

regulatory compliance & validation services

smart tools - swift services - sharp research.

emka TECHNOLOGIES provides regulatory compliance & validation services for the life sciences industry.

we can help you lower validation costs using methods such as risk analysis, gap analysis and impact assessment in relation to the relevant GxP guidelines

→ our services

regulatory compliance in the life sciences industry

we can assist you in meeting the increasing demands and complexity of national and international regulations

our validation teams keep up to date through collaboration with international companies and ongoing contact with regulatory authorities

focusing on regulatory developments and validation activities consumes time and resources that you need to speed your products to market

our team will help you take care of:

- validation strategic planning

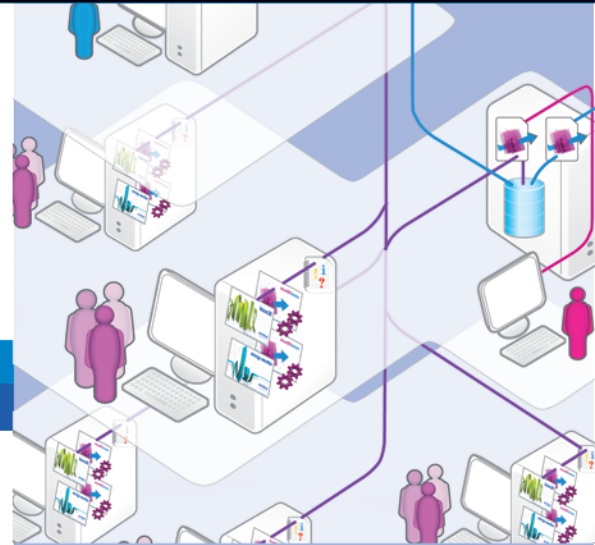
computer systems validation

our validation program covers:

- validation master plan
- risk assessment
- traceability matrix
- user requirement specifications
- functional requirements specifications
- installation qualification
- operational qualification
- performance qualification
- standard operation procedures
- validation documentation

validation outsourcing

outsourcing allows you to meet the periodic validation requirements of your organization, while optimizing use of in-house resources



gamp 4

fda 21 cfr part 11
assessment

gxp

computer system
validation

software
validation