Experience of GMP inspections by PMDA and general advices for manufactures

2018/8/27

PMDA

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Today's Topic

1. Observations and advices for the manufacturing sites in India.

2. Current activities of the observed inspection.

3. Site Master File Templat discussed at APAC meeting.

1.Observations and advices for the manufacturing sites in India.

- Cleaning Validation
- Data Integrity
- Document Control for paper-based system and computerized system.

Cleaning Validation

Manufacturing site (Finished products, API)

Multi-Line or Dedicated Line

Complexity of the Plant

- Non-dedicated equipment should be cleaned between production of different materials to prevent cross-contamination.
- Where equipment is assigned to continuous production or campaign production of successive batches of the same intermediate or API, equipment should be cleaned at appropriate intervals to prevent build -up and carry -over of contaminants.

Data Integrity

Data criticality

- Which decision does the data influence?
- What is the impact of the data to product quality or safety?

Data Integrity

Data risk

- Process complexity.
- Methods of generating, storing and retiring data and their ability to ensure data accuracy, legibility and indelibility.
- Process consistency and degree of automation/human interaction.
- Subjectivity of outcome /results
- The out come of a comparison between of electronic system data and manually recorded events could be indicative for malpractices

Document Control for paper-based systems

- How master documents and procedures are created, reviewed and approved for use.
- Generation, distribution, and control of template used to record data.
- Retrieve and disaster recovery processes regarding records.
- The process for generation of working copies of documents for routine use.
- Guidance for completion of paper based document, specifying how individual operators are identified, data entry formats and amendments to documents are recorded.
- How completed documents are routinely reviewed for accuracy, authenticity and completeness.
- Processes for the filing, retrieval, retention, archival and disposal of records.
- How data integrity is maintained throughout the lifecycle of the data.

Document Control for computerized systems

- Validation documentation/periodical evaluation
- System security/user access controls
- Audit trails for computerized system/new system or old system
- Storage, archival and disposal of electronic data

2.Current activities of Observed GMP Inspection

➢ Objective

The purpose of Observed GMP Inspection is to foster mutual confidence and build capacity in GMP inspection of pharmaceuticals in India and Japan.

➢ Procedure

- PMDA notifies CDSCO of the schedule of GMP inspection. CDSCO selects target inspections for Observed GMP Inspection and joints it as an observer.
- The inspector and observer can have discussions to exchange information of notable points on inspection for a better understanding of findings during break or after inspection.

3.Site Master File Template discussed at APAC meeting

- The Site Master File is prepared by the pharmaceutical manufacturer and should contain specific information about the quality management policies and activities of the site, the production and/or quality control of pharmaceutical manufacturing operations carried out at the named site and any closely integrated operations at adjacent and nearby building. If only part of a pharmaceutical operation is carried out on the site, a Site Master File needs only describe those operations, e.g. analysis, packaging, etc.
- When submitted to a regulatory authority, the Site Master File should provide clear information on the manufacturer's GMP related activities that can be useful in general supervision and in the efficient planning and undertaking of GMP inspections.

3.Site Master File Template discussed at APAC meeting

Site Master File Template

- The working team of MHLW and PMDA drafted and proposed this template.
- The draft was discussed at meeting of APAC(Asia Partnership Conference of Pharmaceutical Associations) and consensus on this draft was achieved on April 10th this year.
- The Asian regulatory Authorities of APAC such as Indonesia, South Korea, Taiwan and Thailand concluded to promote usage of this template.

3.Site Master File Template discussed at APAC meeting

- PMDA would like to promote usage of this template to prepare GMP inspections by manufacturing sites located in India.
- This template is available at PMDA's web site as follows.

http://www.pmda.go.jp/english/review-services/gmp-qms-gctp/gmp/0001.html

Thank you

http://www.pmda.go.jp/