



**CLINIGEN GROUP PLC TO USE
PROCEDURECAPTURE FOR THEIR COMPUTER
SYSTEMS VALIDATION AND TO GENERATE THE
REQUIRED DOCUMENTED EVIDENCE REQUIRED
FOR REGULATED ENVIRONMENTS.**

England, UK– November, 2014

Clinigen Group plc is a fast-growing specialty global pharmaceuticals and services business, dedicated to serving patients, the medical community and the healthcare industry to supply critical life saving treatment.

With offices in the UK, US and Japan, Clinigen is focused on delivering the right drug to the right patient at the right time, whether it's for clinical trial, individual patient need, or as a fully licensed treatment revived from discontinued status to fulfill a need in niche global markets.

England, UK– November , 2014 - Raltus Software, the leading solution for validating computer systems, announced that Clinigen Group, Inc recently selected ProcedureCapture to help validate their computer systems so that they comply with regulatory requirements.

ProcedureCapture is the only solution which generates conclusive and indisputable documented evidence and uses a single license for the whole lifecycle of :

- Requirements Management.
- Risk Assessment.
- Test Script Capture.
- Review and Pre Approval of Scripts.
- Paper and Paperless execution.
- Manual or Automated testing with Electronic Signatures.
- Defect Management and Tracking.
- Trace Matrices and generation of documented evidence.
- End user guides and training materials.

Clinigen demonstrates what customers are directly telling us said Ann Devine, Vice President of Marketing for Raltus – "ProcedureCapture helps companies significantly reduce the cost and resource burden of validating their computer system and this directly translates into a 40% decrease in the time to create test scripts and a 60% decrease in time to execute these scripts". Devine continued "We're pleased to work with Clinigen 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 is capable of both generating image populated compliant documentation and then if required use the same asset to paperlessly run and electronically sign the actual procedures to confirm that they works as expected."

Martin Bill
ICT & Logistics
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Clinigen Group

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