

Application of LINK for Automated Stability Studies

C. Merchant, Ph.D., D. Thomas

Introduction

Stability studies often involve a wide range of analysis techniques utilized across a broad range of time points and stress conditions. Transcribing, manipulating, and processing data from hundreds of analysis runs is very labor intensive. Recent advancements in 'big data' management and visualization have been applied to automate data extraction directly from analytical equipment measurement files, and automate the processing of this data for real-time stability study reporting.

Methods

Parsing scripts were written to automatically transcribe measurement data directly from equipment measurement files into a centralized database. Measurement data files were stored on networked folders, and the software was configured to import data into the database automatically at a fixed frequency. Sample information including time point, storage temperature, and stress condition were also parsed from each data file automatically from the file path or measurement comments field. Analysis templates (specific chart/table/image processing requests) were constructed, capable of updating in real-time with each data import. Finally, a reporting engine was constructed allowing for report export to pdf or spreadsheet file formats.

Sample data from Flow Microscopy (MFI), Light Obscuration (HIAC), and RMM (Archimedes) assigned storage time points of 0, 1, 3, 6, 9, 12, 18, 24, and 36 months at two different temperatures (25C, and 40C) were automatically imported to the LINK database. The following self-populating reports were constructed:

- Particle concentration vs. storage time broken out by storage temp for a single technology
- Particle concentration vs. storage time broken out by storage temp for all technologies
- Consideration of sub-populations based on morphological parameters (MFI)
- Consideration of sub-populations based on density assumptions (Archimedes)
- PDF report
- Excel-compatible spreadsheet file outputs

Results



Figure 1: HIAC vs. Time and Temperature



Figure 2: MFI vs. Time and Temperature



Figure 3: Archimedes vs. Time and Temperature



Figure 4: MFI Sub-Populations



Figure 5: Archimedes Sub-Populations



Figure 6: Multiple Technologies

Results



Figure 7: Multiple Technologies and Size Ranges

Conclusions

It was found that through application of the LINK data management and analysis tool, stability study summaries may be automatically produced and updated as data is generated by the requisite analytical equipment.

Significant time savings were realized through the use of the LINK software. After a one-time setup of the project and analysis template dashboards, new measurement data files from the different instruments were automatically imported and processed from networked PCs at a fixed frequency (e.g. nightly, weekly), with dashboard and report data automatically updated, delivering real-time analysis and trending of results. The automated data importation, processing, reporting, and export capabilities led to time savings in excess of 97%