

How E-WorkBook can Help Produce and Validate Regulatory Documentation in Just a Few Days

Dr. Paul Denny-Gouldson, Product Manager, IDBS, and Simon Beaulah, Head of Product Marketing, IDBS.

The Challenge

The challenge in generating regulatory documentation for many preclinical laboratories comes from validating the content of a report is accurate and no transcription errors have occurred. Report content can take days to prepare but validation can often take many weeks to conduct - because everything needs to be checked across different departments against different electronic and paper based systems. The IDBS E-WorkBook Suite is an

enterprise ELN designed to support data and IP capture and management for the entire preclinical development process. The solution enables data and information required for reports, method validation, INDs and NBEs to be stored in a consistent manner across all departments. Due to the good data management practices implemented in E-WorkBook, it is possible to define and populate reports with experimental results and reviews based

on Microsoft Word templates, which can be generated in mere hours. Furthermore, hyperlinks back to the data embedded in the report provide QA with a radically simplified process of validation. The user can simply click the hyperlink and follow the links back to the source data held in E-WorkBook. The result is a report fully prepared and validated in just days, not weeks.

Defining Report Templates in Microsoft Word

To generate a study or validation report, a template must first be defined in Microsoft Word, based on an appropriately approved FDA format or internal report template. Using a specific add-in (Figure 1), the report template builder tags areas in the Word Document template that relate back to the data in E-WorkBook from the experiments and departments of interest.

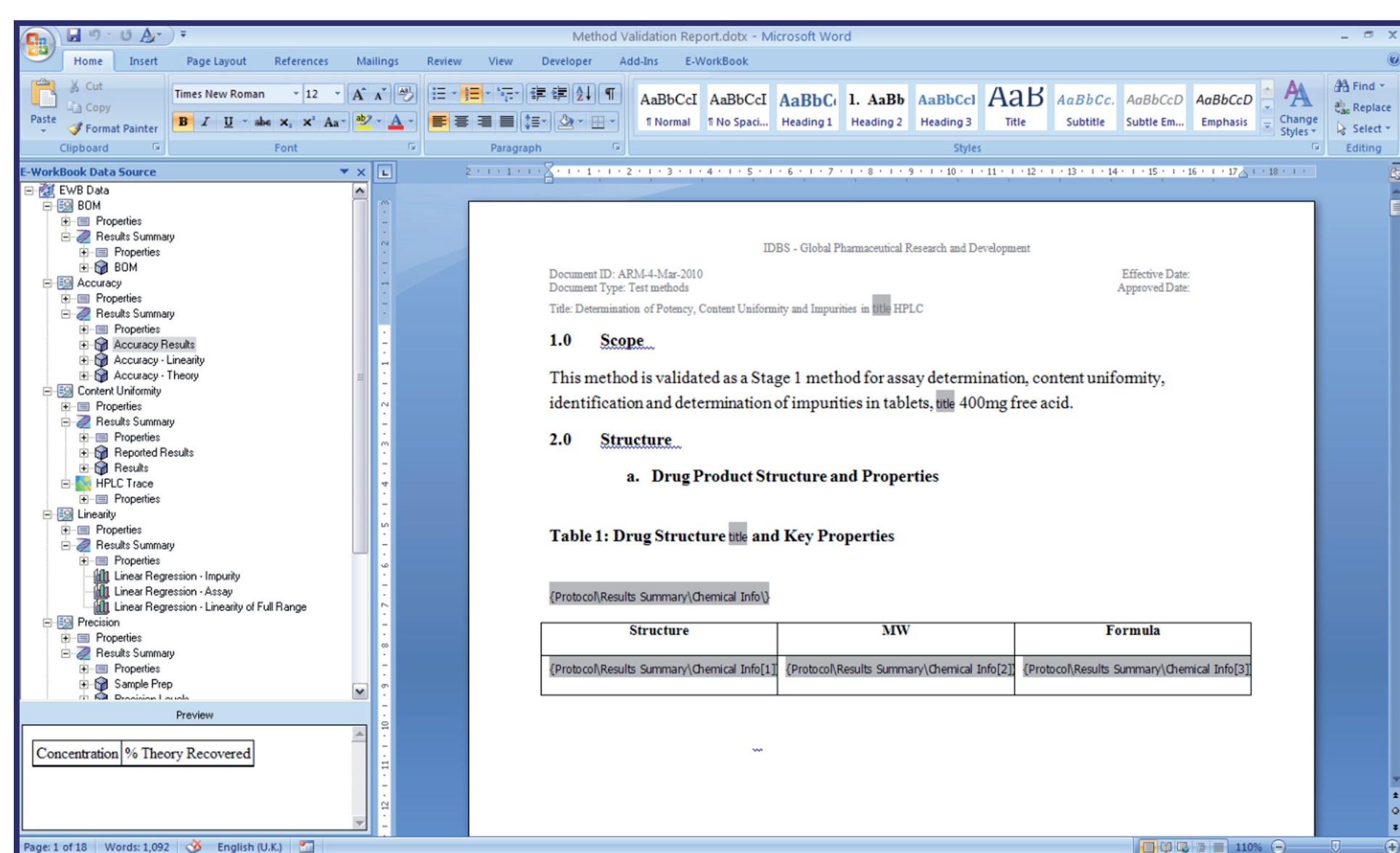


Figure 1: Defining the report template in Microsoft Word

Importantly, template builders can tag areas to be inserted that contain text, images and tabular data, e.g. any data that is present in the experiment. The tagging can be made to experiment templates, which allow Word templates to be produced that are populated based on which template is used to create the experiment, not a specific experiment ID or type. This makes the Word templates flexible, generic and reusable. All templates are version-controlled and fall under the same robust security features of all other data in E-WorkBook (Figure 2).

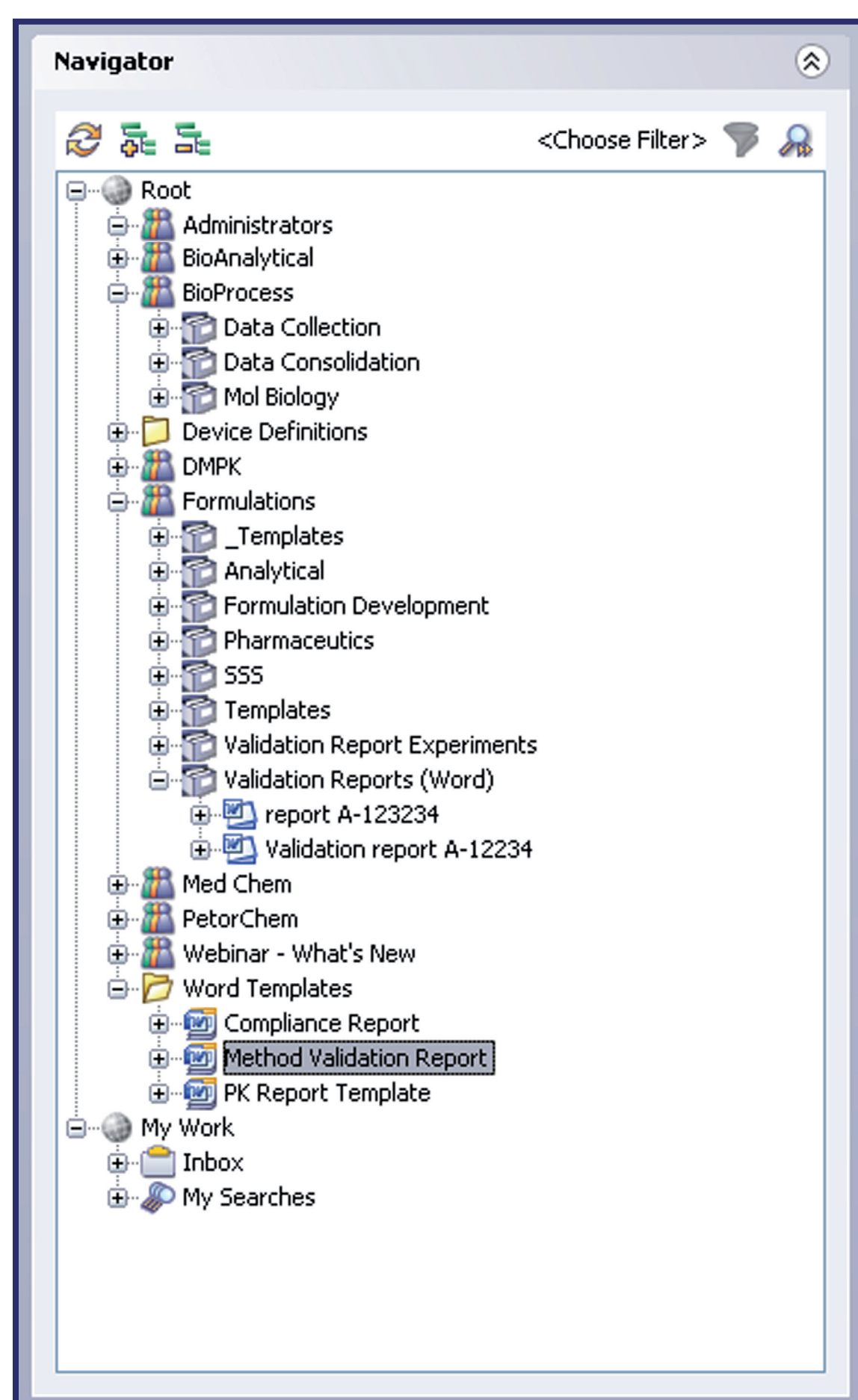


Figure 2: All templates and reports are saved within E-WorkBook

Automatically Generate the Report

To generate the report, the user simply selects the report template to use, identifies the element(s) that defines the report, e.g. compound ID or biologic ID, the departments of interest, the range of dates to take experimental data from, and then clicks OK. The report is generated (Figure 3) by automatically extracting data from E-WorkBook and populating the tags in the Word report.

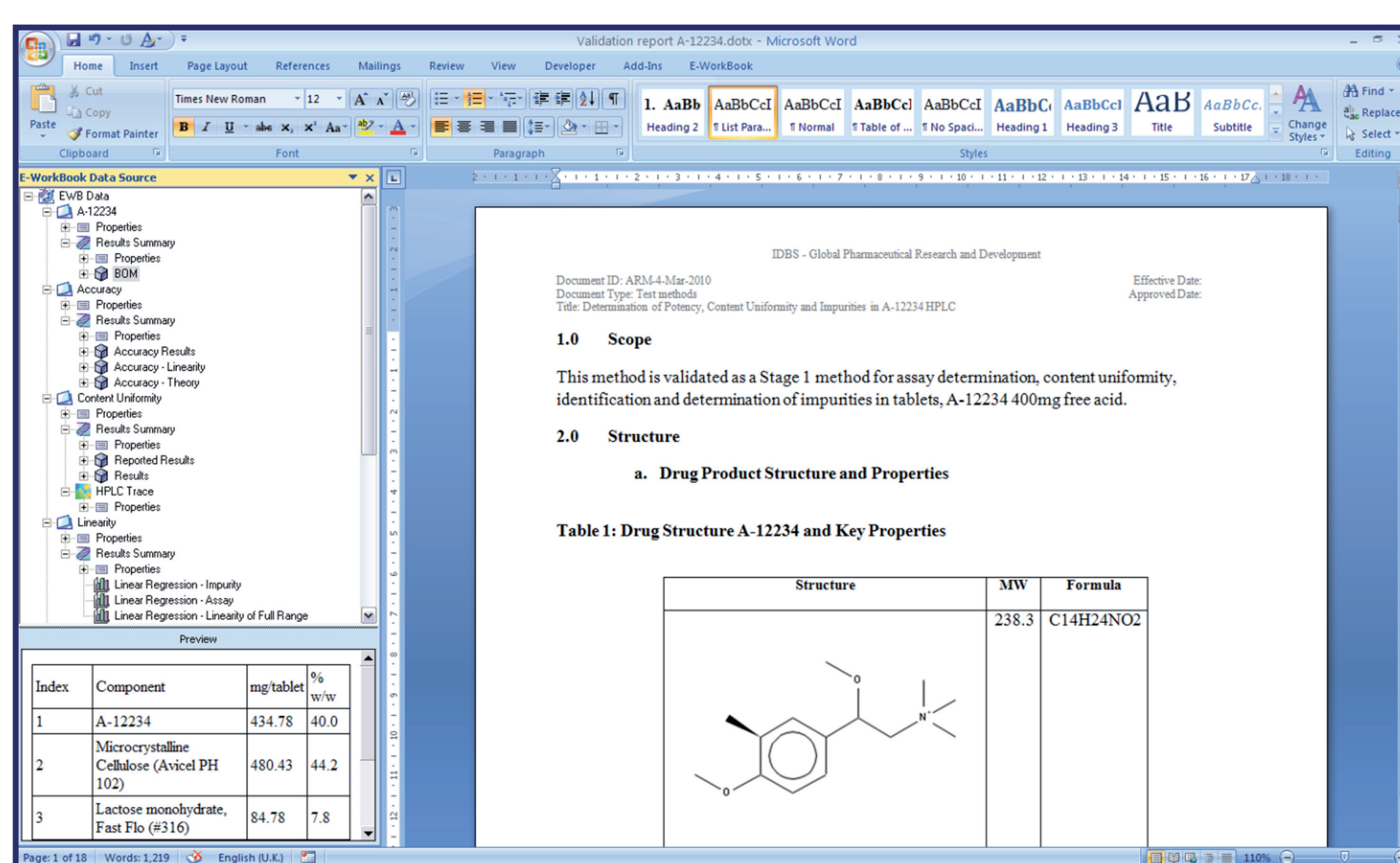


Figure 3: Relevant figures, experimental data and text are loaded into the template

Validate the Report

Once generated, the report can be validated by checking the hyperlinks embedded in the internal version of the report (Figure 4). This is considerably easier than cross-checking against paper and other electronic sources, as is usual, and therefore significantly reduces the validation time.

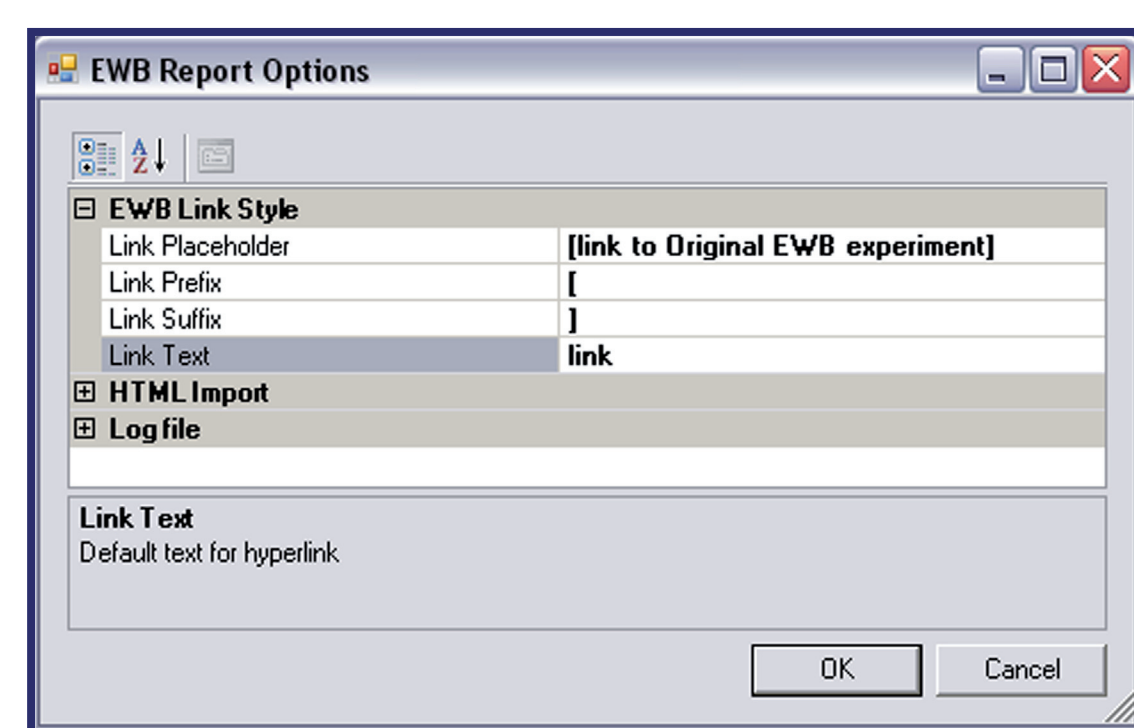
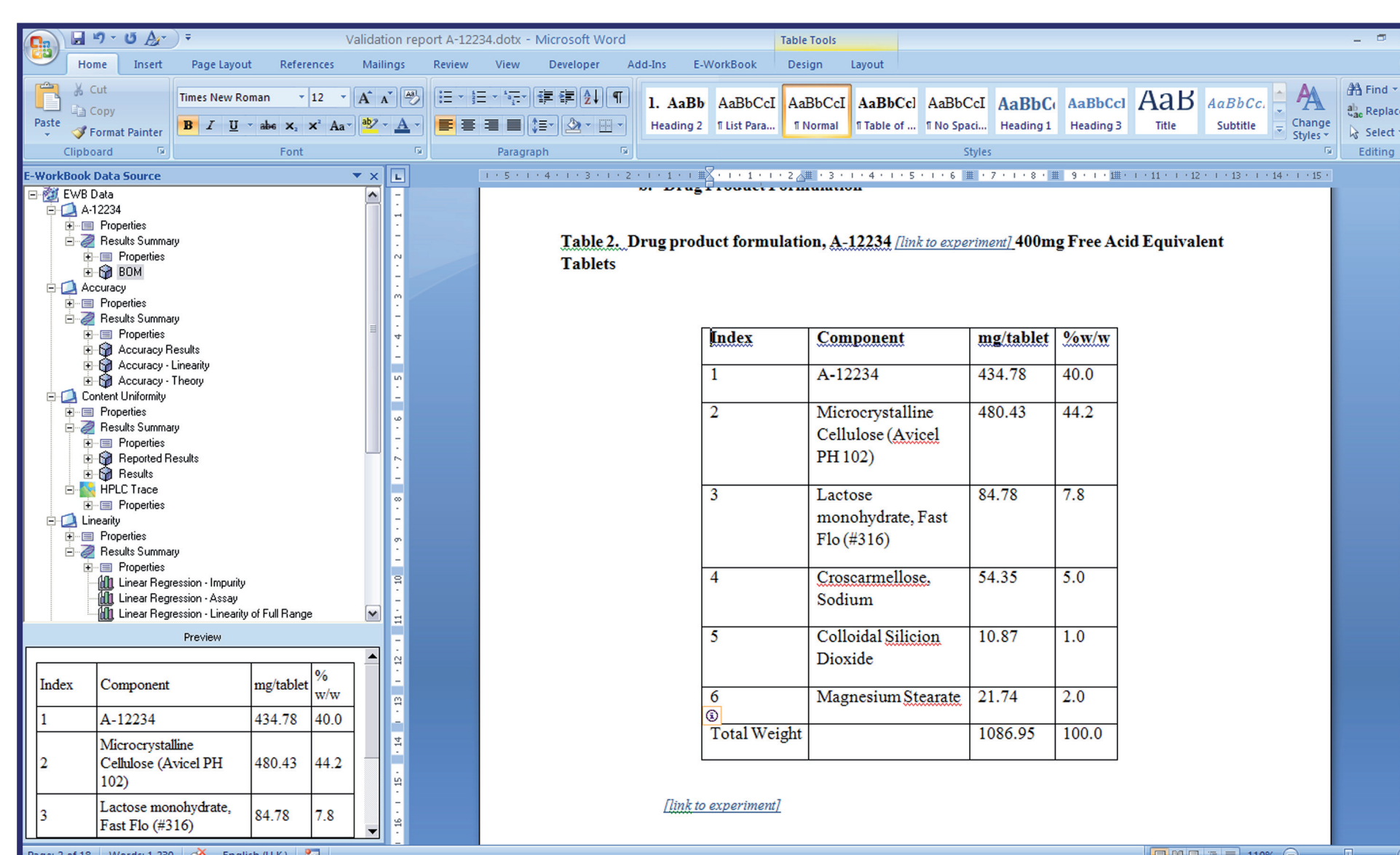


Figure 4: Reports have hyperlinks back to the experimental data and template builders have the option to define what the link looks like.

Foundations are Good Data Management

There are a number of required system fundamentals that make this holistic solution to validation reporting feasible:

- Flexible data capture environment - scientists require an easy to use and flexible system that can match their workflow
- Fact and context data capture - ensuring that all the data is managed and is structured to support downstream reporting

Typically these two things are at odds with each other, but a lack of structure and context around data make reporting difficult, and validation of reports even more troublesome.

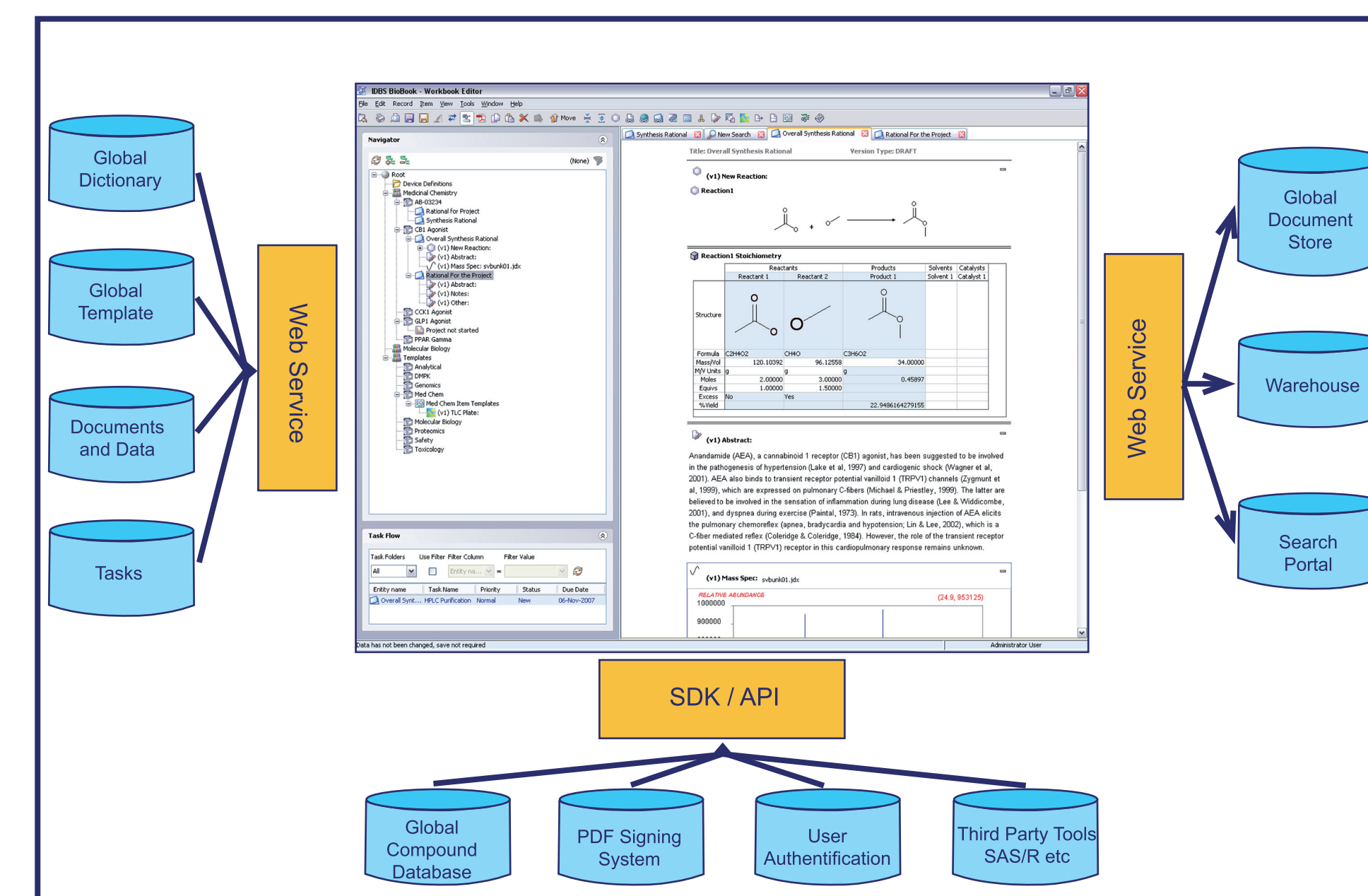


Figure 5: E-WorkBook can help scientists gather, structure, secure and search data.

Conclusion

E-WorkBook is the industry-leading ELN solution that can provide the combination of strong domain expertise and proven data management capabilities required to reduce the time taken to generate and validate regulatory documentation. By leveraging the data management tools and new Word add-ins, IDBS is now delivering significant time savings and quality improvements to validation and regulatory document production.

IDBS

Europe
Guildford (HQ)
London

Asia Pacific
Shanghai, China
Melbourne, Australia

North America
Alameda, CA
Boston, MA
Bridgewater, NJ

www.idbs.com
info@idbs.com

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