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Pharmaceutical Development Data Quality Assessment

THE SITUATION

While contemplating a knowledge management IT strategy for pharmaceutical development, a global pharmaceutical company wondered about the quality of its underlying data. Many of its systems had been implemented independently over numerous years and integration would be one key to the knowledge strategy. Mergers and acquisitions resulted in consolidation of data from many different sources. Data standards and governance applied to the systems was limited. Although the business was confident about its data quality, the system owners and IT expressed concern based on several proof-of-concept knowledge projects they had recently undertaken. They agreed that a data quality assessment might highlight systems and data issues that would need to be addressed before moving forward with more extensive knowledge management investments.

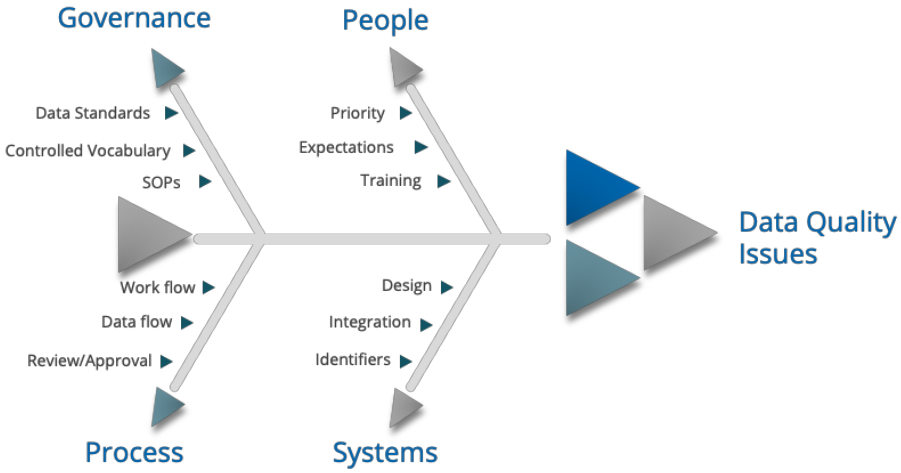
THE SOLUTION

The data quality analysis led by ResultWorks focused on key lab data systems including chromatography (CDS), LIMS, electronic lab notebook (ELN), and formulation systems. Where authoritative data sources were identified, those systems were used as references for the data analysis. The approach taken was to first analyze each data system independently. Then an analysis across systems was conducted inclusive of authoritative sources to determine the accuracy of the linkage among systems. The steps taken include:

1. Defined data objects / sources
2. Determined data quality criteria
3. Analyzed data quality by system
4. Analyzed data quality between systems
5. Assessed root causes of issues
6. Developed recommendations and strategy forward

> "This was exactly what the business needed. We have several other areas that could also use this same type of analysis."
>
> - Director of Data Services

Cause-effect diagrams like the graphic on the right were constructed to organize the issues.



A comprehensive analysis was developed which identified specific issues by stand-alone system and in relation to the other data systems and the authoritative sources. This analysis was presented to senior management along with a set of recommendations for a multi-year strategy to address critical issues and to improve the overall data system environment.

KEY BENEFITS

Data Defined: A list of key data objects was defined for each of the data systems which also showed links to authoritative sources as well as gaps in many cases.

Data Quality Baseline: The queries constructed and reports compiled established baselines for each of the systems which could be leveraged for periodic assessments of the data quality.

Strategy Created: The recommendations were shaped into a 3-year strategy roadmap to address the immediate data quality issues and data governance needs in year one. The next two years would then focus on integration and data access across the development organization.

For more information, visit our website www.resultworksllc.com or contact us at marketing@resultworksllc.com.