Kite Pharma R&D Quality Internship

Devon B. Cooper, RDQ Intern – Technical Intern V
Caitlin Fisher - Manager, R&D Quality; Marjorie Stevenson - Associate Director, R&D Quality

What is R&D Quality?

Supports R&D related functions to ensure compliance to health authority regulations, guidances, and procedural documents.

- Change Management
- Corrective & Preventative Action (CAPA)
- Management Responsibility
- Resources
- Product Surveillance
- Design Control
- Process and Production Control

Quality GCP Training Game

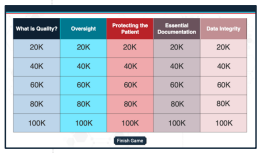
Goal: Create a fun and engaging way for RDQ to introduce and review Quality & GCP topics with other R&D functional areas

Deliverables

- Companion Game for new Quality Program
- Master List of Questions
- Game Template

Team Impact

- Flexible & adaptable training tool
- Alignment with department goals
- Foster a quality culture
- Increase employee engagement
- Real time feedback



Key Take Aways

Inspection Preparation

Why is it Important?

- Ensures compliance and readiness for regulatory inspections conducted by agencies such as the FDA (USA), EMA (Europe), or PMDA (Japan)
- Involves significant coordination including comprehensive planning, effective documentation practices, rigorous training, risk management, and understanding of the regulatory requirements

Preparation Activities

- Reconcile clinical trial timelines and SOP documentation
- Prepare common inspection documents and templates
- Conduct gap analyses
- Collect clinical trial contracts and coordinate mock inspections

SOPs & Trainings

Standard Operating Procedures (SOPs)

- Establish consistent practices and procedures within the organization
- Reduces variability in operations
- Enhances product quality and reliability
- Provide documented evidence of compliance
- Serve as crucial training documents

Why is Employee Training Important?

- Understand their responsibilities
- Develop necessary knowledge and skills
- Adhere to standardized practices

Audit Report Knowledge Gap Analysis

Conduct a training gap analysis to understand the current audit report writing skills of GCP auditors

- Support creation of future trainings that meet the team's collective needs effectively

Compliance

Regulatory Compliance

- Involves adhering to laws and regulations set by governmental agencies or regulatory bodies
- Following guidelines such as Good Clinical Practices (GCP) and Good Manufacturing Practices (GMP)

Why is it Important?

- Ensures the company operates responsibly, ethically, and in accordance with applicable laws and standards
  - Protecting Patients
  - Ensuring product quality
  - Managing Risks

QA-QA Collaboration Meetings

- Learn about collaboration expectations and delegation of responsibilities
- Gain practical experience with document and relationship management

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2024 Intern Cohort