

CAPABILITY STATEMENT

Quality & Regulatory Compliance Experts for Life Sciences

Bridgepoint provides Quality & Regulatory Compliance consulting and specialized staffing for pharmaceutical, biotech, and medical device companies, including the CDMOs and CMOs that serve them. Bring us in as a project team, or add an experienced consultant to your own team for interim, contract, or surge needs.

Two Ways to Work With Us

SERVICE 01

Consulting & Project Support

For work that needs its own structure. We put the team together, agree on milestones with you, and report against them until the deliverables are done.

- Audit programs and gap assessments
- Inspection readiness, and remediation after FDA findings
- Quality system assessments
- Validation and CSV remediation programs

SERVICE 02

Specialized Staffing

For when you have the plan and the managers but not enough experienced people. Our consultant joins your team, reports to your managers, and follows your procedures.

- Work with a defined end date or scope
- Extra hands for a specific project
- Covering a role while it is open
- Start on contract, then extend, convert, or end

Areas of Expertise

01 Quality Systems

Designing and fixing QMS processes, including CAPA, deviations, and document control.

03 Medical Device Quality & Regulatory

QMSR and ISO 13485 readiness, design controls, and EU MDR/IVDR.

05 Validation & CSV / CSA

CSV and CSA under GAMP 5, Part 11, and Annex 11, scoped to each system's risk.

07 Manufacturing & Laboratory Systems

Validation and lifecycle management for MES and LIMS.

02 Regulatory Compliance & Audit

Internal audits, supplier audits, mock inspections, and gap assessments.

04 Remediation & Inspection Readiness

Form 483 responses, warning letter remediation, and cleanup before an inspection.

06 ERP & Enterprise Systems

Validation for SAP, Oracle, and similar platforms through implementations and upgrades.

08 Quality & Compliance Leadership

Interim QA and compliance directors, remediation leads, and validation project managers.

Industries We Work In

Pharmaceutical & Biotech

Drug and biologics manufacturers working under 21 CFR Parts 210/211.

Medical Device

Class II and III device makers under the QMSR, ISO 13485, and EU MDR/IVDR.

Cell & Gene Therapy

Developers moving patient-specific processes toward commercial manufacturing.

CDMOs & CMOs

Multi-client GMP operations running on shared equipment and systems.

Roles We Support

01 Compliance and audit specialist

02 CSV / CSA specialist

03 Validation project manager

04 Quality systems consultant / manager

05 ERP validation lead or analyst

06 Interim QA or compliance director

07 Medical device quality professional

08 MES / LIMS validation professional

09 Remediation program leader

Situations We See

FDA Warning Letter Response

A drug manufacturer has committed to a remediation schedule. It needs a compliance lead and a CSV specialist to meet those dates.

Medical Device QMSR Transition

A device maker needs to bring its procedures, design controls, and CAPA process in line with the QMSR and ISO 13485.

Pre-Approval Inspection Readiness

A biotech facing its first pre-approval inspection needs a mock inspection, a documentation review, and electronic records that hold up under Part 11 and Annex 11.

CDMO Quality System Build

A CDMO is adding clients faster than its quality system can absorb them. It needs a Quality Systems Manager who has run a multi-client operation.

How We Work

We start with the problem.

Before we talk about people, we want to know what systems you run, what your last audits found, and what is driving the timeline.

We check the experience.

Every consultant walks us through work they have actually done: what they wrote, what an auditor questioned, and how they answered.

We work to the agency's dates.

Form 483 responses, warning letter commitments, and inspection dates do not move. We plan backward from them.

Leadership



Ross Berge

PRINCIPAL

Ross started Bridgepoint to give pharmaceutical, biotech, and medical device companies a better way to get experienced help with quality and compliance work. He has worked in quality, validation, regulatory compliance, and ERP software. BA, Hamline University; MBA, University of St. Thomas.

Bring Us Your Compliance Challenge.

Schedule a call to discuss your project, timeline, and staffing needs.

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