bridgepointgxp.com
info@bridgepointgxp.com · (715) 564-4480

CAPABILITY STATEMENT

Quality & Regulatory Compliance Consulting and Specialized Staffing for Life Sciences

Bridgepoint has one focus: Quality & Regulatory Compliance for pharmaceutical, biotech, and medical device companies, and the CDMOs and CMOs that serve them. We provide experienced consultants for defined projects and embed specialists in your team for contract and interim needs.

Two Ways We Work

SERVICE 01

Consulting & Project Support

Expert resources working alongside your team within a dedicated project management structure, with clear milestones and defined deliverables. One expert or a full team.

- Audit and gap assessment programs
- Inspection readiness and remediation tied to regulatory findings
- Quality system assessments
- System validation and CSV remediation programs

SERVICE 02

Specialized Staffing

Quality, Regulatory Compliance, and Validation consultants embedded in your team, matched on regulatory depth, industry experience, and fit. They start quickly and work independently.

- Temporary needs with a defined duration or scope
- Added capacity for a specific project or initiative
- Interim coverage while a role is open
- A path to permanent: extend, convert, or close

Areas of Expertise

Quality Systems
QMS design and improvement, CAPA, deviation handling, and document control.

Medical Device Quality & Regulatory
FDA QMSR and ISO 13485 readiness, design controls, and EU MDR/IVDR.

Validation & CSV / CSA
Computer System Validation and Computer Software Assurance under GAMP 5, Part 11, and Annex 11.

Manufacturing & Laboratory Systems
Validated integration and lifecycle management for MES and LIMS.

Regulatory Compliance & Audit
Internal, supplier, and mock inspection audits, plus gap assessments.

Remediation & Inspection Readiness
Form 483 responses, warning letter remediation, and pre-inspection preparation.

ERP & Enterprise Systems
Validation lifecycle ownership for SAP, Oracle, and related platforms.

Quality & Compliance Leadership
Interim QA and compliance directors, remediation program leaders, and validation project managers.

Bridgepoint | Quality & Regulatory Compliance Experts for Life Sciences

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Industries We Serve

Pharmaceutical & Biotech
Quality, compliance, and validation for drug and biologics manufacturers.

Medical Device
Quality and compliance under the FDA QMSR, ISO 13485, and EU MDR/IVDR.

Cell & Gene Therapy
Quality and validation for advanced therapies moving to commercial manufacturing.

CDMOs & CMOs
Quality systems and validation across multi-client GMP operations.

Roles We Staff

- ✓ Compliance and audit specialist
- ✓ Quality systems consultant / manager
- ✓ Medical device quality professional
- ✓ CSV / CSA specialist
- ✓ ERP validation lead or analyst
- ✓ MES / LIMS validation professional
- ✓ Validation project manager
- ✓ Interim QA or compliance director
- ✓ Remediation program leader

When Clients Call

FDA Warning Letter Response
A compliance lead, quality systems consultant, and CSV specialist to support remediation commitments within the agency's timeline.

Pre-Approval Inspection Readiness
Mock inspections, documentation review, and Part 11 / Annex 11 compliant systems before the inspection window.

Medical Device QMSR Transition
Closing gaps against the FDA QMSR and ISO 13485 across procedures, design controls, and CAPA.

CDMO Quality System Build
A contract Quality Systems Manager with multi-client GMP experience to build out compliance infrastructure.

Why Bridgepoint

Senior expertise, not a handoff
Engagements are staffed with experienced consultants matched to the work, not routed through account layers or junior staff.

One field, not a practice-area list
Quality & Regulatory Compliance for life sciences is the whole practice, not one line item among several.

A deliberately focused client list
We work with a limited number of clients at a time so every engagement gets full attention.

Leadership

Ross Berge
PRINCIPAL

Ross founded Bridgepoint to quickly connect life sciences companies with experienced consultants who help them meet their quality and regulatory compliance requirements. His background covers quality, validation, regulatory compliance, and ERP software. BA, Hamline University; MBA, University of St. Thomas.

Let's Discuss Your Need.

Start with a confidential conversation about what you're facing. No obligation.

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