

Eliana Rich

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SUMMARY

Clinical quality and risk management leader with 11 years of healthcare and pharmaceutical experience across GCP quality, **clinical trials**, risk based oversight, inspection readiness, CAPA, quality investigations, and cross functional governance. Leads global teams through protocol, study setup, trial, and compound level risk assessment while protecting participant safety, rights, well being, and **data integrity**. Builds practical mitigation plans, maintains **Clinical Quality Plans**, guides Significant Quality Issue decisions, and supports FDA and EMA inspections. Uses Tableau, Spotfire, Microsoft Office, and structured data review to turn operational signals into clear decisions. Brings working knowledge of ICH guidelines, GMP, GLP, GPvP, **Real World Evidence**, and Digital Health. Ready to contribute sound judgment, clear communication, and steady quality leadership across clinical development programs.

EXPERIENCE

Senior Manager, Clinical Quality Risk

January 2023 - Present

Alder Creek Biopharma

Raleigh, NC

Directs quality risk oversight across global clinical development programs, guiding risk governance, **inspection readiness**, investigations, CAPA, and senior stakeholder decisions.

- Established risk reviews linking protocol complexity with participant protection and data integrity.
- Challenged mitigation evidence during recurring reviews, surfacing emerging concerns for **risk owners**.
- Recorded decisions in **Clinical Quality Plans** and controlled quality repositories for governance.
- Guided Significant Quality Issue assessments, investigations, and senior management escalation.
- Advised CAPA plans and **effectiveness checks** after audits, inspections, and self identified issues.
- Shaped **inspection narratives**, confirmed essential records, and coordinated **mock inspections**.
- Coached quality professionals on GCP and ICH application across diverse global teams

Clinical Quality Risk Manager

July 2020 - December 2022

Meridian Clinical Sciences

Durham, NC

Managed trial level quality risk activities for Phase II and Phase III studies, combining **data visualization**, GCP guidance, governance, and inspection preparation.

- Converted Phase II and Phase III protocol risks into prioritized mitigation plans.
- Built Tableau views combining operational signals with quality trends for focused reviews.
- Created **Spotfire** analyses that highlighted outliers and areas requiring deeper investigation.
- Maintained **Clinical Quality Plans** and repository records for governance discussions.
- Facilitated quality forums, clarifying owners, actions, escalation paths, and compliance interpretations.
- Prepared **FDA** and **EMA** inspection teams through records review and mock interviews.
- Provided independent **GCP** guidance with regulatory compliance and specialist colleagues

Senior Clinical Quality Specialist

March 2018 - June 2020

HarborPoint Research Partners

Charlotte, NC

Performed sponsor trial quality reviews and supported investigations, CAPA, inspection preparation, and regulatory interpretation across clinical operations programs.

- Reviewed monitoring information and protocol deviations for participant and data risks.
- Organized investigation evidence and issue narratives for consistent escalation decisions.
- Linked **CAPA** actions with identified causes and practical **effectiveness checks**.
- Prepared investigator sites through document reviews and focused **pre inspection visits**.
- Applied GCP and ICH principles to clinical operations execution questions.
- Presented risk summaries and action status through **Microsoft Office** trackers

Clinical Quality Specialist

June 2015 - February 2018

Blue Ridge Medical Research Network

Greensboro, NC

Supported hospital based clinical research quality oversight through GCP review, site readiness, investigations, corrective action planning, and stakeholder communication.

- Reviewed trial documentation and study processes against GCP and institutional procedures.
- Organized protocol deviation evidence for **quality investigations** and escalation decisions.
- Confirmed essential records and traceability during investigator site readiness checks.
- Documented findings, ownership, and completion evidence for corrective actions.
- Prepared **Microsoft Office** summaries translating study details into clear risk updates.

- Partnered with investigators, coordinators, pharmacy, laboratory, and compliance personnel

PROJECTS

Clinical Risk Signal Visualization 📅 2022

Connected Tableau and Spotfire views with clinical quality signals, helping trial teams focus governance conversations on trends, outliers, and emerging concerns.

Global Inspection Readiness Program 📅 2024

Structured narratives, site preparation, mock interviews, and record checks for sponsor, investigator, FDA, EMA, and third party inspections.

LEADERSHIP & AWARDS

- Recognized by clinical leadership for strengthening cross functional risk governance and inspection readiness.
- Selected to coach quality colleagues on GCP risk reviews, escalation judgment, and mitigation evidence.
- Earned trust as a practical advisor during complex quality investigations and CAPA reviews.

EDUCATION

Bachelor of Science in Biological Sciences

2015

North Carolina State University GPA: 0

Raleigh, NC

Coursework: Clinical research, biology, pharmacology, statistics

CERTIFICATIONS

- Certified Clinical Research Professional, SOCRA 📅 2018
- Regulatory Affairs Certification, Drugs 📅 2022

TECHNICAL SKILLS

- **Clinical Quality:** GCP Quality, Clinical Trials, Clinical Quality Plans
- **Risk Management:** Risk Based Oversight, Protocol Risk Assessment, Mitigation Reviews
- **Quality Systems:** Quality Repositories, Quality Investigations, Significant Quality Issues
- **Corrective Action:** CAPA, Root Cause Analysis, Effectiveness Checks
- **Inspection Readiness:** FDA Inspections, EMA Inspections, Mock Inspections
- **Regulatory Standards:** ICH Guidelines, GMP, GLP
- **Safety Practices:** GPvP, Participant Safety, Data Integrity
- **Data Visualization:** Tableau, Spotfire, Data Visualization
- **Data Evidence:** Data Analytics, Operational Signals, Trend Analysis
- **Business Applications:** Microsoft Office, Quality Trackers, Controlled Records
- **Clinical Evidence:** Real World Evidence, Real World Disease, Digital Health
- **Program Delivery:** Project Planning, Escalation Management, Governance Forums

SKILLS

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|----------------------------|--------------------------|--------------------------|-------------------------|
| • GCP Quality | • Clinical Quality Plans | • Quality Investigations | • Regulatory Compliance |
| • Clinical Trials | • ICH Guidelines | • Inspection Readiness | • Data Analytics |
| • Clinical Risk Management | • CAPA | • FDA Inspections | • Project Planning |
| • Risk Based Oversight | • Effectiveness Checks | • EMA Inspections | |

PROFESSIONAL AFFILIATIONS

- Society of Clinical Research Associates, professional member since 2018.
- Regulatory Affairs Professionals Society, clinical and regulatory member.

LANGUAGES

- English (Native)
- Spanish (Intermediate)

ADDITIONAL INFORMATION

Work Status : Authorized to work in United States. No sponsorship required.

REFERENCES

AVAILABLE ON REQUEST