

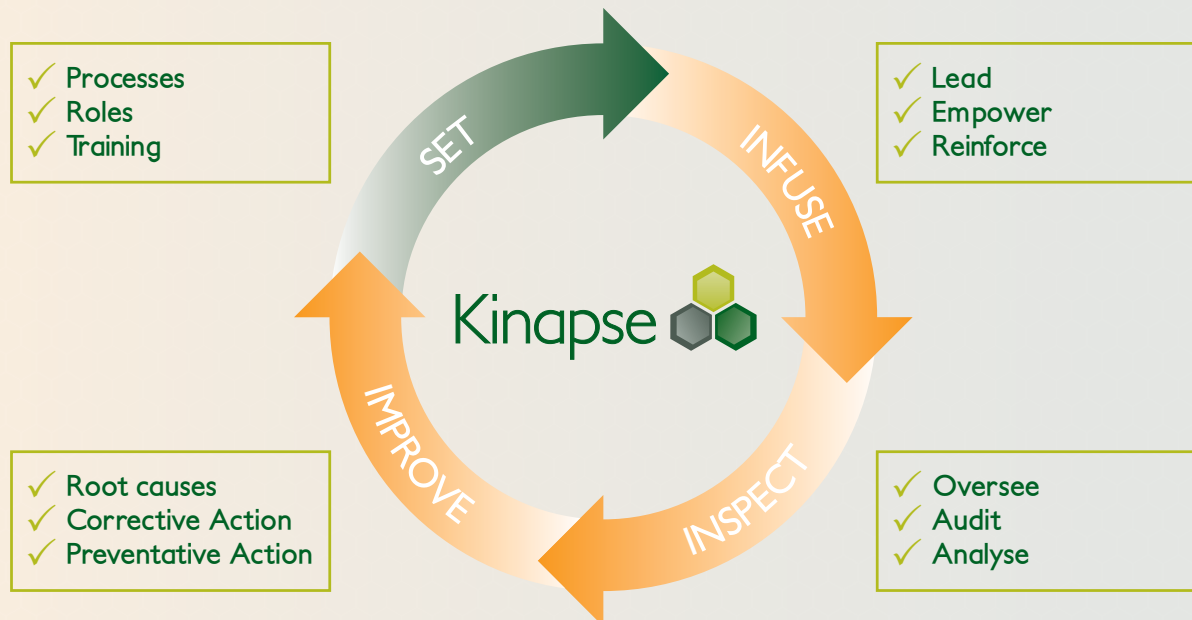
Quality & Compliance Services



We believe that quality must be owned by the whole organisation. A quality culture must be firmly embedded in each and every part of the business to make it successful.

Kinapse helps clients establish industry-leading Quality & Compliance organisations, build quality into all aspects of R&D from the start, manage risk with limited resource, and meet the varied challenges facing Quality & Compliance today.

Embedding Quality & Compliance in the organisation



Benefits to our clients include:

- ▶ We understand the complex issues faced throughout the life sciences value chain and offer innovative insights, advice and delivery to all functional areas
- ▶ We form strong, trust-based relationships with our clients' personnel at all levels
- ▶ We have built an extensive network of industry experts with senior leadership experience in leading global pharmaceutical, biotechnology and device companies as well as service providers
- ▶ We deliver innovative solutions through our blended onshore-offshore delivery model and hold ourselves accountable to results

Quality & Compliance Services

Recent Kinapse Quality & Compliance Projects

R&D Quality Assurance Redesign

Kinapse helped re-build an R&D QA organisation which had failed to meet customer needs. We designed and implemented a new operating model and re-evaluated the entire portfolio to implement a risk based approach to auditing.

Promotional Compliance Improvement

Kinapse designed a global process for review and approval of promotional materials in a global healthcare company. We created a robust, streamlined process that clearly separated responsibilities at regional and local level and helped improve the quality of promotional materials.

Inspection Readiness

Kinapse worked with a major specialty pharma company to complete GxP inspection readiness activities. We identified risk areas and implemented mitigation strategies, provided inspection training and overall project management support.

SOP Remediation

Kinapse worked with a top-10 global pharma company to bring a large number of clinical SOPs into line with company policies and streamline them. Onshore process mapping was followed by offshore delivery of revised SOPs, providing significant cost advantages.

Kinapse Services in Quality & Compliance include:

Consulting

- ▶ Organisation-wide quality and compliance strategy
- ▶ Audit practice redesign
- ▶ Risk mapping
- ▶ Inspection readiness assessment and planning
- ▶ GxP training
- ▶ Healthcare compliance approval process improvement
- ▶ CAPA process improvement
- ▶ IT solution selection and implementation

Outsourcing

- ▶ SOP development and maintenance
- ▶ SOP/Procedure GAP analysis
- ▶ GxP auditing
- ▶ Clinical trial disclosure support
- ▶ Medical writing
- ▶ Pharmacovigilance
- ▶ Regulatory, CMC and Publishing Operations

Contact Information

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Suzanne Budsworth

Suzanne has over 20 years of pharmaceutical industry and consulting experience. She has consulted extensively on the design and implementation of effective R&D quality and compliance organisations.

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Collaborating with our clients to innovate for exceptional results

www.kinapse.com

