Regulatory Compliance Solutions
Computer System Validation

Raland Compliance Partners is your trusted partner delivering **sustainable** Quality, Regulatory, and Clinical compliance solutions.

Computer System Validation (CSV) is a core competency of Raland. FDA guidance defines software validation as "confirmation by examination and provision of objective evidence that software specifications conform to user needs and intended uses, and that the particular requirements implemented through software can be consistently fulfilled".

There is no such thing as "Validated" off the shelf software, since no software is going to match **your** specific "intended use" (User Requirements). The entire Software Development Life Cycle (SDLC) of a software product may be documented to prove that it functions as designed and may have Electronic Record/Electronic Signature (ERES) and Audit Trail functionality to satisfy 21CFR Part 11, but that still doesn't make it "Validated".

Our CSV professionals, following our risk-based approach and leveraging the vendor's testing and documentation, and adhering to your internal policies and procedures, will walk you through documenting your project, from business processes flows and user requirements to developing and executing test protocols which document that the software satisfies your intended use of the system.

We will develop customized documentation for your project that is aligned with your risk tolerance, your internal processes and procedures, and leverage accepted vendor documentation to assure your system meets your user requirements and intended use.

Examples of our experience includes qualification the following types of software:

- ERP/MRP Systems
- Quality Management Systems (eQMS)
- Electronic Document Management Systems (EDMS)
- Building Management Systems (BMS)
- Manufacturing Execution Systems (MES)
- Laboratory Information Management Systems (LIMS)
- Software as a Service (SaaS)
- Software as a Medical Device (SaMD)

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