THE QUICK GUIDE TO DATA INTEGRITY AND QUALITY METRIC GUIDANCES

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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.”

SOURCE: 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>
</tr>
<tr>
<td>US site WLs citing data integrity</td>
<td>0 / 13 (0%)</td>
<td>0 / 4 (0%)</td>
<td>1 / 3 (33%)</td>
</tr>
<tr>
<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
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 September 2015, tinyurl.com/h8e8ab3
- EMA Questions and answers: Good manufacturing practice Data integrity tinyurl.com/znbvuga

Key Points for On-site Verification of Drug Clinical Trial Data published November 2015
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, August 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
INDUSTRY ASSOCIATIONS DOCUMENTS

Assuring Data Integrity for Life Sciences

Don’t miss your chance to win a copy!

tinyurl.com/h88mnxf
Considerations for a Corporate Data Integrity Program
ISPE GAMP Community of Practice Concept Paper, 2016, tinyurl.com/grn5z68

Special Report: Data Integrity - Here, Large and Not Going Away
Pharmaceutical Engineering, March-April 2016, Vol. 36, No. 2
INDUSTRY ASSOCIATIONS DOCUMENTS

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

FEDERAL REGISTER
The Daily Journal of the United States Government

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

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?
1. How many companies are experiencing issues with the FDA metrics? What kind of issues?

2. Have they been inspected against the metrics guidance?

3. Have data integrity inspection questions been limited to the lab? If not, what else and what pieces of equipment?

4. Are companies having challenges finding suppliers that fully comply with the data integrity guidances that exist?
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THANK YOU