



Männedorf, 2007-11-27

Dear Mr Larsson,

Please allow me to express my gratitude for your excellent work during the last five month period.

Having nearly completed the Design History File migration of two of our largest diagnostic products to Aligned Elements, we are now in a good position to draw the conclusion of our joint efforts.

Keeping all the relevant DHF documentation in one single system provides us with a significantly increased transparency and control of our work and we can quickly pin-point gaps and weaknesses in our documentation.

The Risk Management, which previously done manually in Excel and Word is now to 90% integrated with the rest of the DHF documents and kept under strict consistency checks. Trace tables that range over more than 100 pages are today generated automatically at the click of a button.


Thanks to the "linked projects" feature we are able to reduce duplication of module documentation to a minimum. We have thus obtained a clear understanding of the current status our DHF documentation and we have laid a solid foundation for future handling and management of our DHFs.

Aligned has shown profound knowledge in the regulatory environment in which we operate and shown great understanding concerning the specific challenges our organization and our complex product hierarchy present to us. It has been a stimulating experience to exchange ideas and develop viable solutions for the situations we have encountered. Your commitment on continuous requirement gathering, development and implementation of customer requests such as ours, has been very important to us. We greatly appreciate the professionalism and responsiveness Aligned has shown through out the project.

Due to our increased awareness of the possible benefits and leverage rendered by Aligned Elements, we are currently investigating the possibilities of evaluating the system in additional departments within our organization.

Best Regards

Christoph Karthaus,
Project Manager, Tecan Switzerland


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