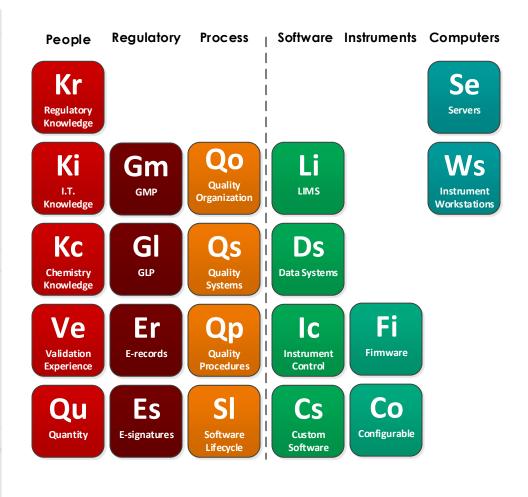
Periodic Table of Laboratory Validation Elements

Laboratory system validation may appear to be a dark art, but a logic can be applied to measure success factors. This chart depicts those factors (on the left) which can be applied to system components (on the right).

PEOPLE			
Kr	Regulatory	Staff have knowledge of all applicable regulations	
Ki	I.T. Knowledge	The I.T. systems and interactions are well understood	
Kc	Chemistry Knowledge	Chemistry skills are available to understand functions and interactions of lab systems	
Ve	Validation Experience	Staff have experience and judgment in appropriate validation approaches	
Qu	Quantity	Enough qualified staff are available	
	REGULATORY		
Gm	GMP	Good Manufacturing Practice (21CFR Parts 210 and 211)	
GI	GLP	Good Laboratory Practice (21CFR Part 58)	
Er	E-Records	Electronic records per 21CFR Part 11	
Es	E-Signatures	Electronic signatures per 21CFR Part 11	
	PROCESS		
Qo	Quality Organization	An independent Quality Organization exists and is appropriately staffed.	
Qр	Quality Procedures	Putting Change Control, CSV, Deviations & Incidents, CAPA, Periodic Review, IT Security, etc. in place.	
Qs	Quality Systems	Quality Systems are defined and in place	
SI	Software Lifecycle	There is a process for software development/deployment/retirement	



SOFTWARE		
Li UMS	Laboratory Information Management System. Also includes ELN and SDMS.	
Ds Data Systems	Central data systems such as Chromatograph Data Systems (CDS)	
Ic Instrument Control	Instrument Control software used for control and data acquisition	
Cs Custom Software	Software custom-written for data reduction or similar functions	
IN	STRUMENTS	
Fi Firmware	Systems controlled with firmware (See GAMP 5 definitions)	
Co Configuratble	Systems controlled with configurable software (See GAMP 5 definitions)	
С	OMPUTERS	
Se Servers	File and application servers	
Ws Instrument Workstations	Instrument control/data acquisition workstations	



Premier Laboratory Informatics Experts
© 2014, 2020 CSols, Inc.