2015 - Achievements and challenges

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Assistant Secretary
Manufacturing Quality Branch
Overview

• 2015: Achievements and challenges
  • GMP clearances
  • Inspections performance data

• Looking ahead to 2016
  • Inspection close out process improvement
  • Rewarding consistent high levels of compliance
GMP clearance applications

To 23 October
What are we doing to reduce clearance times?

Improving our ability to meet demand

- OMQ restructure: aligning structure with function
- Improved application triaging
- Improved information management

Communication

- Updates on TGA website
- PDA presentations!
- TGA - Industry Working Group on Manufacturing Quality
GMP clearance processing times - median

<table>
<thead>
<tr>
<th>Date Range</th>
<th>Median</th>
<th>Number of Applications</th>
</tr>
</thead>
<tbody>
<tr>
<td>08-19 June</td>
<td>18.80</td>
<td>153</td>
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<tr>
<td>22-03 June-July</td>
<td>14.14</td>
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<td>06-17 July</td>
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<td>20-31 July</td>
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<td>31-11 August-Septembe</td>
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<td>28-09 Septembe</td>
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<td>12-23 October</td>
<td>4.86</td>
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GMP clearances

GMP clearance processing times - average

Average Weeks Till Completion

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What’s in store for 2016?

Helping sponsors understand their role

• GMP clearance application tool
• GMP clearance guideline revision

Reducing impact of poor quality applications

• Decisions will be made based on information provided by the sponsor in the application
Inspection performance

2014 - 15

• 92% of domestic initial inspections conducted within target timelines (3 months)

2015 – 16 to end October

• 94% of domestic reinspections (44/47) conducted within target timelines (6 months)
What’s in store for 2016?

Revised inspection close out process

• Objective:
  o Predictable inspection close out times for manufacturers who comply with requirements

• How:
  o No objective evidence required if acceptable CAPAs
  o Next inspection will include assessment of CAPAs
  o Limited rounds of additional information requests
What’s in store for 2016?

Rewarding consistent high levels of compliance.

- **Objective:**
  - Reduced regulatory burden for manufacturers with repeat A1 rating

- **How:**
  - 3 year reinspection frequency for A1 manufacturers of high risk products (currently 2 years)
  - Second and subsequent A1 ratings: reduced scope inspection
Questions?