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Fractional Head of Quality

Challenge

An emerging biotechnology company required executive Quality leadership without establishing a full-time Quality organization.

Key Pharma Role

- Provided interim Head of Quality leadership
- Built phase-appropriate Quality Systems
- Led CAPA and compliance initiatives
- Oversaw batch review and quality operations
- Prepared organization for regulatory inspections

Business Impact

Established a scalable Quality organization while reducing operational cost and accelerating development.

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International GMP Audits of CDMOs

Challenge

A sponsor required qualification and oversight of international CDMOs to support global manufacturing activities.

Key Pharma Role

- Conducted GMP and Quality audits
- Evaluated technical capabilities
- Assessed data integrity and compliance
- Developed remediation strategies
- Supported supplier qualification

Business Impact

Improved supplier performance, strengthened GMP compliance, and reduced manufacturing risk.

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AI Applications in CMC & Quality

Challenge

Increasing program complexity required more efficient management of CMC documentation, Quality Systems, and technical data.

Key Pharma Role

- Applied AI to CMC authoring
- Developed AI-enabled QMS workflows
- Supported risk assessment and CAPA
- Accelerated document review
- Improved technical decision-making

Business Impact

Reduced manual effort, improved documentation quality, and accelerated CMC and Quality activities.