

# 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)
Gl	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.
Qp	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
Sl	Software Lifecycle	There is a process for software development/deployment/retirement

People	Regulatory	Process	Software	Instruments	Computers
<b>Kr</b> Regulatory Knowledge					<b>Se</b> Servers
<b>Ki</b> I.T. Knowledge	<b>Gm</b> GMP	<b>Qo</b> Quality Organization	<b>Li</b> LIMS		<b>Ws</b> Instrument Workstations
<b>Kc</b> Chemistry Knowledge	<b>Gl</b> GLP	<b>Qs</b> Quality Systems	<b>Ds</b> Data Systems		
<b>Ve</b> Validation Experience	<b>Er</b> E-records	<b>Qp</b> Quality Procedures	<b>Ic</b> Instrument Control	<b>Fi</b> Firmware	
<b>Qu</b> Quantity	<b>Es</b> E-signatures	<b>Sl</b> Software Lifecycle	<b>Cs</b> Custom Software	<b>Co</b> Configurable	

SOFTWARE		
Li	LIMS	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
INSTRUMENTS		
Fi	Firmware	Systems controlled with firmware (See GAMP 5 definitions)
Co	Configurable	Systems controlled with configurable software (See GAMP 5 definitions)
COMPUTERS		
Se	Servers	File and application servers
Ws	Instrument Workstations	Instrument control/data acquisition workstations



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