MHRA GMP Symposium

Novotel London West, London
9 & 11 December 2015
Inspection trends and common deficiencies

Presented by: Vivian Rowland, GMDP Inspector
Presentation Outline

• Improvement in deficiency data trending

• The New Look Data Trend

• 2015 ‘High impact’ inspection findings

• Summary
Question Time
Improvement in deficiency data trending
Data Trending 2013

UK Inspections by Type

Overseas Inspections by Type

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<td>Quality management – product quality review</td>
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<td>Quality management – risk management</td>
<td>Warehousing and distribution activities - Lack of inventory control and segregation</td>
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<td>Self inspection</td>
<td>Warehousing and distribution activities - Records – receipt and distribution</td>
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<td>Investigation of anomalies</td>
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<td>Investigation of anomalies – CAPA</td>
<td>Starting material - API compliance with GMP</td>
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<td>Regulatory issues – non compliance with MIA</td>
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<td>Design and maintenance of equipment</td>
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<td>Sterility Assurance - Sterilisation</td>
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<td>Failure to respond to previous inspection findings</td>
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<td>Sterility Assurance - Process Design</td>
<td>Calibration of measuring and test equipment</td>
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<td>Sterility Assurance - Sterility Investigations</td>
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<td>Sampling procedures &amp; facilities – retention &amp; retest samples</td>
<td>Personnel issues – duties of key personnel</td>
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<td>Line clearance, segregation and potential for mix-ups</td>
<td>Starting material and packaging component testing</td>
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<td>Housekeeping – cleanliness and tidiness</td>
<td>Computerised systems – data manipulation</td>
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<td>Contamination, microbial – potential for contamination</td>
<td>Finished product testing - chemical</td>
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<td>Finished product testing - microbiological</td>
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<td>Finished product testing – ongoing stability monitoring</td>
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<td>In-process control and monitoring of production operations</td>
<td>Intermediate and bulk product testing</td>
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#GMDPevents
Changes following stakeholders discussions

Data changes:
- High impact vs high frequency issues
- All classifications (C, M, O)
- Example deficiencies, with context
- ‘Big data’ opportunities

Reporting and analysis:
- Sub-chapters of EU GMP Guide
- Low frequency-high impact and high frequency low impact issues
- CMT/ IAG/ Regulatory action
- Sector, geography, size
Benefits for Industries

Industries use:

• Organisational learning, self inspection, risk based resource allocation
The New Look Data Trend
New trending tool: example 1
New trending tool: example 1

Findings Annex 1 per Section

Number of findings

Total Critical:
Total Major:
Total Other:
2015 ‘High impact’ inspection findings
Deficiencies resulted in CMT Referrals

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Chapter 1 Principle, 1.1, 1.3, 1.4, 1.5, 1.6, 1.7, 1.8, 1.10
Chapter 2 Principle, 2.1, 2.2, 2.4, 2.10, 2.11
Chapter 4 Principle, 4.1, 4.2, 4.3, 4.6, 4.8, 4.12, 4.29
Chapter 5 Principle, 5.2, 5.8, 5.12, 5.13, 5.14, 5.15, 5.21
2015 ‘High impact’ inspection findings

Failing PQS
Risk based investigations and actions
Personnel knowledge / experience
Documentation issues
Deficiencies resulted in IAG Referrals

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Chapter 1 Principle, 1.4, 1.5, 1.8, 1.9, 1.10, 1.11, 1.12

Chapter 6: 6.27

Chapter 8 Principle, 8.9, 8.13, 8.15, 8.16
2015 ‘High impact’ inspection findings

Failing PQS
Mgmt oversight and resourcing – ICH Q10
Quality defect investigations and actions
Operational cross contamination controls

Failing PQS
Risk based investigations and actions
Personnel knowledge / experience
Documentation issues
Deficiencies resulted in IAG with SONC

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Chapter 1: 1.1, 1.4, 1.8
Chapter 6: 6.27
Chapter 8 Principle, 8.9, 8.13, 8.15, 8.16
2015 ‘High impact’ inspection findings

Serious PQS failure
On-going stability programme
Quality defects with public health impact
Data Integrity (basic ALCOA)

Failing PQS
Mgmt oversight and resourcing – ICH Q10
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Documentation issues

Common themes: increasing severity
Important notes

• Deficiencies not from the latest update in Chapters or Annexes, they are failures to be in compliance with basic GMP requirements, e.g.

  – Deficiencies related to DI from Chapter 4

  – Deficiencies related to Chapter 3 & 5 are due to lack of operational controls

  – Lots of IAG/CMT cases were due to the lack of management oversight from Chapter 1
Summary – What we have done

- Trending of all deficiency classifications including “Other” category

- Improved deficiency trending by breaking down into specific sub-chapter of the EU GMP Guide

- Reporting of low frequency-high impact and high frequency low impact issues rather than just frequency

- Set the framework to include data from other regulators to provide a ‘big data’ view in the future
Summary - How we hope this data will be used

• 2015 Trending data will be published in early 2016

• Look out for the Blog with links to GOV.UK to obtain the trend data

• Conduct analysis against the relevant chapters / annexes that are applicable to the organisation / site
New….but Exciting

KEEP CALM AND LET'S MAKE A NEW START
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