activity
- Reporting

# Preparation for Inspection

- Planning for inspection
  - Surprise
  - Mutually agreed
- Know your customer
  - Activities of client
  - License details
  - Special information if any
- Attending to all issues





# Inspection Activity

- Pre inspection
- During inspection
- Break in inspection
- Closure of inspection

# Preparation of Report

- In consultation with the licensee
- Confidential

# Scheme of Inspection

- Schedule M – Assessment
- General Conditions: Emphasis on
  - Site Layout
  - Environmental
  - Water system
  - HVAC
  - Uniflow
  - Prevention of mix-up, contamination, cross-contamination

# Scheme of Inspection

- Evaluation of SOP's
  - Who, When, How prepared?
  - Relevance to activity
  - Revision procedures
  - Comparison with the earlier and existing one
  - Reasons for revision
- Sampling

# Scheme of Inspection

- Product release procedures/practices
- Critical evaluation of COA's
  - Test performed
  - Equipment available
  - Reference standards
- Quality Assurance

# Follow up Action

- Timely submission of report to higher ups
  - Specific w.r.t Rule/Section of law violated
  - Language
  - Vital documents to be enclosed
- SCN
- SPO's/Watch on activities
- Compliance verification
- Reporting
- Cancellation
- Watch on activities



Any Questions ??

Thanks for your attention 😊