

Computer Systems Validation



Validation services for GxP-regulated Pharmaceutical, Medical Device and other life science companies

PharmOut offers both consulting and contracting services to support computer systems validation.

Our consulting services can help you with high-level decisions such as:

- Taking a risk-based approach to determining which of your computer systems to validate
- Determining the documentation needed to support decisions about what to validate and what to not.

We can also perform an audit to find out if your systems are compliant with global GxP regulations. If they aren't, we can give you practical solutions on how to achieve compliance and pass an audit by a regulatory body.

Our contracting offering supplies people with the knowledge and experience to do the hands-on validation.

Our validation staff can help you with:

- Writing a Validation Master Plan
- Determining which software functions to test
- Creating the documentation needed for testing
- Writing a requirements traceability matrix.

Plus, we can do the testing — which you probably don't have the time or resources to do.

Our methodology is compliant with GAMP5 - a Risk Based Approach to Compliant GxP Computerised Systems.

Refer to www.pharmout.net for contact details.