MHRA GMP Inspection Deficiency Data Trend 2016

This summary was prepared by the Rx-360 Monitoring and Reporting Working Group which tracks regulatory, legislative and policy developments relevant to pharmaceutical/medical device supply chain integrity. The summary is not intended to serve as comprehensive and formal interpretation or guidance (and should not replace your own review and analysis of any referenced source documents). If you have questions, please contact Brittany Tobery, Rx-360 Secretariat, at 301-710-9399 or btobery@rx-360.org.

Introduction

The GMDP Inspectorate has improved the way of gathering the inspection deficiency data for 2016. The new data trending can allow industries to identify:

- The severities and frequencies by the EU GMP references
- The overall number of deficiencies by categories: Critical, Major, Other
- The high impact vs. high frequency issues

The purpose for publishing the inspection deficiency data is to allow industries to perform their own assessment against the deficiency findings as part of self-inspection and continuous improvement. It should be noted that the data set is for dosage forms only.

Top 10 Most cited deficiency groups 2016 and 2015

	2016	2015
Ranking	Groups	Groups
1	Quality System	Quality System
2	Sterility Assurance	Complaints and Recall
3	Production	Documentation
4	Complaints and Recall	Quality Control
5	Qualification/Validation	Computerised Systems
6	Premises & Equipment	Production
7	Computerised Systems	Premises & Equipment
8	Personnel	Validation
9	Documentation	Personnel
10	Quality Control	Materials Management

Deficiency examples

- Chapter 1
  - Investigations and CAPA implementation
  - Lack of management oversight
  - Product return
  - Change control
  - Product quality review
  - Regulatory monitoring
- Chapter 2
  - Training

Deficiency examples

- Chapter 3
  - Lack of contamination / cross contamination prevention
  - Deficiencies related to premises and equipment
  - Controlled temperature storage

- Chapter 4
  - Document control
  - Data integrity

Deficiency examples

- Chapter 5
  - Material management and controls
  - Inadequate control to prevent cross contamination
  - Production controls

- Chapter 6
  - General QC laboratory control
  - OOS/OOT investigations
  - Management of stability studies

Deficiency examples

- Chapter 7
  - Management of outsourced activities
  - Technical agreements
- Chapter 8
  - Complaint investigations
  - Product recall and mock recalls
- Chapter 9
  - Internal audit and self-inspection programs

Deficiency examples

- Annex 1
  - Increased risk of microbial contamination and failure to ensure sterility assurance
  - Media fills
- Annex 2
  - Risk and inadequate control of contamination
- Annex 3
  - Controls for cleaning, verification and validation
- Annex 6
  - Batch release and receipt & storage

Deficiency examples

- Annex 8
  - Sampling and receipt of packaging materials
- Annex 9
  - Production controls
- Annex 11
  - Data back-up
  - General control of computerized systems
- Annex 12
  - Control of dosimeter readings was deficient

Deficiency examples

- Annex 13
  - Product specification file (PSF)
- Annex 15
  - Validation and qualification
- Annex 16
  - Batch certification
  - Failure of the QP to fulfill their duties
- Annex 19
  - Retention samples

Thank you

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