PRISMEA™

AUDIT-READY COMPLIANCE

BIOTECH SDLC REGULATIONS

Biotech, healthtech and medtech products increasingly include significant **software components:** from apps and devices, to complex bioinformatics and data analytics.

Software development life cycle (**SLDC**) comprises coding, testing, deployment and protection of software components.

Many national and international regulations include **strict controls on the SDLC** for these applications.

Compliance is an **opportunity to improve** quality, repeatability and increase MI.

Dynamic medical testing lab moving to help public health through **high-throughput Covid testing** during pandemic.

"Prismea were able to quickly assess our requirements in order to meet our regulatory obligations, provide a detailed action plan and were able to **execute on this plan** perfectly."

"The policies and procedures that Prismea created for us successfully met our needs for software development using Microsoft Azure DevOps under ISO15189.

PRISMEA ADVANTAGE

Prismea's **unique perspective** comes from both sides of the regulatory divide: as regulator and as regulatee.

Our two principal consultants, Dr Mark D Preston and Andrew Smith combine over 20 years experience at the **MHRA and developing clinical trials software.**

AUDIT-READY SDLC

We offer

- Gap analyses to standards
- Process evolution plan
- Policy writing and management

Call us today to be audit-ready

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