



**BIOCARTIS TO USE PROCEDURECAPTURE TO GENERATE THE DOCUMENTED EVIDENCE REQUIRED FOR THEIR COMPUTER SYSTEM VALIDATION BASED ON GAMP, CGMP AND 21 CFR PART 11.**

*Belgium, Europe– April , 2013*

Biocartis is an innovative commercial stage molecular diagnostics (MDx) company providing next generation diagnostic solutions aimed at improving clinical practice for the benefit of patients, clinicians, payers and industry.

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Raltus Software, the leading solution for improving quality and reducing testing costs, announced that Biocartis recently selected ProcedureCapture to help validate their Software procedures so that they comply with regulatory requirements.

ProcedureCapture helps companies significantly reduce the resource burden of validating their computer systems.

In particular the tool helps by:

- **Live capture of IQ/OQ Test scripts in your actual software environment.**
- **MS Word output for 'wet ink' signing. - document pre-populated with both screenshot imagery and test script properties.**
- **Bi-directional traceability requirements matrices and full audit trail output capabilities (including pass/fail reports and expected vs. actual screenshots).**
- **Option to execute scripts paperlessly (manual or automated) and sign using electronic signatures.**
- **Automatic production of End User documentation and training materials (Word or PDF).**

Biocartis demonstrates what customers are directly telling us said Ann Devine, Vice President of Marketing for Raltus – "Being able to easily capture IQ/OQ test scripts and then being able to execute them in a paper or paperless way plays a crucial role in fulfilling their CSV requirement". Devine continued "We're pleased to work with Biocartis and are proud to be able to make such a positive impact on their validation efforts".

"ProcedureCapture is the only tool we have found which has all the functionality we need for our CSV effort in one place. It has Requirements, Risk, Testing and Defect tracking along with eSigs, all in one easy to use tool—would absolutely recommend it."

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