



SmartLab™ Technical Brief

Customer Implementation: Bristol-Myers Squibb

Achieving a Paperless Laboratory for Long Term Stability Studies

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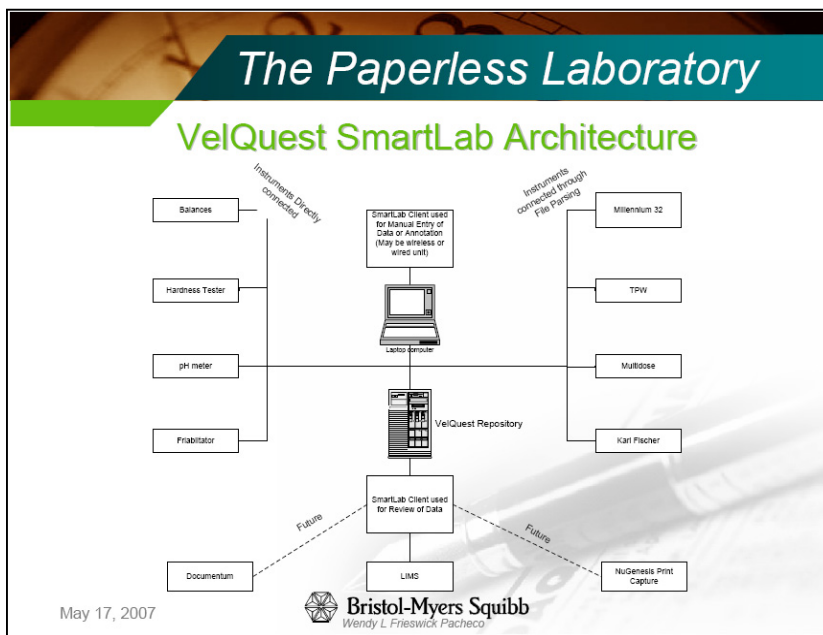
Abstract: Analytical Research and Development (AR&D) was challenged to bring in high-volume sample testing into a research organization while maintaining quality, timeliness and thorough data evaluation. Fast tracked NDA filings require quality data for the critical long term stability studies (LTSS) and process justification (PJ) testing while maintaining compliance excellence. In response to this challenge, the AR&D Stability group implemented the SmartLab™ paperless electronic procedure execution and compliance management system from VelQuest. The use of the SmartLab™ electronic notebook has significantly reduced the data management bottleneck on the AR&D Stability laboratory while simultaneously improving the integrity of the data.

In 2002, BMS decided to in-source analytical testing for key registrational stability studies. This capability provides a means to capture knowledge of the drug product’s performance, and define rugged analytical methods used to test those products for quality and safety. In addition, an internal testing capability facilitates quicker recognition of stability or method-related problems, which enables timely problem solving. Finally, in-sourcing of registrational stability testing provides substantial cost savings at a point when the future approval status of a product is not yet assured. For an analytical R&D lab of this type, the key challenges in bringing in “high volume” sample loads with a small dedicated workforce are large.

To meet the challenges, the Analytical Research and Development (AR&D) Stability group at BMS introduced automation technologies to overcome the resource constraints posed by a large stability testing workload, while allowing scientists sufficient time to carefully collect, review results and maintain a cGMP focus on quality and compliance.

One of the automation technologies is a paperless electronic method execution and compliance management system from VelQuest. This electronic notebook system provides consistent method execution, control of laboratory documentation, integrated data management, rapid data review and reduced compliance risk. By improving operational efficiencies, stability scientists can devote more time to value-added activities for these “fast-tracked” candidates.

Figure 1: All stability methods and lab instruments are integrated with SmartLab for automated data capture, documentation review and approval, and results transfer to LIMS.



Source: Proceedings of IMACS 2007, May 16, 2007, Princeton, NJ

Figure 2:

Benefits of a Paperless Lab

- Consistent stepwise method execution
- Control of laboratory documentation
- Direct electronic capture of instrument data
- Fast/Easy Storage and Retrieval of records
- Sample data pushed from LIMS to ELN
- Transfer results from ELN to LIMS
- Efficient workflow Flexibility

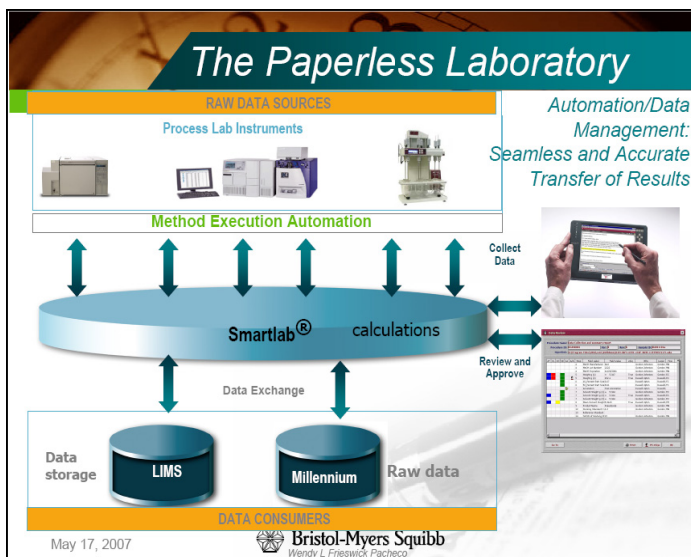


Figure 3:

Data entry: Time/Resource Savings

- Elimination of transcription errors and problems due to handwriting illegibility
- Elimination of errors through use of validated automatic calculations
- Significant impact on overall laboratory cycle times through reduced analyst administrative workload
- Provides additional capacity to the lab while maintaining existing headcount

The Paperless Laboratory

Approximate Time and Resource Savings for Data Entry with Electronic Notebook

| TEST | TIME | | |
|--------------------|-------------|---------------------|--------------------|
| | Paper Based | Electronic Notebook | % Resource Savings |
| Hardness | 20 Min. | 10 Min. | 50% |
| Appearance | 20 Min. | 10 Min. | 50% |
| Dissolution | 3 Hr. | 2 Hr. | 33% |
| Potency/Impurities | 2 Hr. | 1.5 Hr. | 25% |

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Figure 4:

Data review: Time/Resource Savings

- Electronic data review and approval improves operating efficiency
- Drastic reductions in data review cycle times means faster usage decisions
- Snapshot view of lead indicators in the lab

The Paperless Laboratory

Approximate Time and Resource Savings for Data Review with Electronic Notebook

| TEST | TIME | | |
|--------------------|-------------|---------------------|--------------------|
| | Paper Based | Electronic Notebook | % Resource Savings |
| Dissolution | 2 Hr. | 1 Hr. | 50% |
| Potency/Impurities | 2 Hr. | 1 Hr. | 50% |

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