Modernising Quality Systems: Implementing ICH E6 R3 and CSA Through Strategic IT Support

A Practical Approach for Clinical Trial Sponsors and CROs

Introduction

- ICH E6 R3 driving enhanced clinical trial quality management
- FDA's Computer System Assurance (CSA) transforming validation approaches
- Both converging in today's digital clinical trial environment

Our Focus Today

- How fractional IT quality support enables efficient implementation
- Tailored approaches for different organisational sizes
- Practical, burden-reducing strategies that yield high compliance value

Understanding the Current Landscape

The Evolution of Regulatory Expectations

- ICH E6 R3: Beyond GCP revision to holistic quality management framework
- CSA: Moving from documentation-heavy CSV to risk-based critical thinking
- How these frameworks complement rather than conflict

The Resource Reality

- Large sponsors: Infrastructure exists but adaptation required
- Mid-sized organisations: Balancing resources with mounting requirements
- Emerging biotechs: Maximising limited quality and IT headcount

Shared Principles Between CSA and ICH E6 R3

Critical Thinking Approach

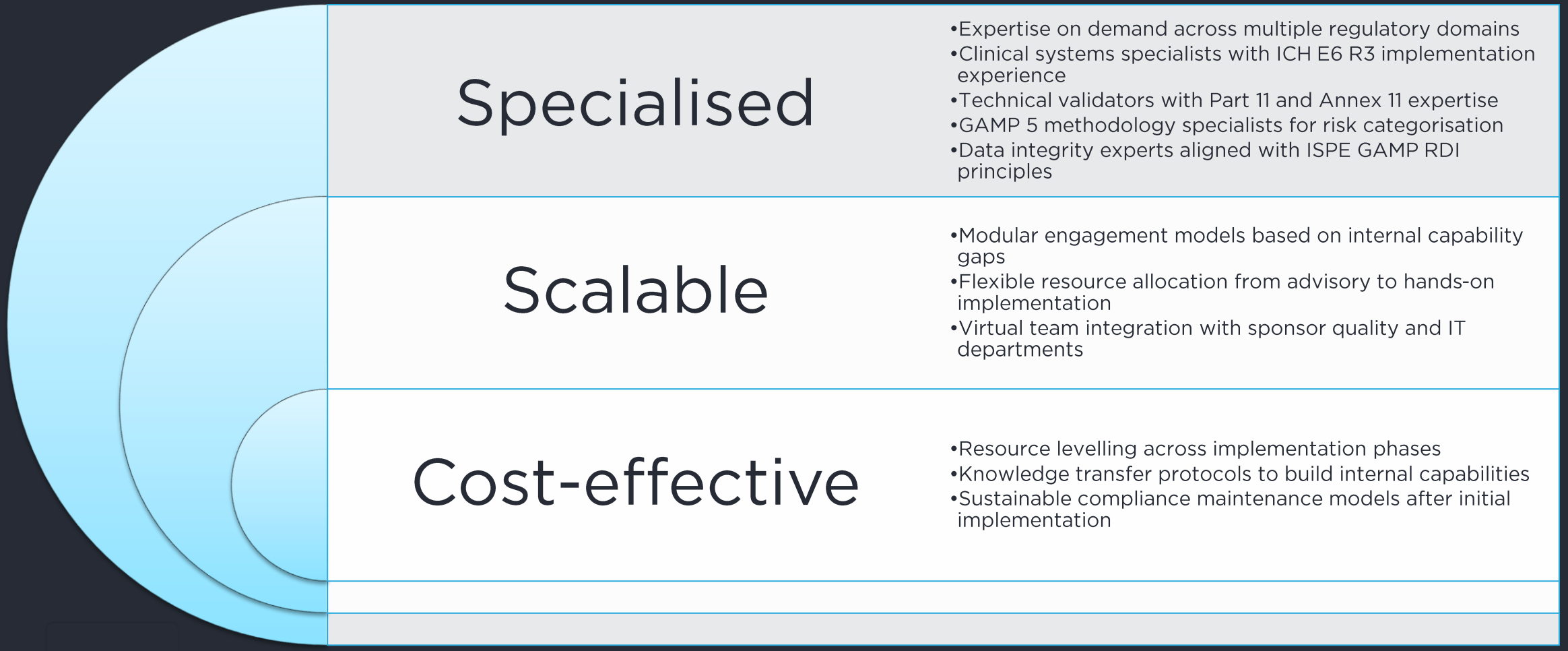
- CSA's emphasis on critical thinking aligns with R3's risk-based quality management
- Both frameworks prioritise actual quality outcomes over documentation volume
- Focus on "what could go wrong“ vs. "what must be documented"

Risk-Based Methodology

- R3's risk-based quality management system requirements
- CSA's risk tiering for computer systems validation
- Harmonised approach to risk assessment and mitigation

Strategic IT Support for Implementation

The Fractional Quality Support Model



Integrated Risk Assessment Methodology

Determining appropriate validation intensity across regulatory requirements

- Progressive testing strategies based on risk classification
- Leveraging vendor documentation in validation packages
- Optimising test case coverage for critical functionality

21 CFR Part 11 and Annex 11 compliance integration

- Electronic signature controls risk evaluation
- Audit trail criticality assessment
- System security and access control mapping

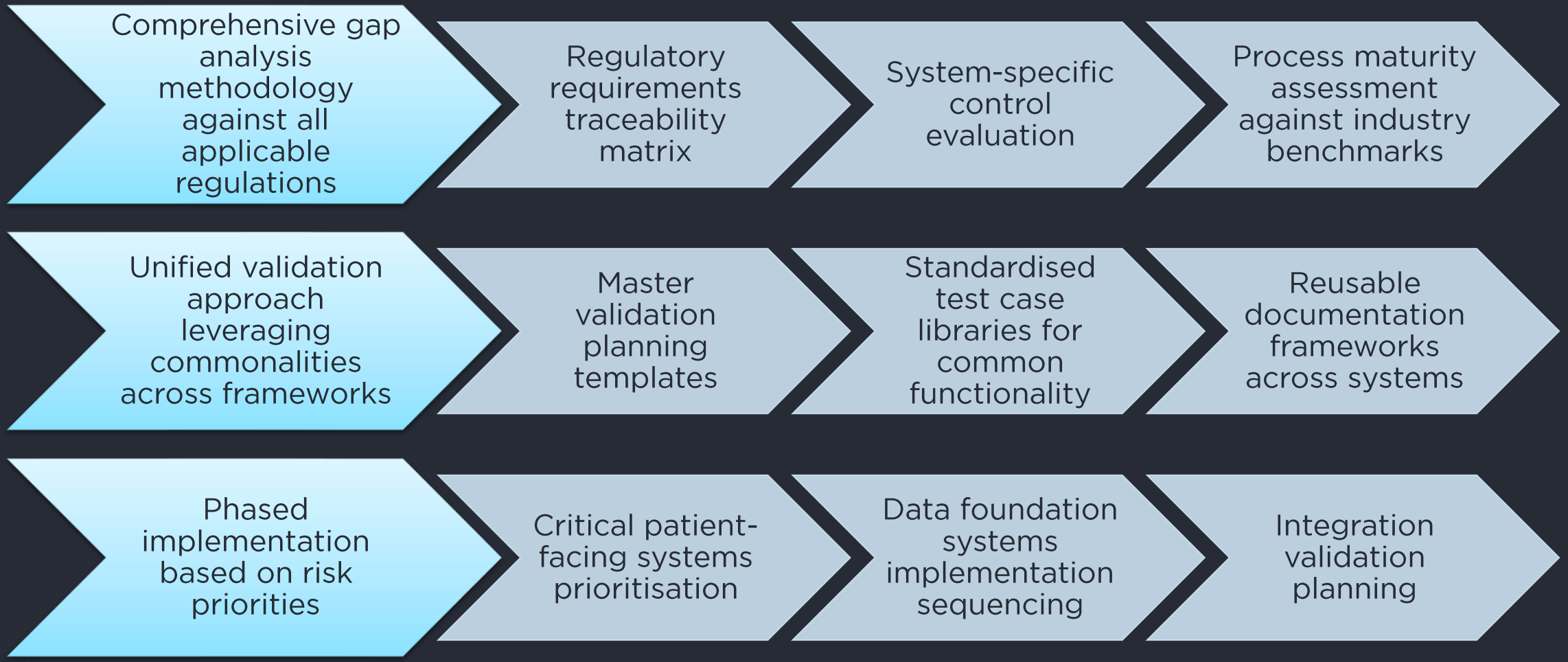
ICH Q9 risk management principles application

- Failure Mode and Effects Analysis (FMEA) for critical processes
- Risk Control matrices with mitigation effectiveness scoring
- Residual risk evaluation and acceptance criteria

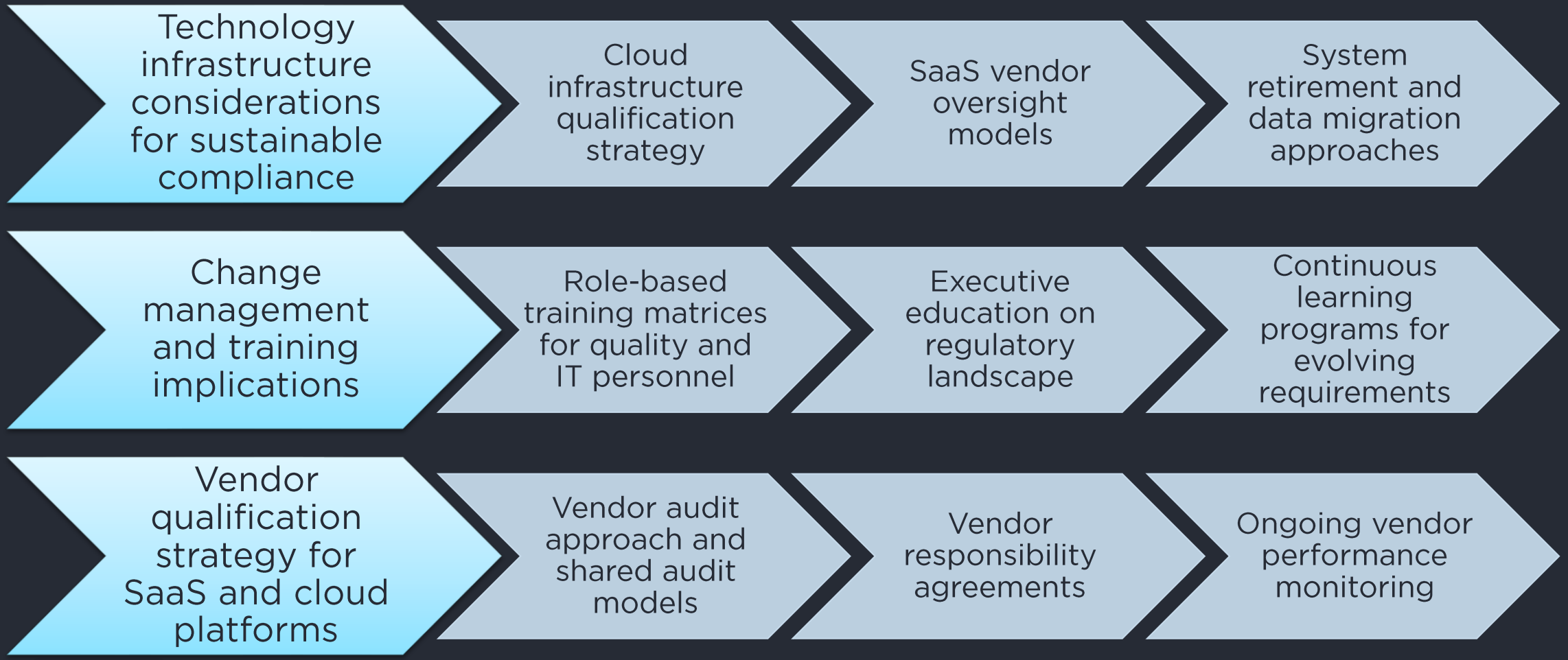
ISPE GAMP RDI data integrity risk evaluation

- ALCOA+ principles mapping (Attributable, Legible, Contemporaneous, Original, Accurate)
- Data lifecycle assessment from generation to archive
- Metadata management and audit trail review protocols

Implementation Roadmap



Implementation Roadmap



Enabling Tools and Technologies

- Validation lifecycle management systems
- Requirements and test case repositories
- Risk assessment databases
- Electronic approval workflows
- Automated testing frameworks
- Test script development for critical functionality

- Regression testing automation
- Continuous validation models
- Compliance monitoring dashboards
- Real-time compliance status visualisation
- Audit trail review efficiency tools
- Key risk indicator tracking

ROI and Business Impact Analysis

- Regulatory inspection readiness benefits inspection finding reduction metrics
- Remediation cost avoidance
- System deployment efficiency gains
- Validation cycle time reductions
- Study startup timeline improvements

Case Study 1 - Small Biotech Implementation

Company Profile

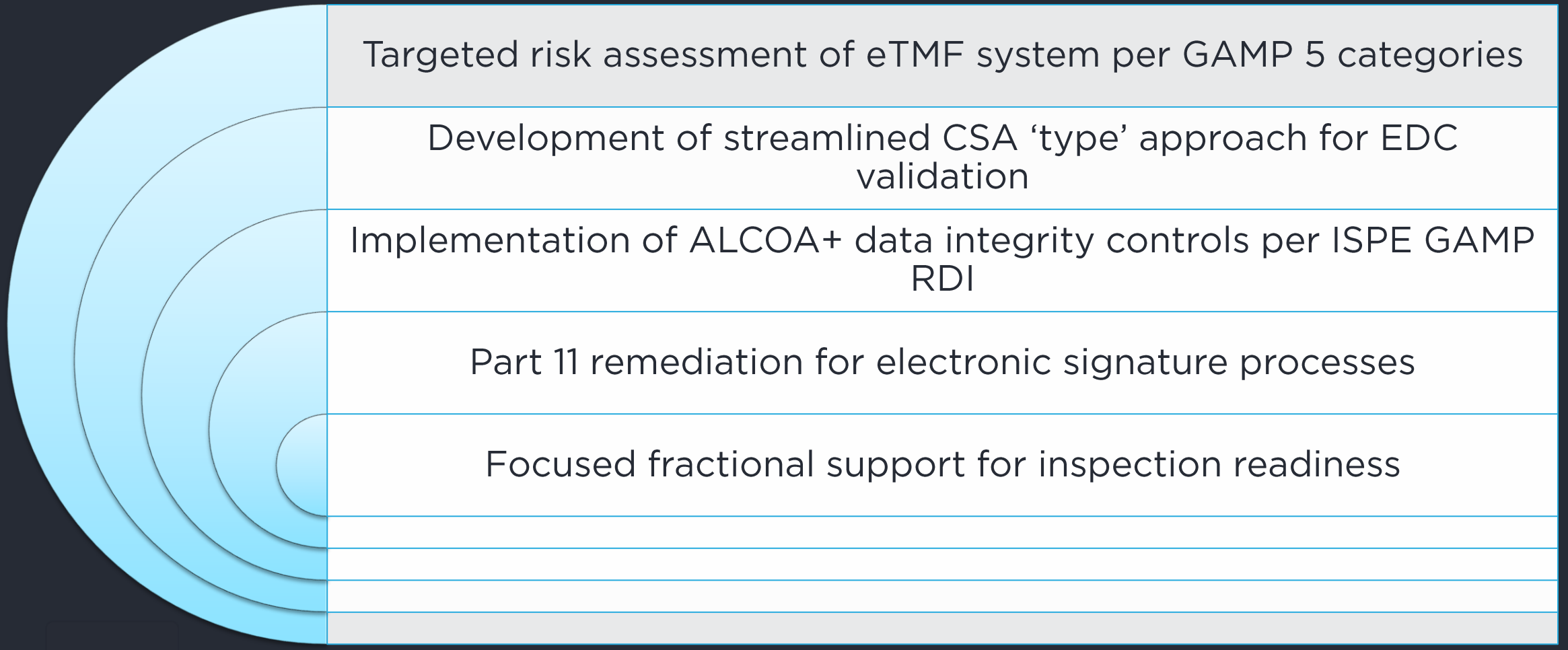
Company Profile

- Virtual CRO model with 35 employees
- Phase II oncology trials
- Limited internal IT quality resources

Challenge

- Implementing R3 principles with minimal infrastructure
- Meeting 21 CFR Part 11 requirements for critical systems
- Constrained budget and timeline
- Regulatory inspection preparation

Fractional IT Quality Solution



Outcomes

- Approx. 60% reduction in validation documentation
- Successful regulatory inspection addressing Part 11 and ICH E6 requirements
- Enhanced data oversight despite limited resources
- Patient data integrity maintained per ISPE GAMP RDI principles
- Seamless integration of eTMF and EDC systems per EMA computerised systems guidance
- Compliance achieved with minimal internal resource burden

Case Study 2 - Mid-Size Pharma Implementation

Company Profile

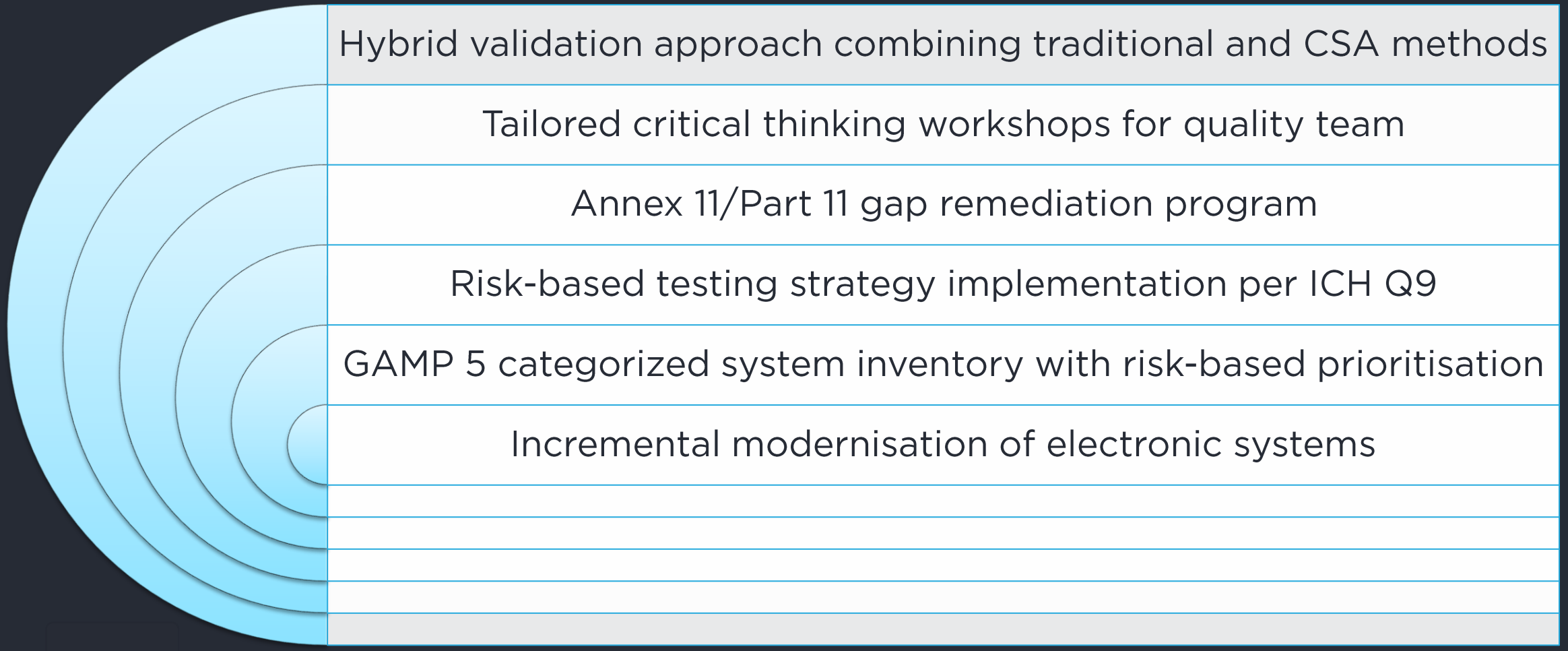
Company Profile

- 250 employees across 3 sites
- Multiple Phase II-III CNS studies
- Established but outdated quality systems

Challenge

- Legacy systems requiring modernisation to meet risk proportionate requirements
- Complex integration requirements between clinical and quality systems
- Balancing GAMP 5 and CSA approaches
- Resistance to change from established team

Fractional IT Quality Solution



Outcomes

- 45% faster validation cycles through risk proportionate GAMP 5 and CSA approach
- Improved cross-functional collaboration across quality and IT
- Enhanced remote monitoring capabilities meeting ICH E6 R3 expectations
- Successful migration to 21 CFR Part 11 and Annex 11 compliant platform
- Comprehensive data integrity controls aligned with ISPE GAMP RDI guidance
- Increased sponsor confidence in data quality and regulatory readiness
- Significant reduction in audit findings across multiple regulatory domains

Case Study 3 - Global Pharma Implementation

Company Profile

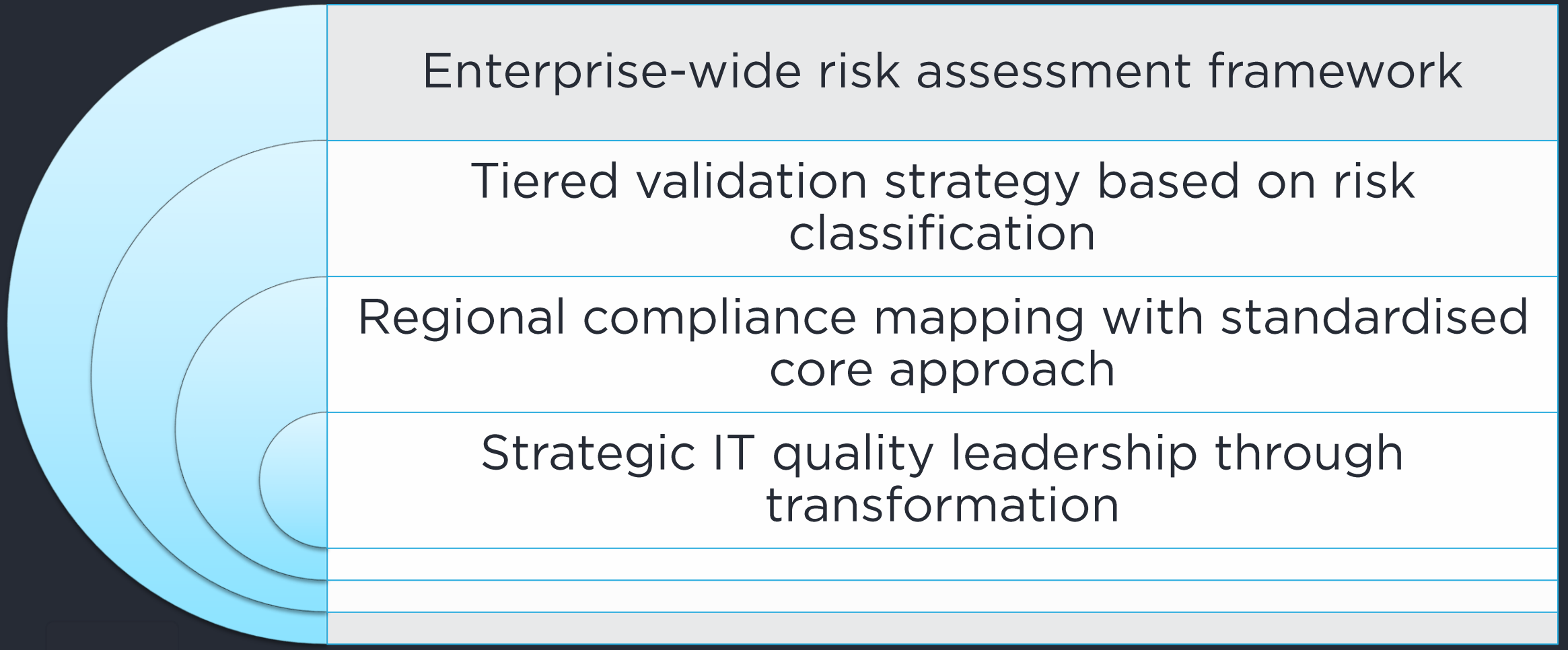
Company Profile

- Multinational pharmaceutical company
- 25+ concurrent studies across therapeutic areas
- Complex regulatory environment

Challenge

- Inconsistent quality processes across regions
- Multiple legacy systems requiring harmonisation
- Need for standardised approach while maintaining regional compliance

Fractional IT Quality Solution



Outcomes

- Harmonised approach across global operations meeting varied regional requirements
- 70% reduction in validation effort for low-risk systems
- Enhanced data integrity controls satisfying ISPE GAMP RDI expectations
- Comprehensive compliance with FDA, EMA and ICH requirements in a unified framework
- Accelerated study startup timelines through risk-based validation prioritisation
- Improved patient experience through streamlined technology interactions
- Seamless regulatory inspection performance across multiple agencies
- Single validation packages addressing multiple regulatory requirements simultaneously

Conclusion and Key Takeaways

The Strategic Value Proposition

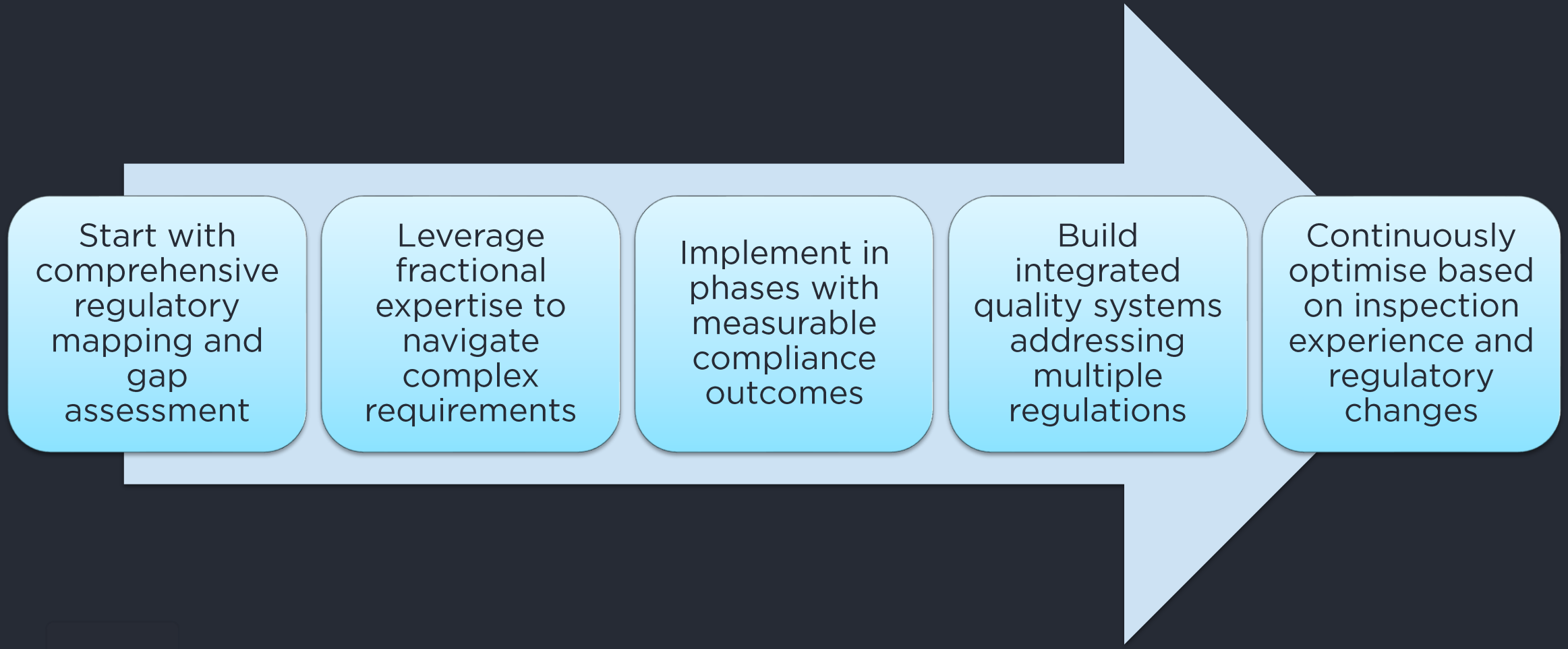
Unified compliance approach across multiple regulatory frameworks

Enhanced quality with optimised resource utilisation

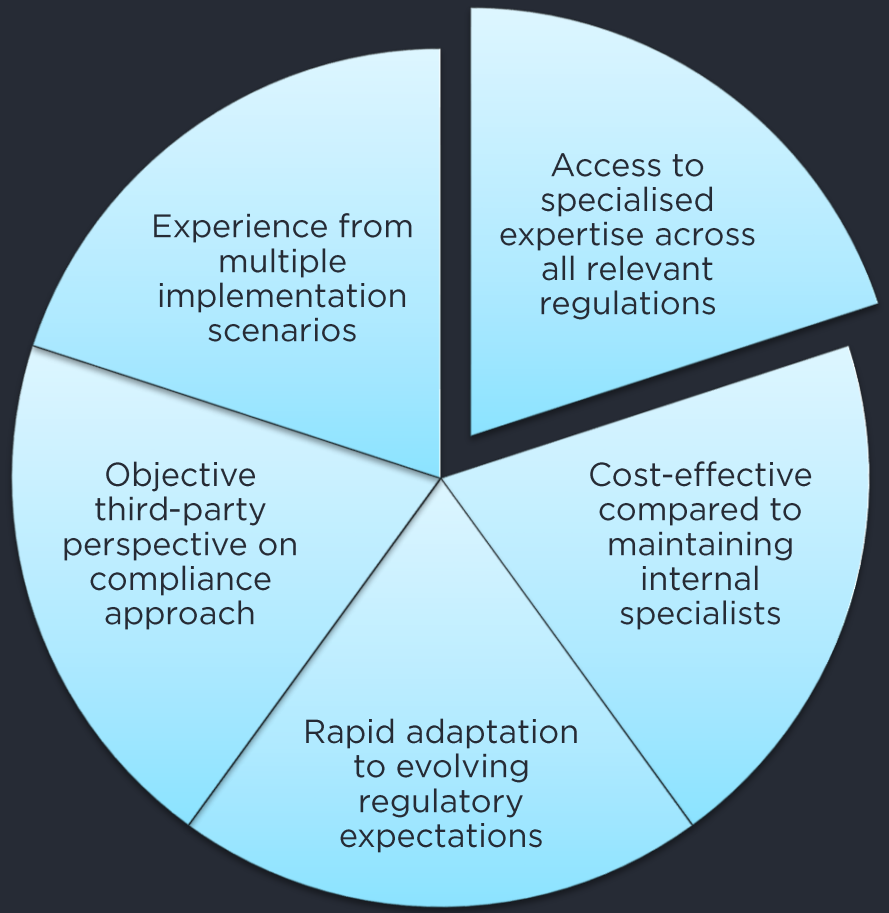
Scalable fractional support solutions for organisations of all sizes

Focus on what matters: patient safety and data integrity across global requirements

Implementation Path



The Fractional Advantage



Looking Forward

- The converging regulatory landscape and harmonisation trends
- Emerging technologies and their validation implications
- AI and machine learning in validation approaches
- Becoming a leader in modern quality approaches
- Preparing for the next wave of regulatory evolution

Thank you for listening

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