THE QUICK GUIDE TO DATA INTEGRITY AND QUALITY METRIC GUIDANCES

February 2017
Siegfried Schmitt
OPENING REMARK

“In the inspection realm, we find too many, disturbing examples of firms providing us with false information, and doing so deliberately.

In order for those of us at FDA to do our jobs, we must receive accurate information from firms. Quality metrics based on false data are meaningless. An NDA or ANDA based on false information can be a danger to the public.

Fundamentally, data integrity is a corporate responsibility. There are other examples of corporate responsibility that our Office of Criminal Investigations has emphasized.”

Howard Sklamberg, Deputy Commissioner, Global Regulatory Operations and Policy, U.S. Food and Drug Administration, 2015 Annual Conference / Food and Drug Law Institute
### DATA INTEGRITY - US GUIDANCE DOCUMENTS

FDA Data Integrity and Compliance With CGMP Guidance for Industry (Draft), April 2016 tinyurl.com/htj4xff

<table>
<thead>
<tr>
<th></th>
<th>FY2013</th>
<th>FY2014</th>
<th>FY2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total WLs Issued</td>
<td>38</td>
<td>22</td>
<td>19</td>
</tr>
<tr>
<td>WLs citing data integrity</td>
<td>10 (26%)</td>
<td>1 (55%)</td>
<td>14 (74%)</td>
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<tr>
<td>US site WLs citing data integrity</td>
<td>0 / 13 (0%)</td>
<td>0 / 4 (0%)</td>
<td>1 / 3 (33%)</td>
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<td>OUS site WLs citing data integrity</td>
<td>10 / 25 (40%)</td>
<td>12 / 18 (67%)</td>
<td>13 / 16 (81%)</td>
</tr>
</tbody>
</table>

Data Integrity: Surveying The Current Regulatory Landscape, B. Unger 2016
DATA INTEGRITY - EU GUIDANCE DOCUMENTS

MHRA GxP Data Integrity Definitions and Guidance for Industry Draft version for consultation July 2016 tinyurl.com/jay8stc

MHRA blog tinyurl.com/nflj4kb

MHRA Position Statement and Guidance Electronic Health Records 16 September 15 tinyurl.com/h8e8ab3

EMA Questions and answers: Good manufacturing practice Data integrity tinyurl.com/znbvuga
DATA INTEGRITY - CFDA GUIDANCE DOCUMENTS

www.sda.gov.cn/WS01/CL0778/165110.html

Key Points for On-site Verification of Drug Clinical Trial Data published 10 November 2015
DATA INTEGRITY - WHO & PIC/S GUIDANCE DOCUMENTS

WHO Expert Committee on specifications for pharmaceutical preparations (Fiftieth report), WHO technical report series; no. 996, Annex 5, Guidance on good data and record management practices, May 2016 tinyurl.com/jmep977

PIC/S Good Practices for Data Management and Integrity in Regulated GMP/GDP Environments (Draft), PI 041-1 Guidance on Data Integrity, 10-Aug-2016 tinyurl.com/hlhc7n6
Elements of a Code of Conduct for Data Integrity in the Pharmaceutical Industry, February 2016
http://www.pda.org/CodeofConduct

The PDA Data Integrity Task Force
https://www.youtube.com/watch?v=DH3P1CeJDoU
DATA INTEGRITY - INDUSTRY ASSOCIATIONS DOCUMENTS

Assuring Data Integrity for Life Sciences

Edited by Siegfried Schmitt

Don’t miss your chance to win a copy!

tinyurl.com/h88mnxf
Special Report: Data Integrity - Here, Large and Not Going Away, Pharmaceutical Engineering, March-April 2016, Vol. 36, No. 2

Considerations for a Corporate Date Integrity Program, ISPE GAMP Community of Practice Concept Paper, 2016 tinyurl.com/grn5z68
GAMP® Data Integrity Special Interest Group

Core Team Leaders: Lorrie Schuessler, Mark Newton, Christopher White, Nigel Price and Charlie Wakeham

Sponsor: Michael Rutherford

ISPE GAMP Guide: Electronic Records and Data Integrity
QUALITY METRICS

FDA Submission of Quality Metrics Data Guidance for Industry, Revision 1, November 2016

Submission of Quality Metrics Data; Revised Draft Guidance for Industry; Extension of Comment Period

A Notice by the Food and Drug Administration on 01/09/2017

QUALITY METRICS

Open questions:

- Does FDA have the legal authority to request quality metrics?
- How should FDA implement the program?
- Product segmented by site or Site segmented by product?
- Optional Metrics?
- Should FDA share peer ranking?
- Metric reporting leading to more drug shortages?
ISPE Quality Metrics Initiative

Quality Metrics Pilot Program
Wave 2

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