

Establishing a Culture of Quality in Clinical Trials

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Is there any area where quality is more paramount than in clinical research?



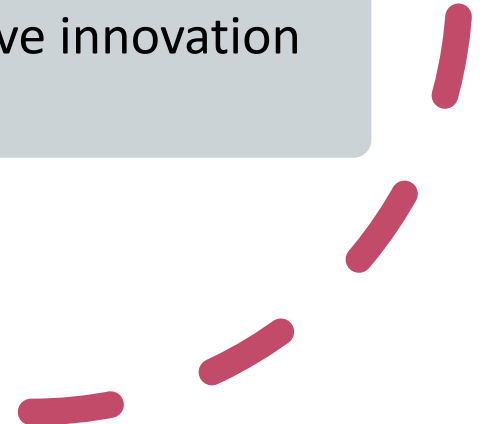
Are the traditional quality management tools and metrics enough?



What are the strategies to embed quality deep in the clinical research culture?



How would the culture of quality drive innovation in clinical research?



Agenda

- Introduction
- Defining Quality and Culture
- Embedding the Culture of Quality in Clinical Research
- ICH Guidelines
- Quality by Design
- Culture of Quality Enablers
- Critical Thinking and Open Dialogue
- Conclusion



What is Quality?

How well a product is suited to the purpose it was made for



A variety of perspectives

- Employees perceive Quality as the overall value they derive.
- Customers view Quality as meeting their needs and expectations.
- Organizations define Quality in terms of customer satisfaction, higher profits and market share.



The common element

- Quality drives trust and enhances reputation—it's the foundation upon which lasting professional partnerships are built.
- In a world where competition is fierce, Quality is not just a goal—it's the standard for success.



The Ecosystem Balance

- As a thriving ecosystem relies on the balance between species, processes, and environmental factors, in an organization Quality depends on every team member.
- When we address weaknesses, foster collaboration, and adapt change, we create a resilient ecosystem of excellence.

What is Culture?

A central concept in anthropology, an intrinsically human attribute and not just a buzzword



Culture encompasses the social behaviors, institutions, and norms in human societies.



Culture includes the knowledge, beliefs, arts, laws, customs, capabilities, and habits of the individuals in these groups.



Culture is transmitted through social learning in human societies.



Culture is deeply rooted in our social nature and capacity to evolve through experiences, emotions, and interpersonal connections, setting us apart from artificial intelligence.

The Culture of Quality

Embedding it in clinical research



The Culture of Quality

The Ecosystem of Excellence

Realizing the Value of Culture

- Culture is the invisible thread that weaves through our interactions, shaping our behaviors, beliefs, and norms.
- There's something uniquely human about culture—it's deeply rooted in our social nature and unlike artificial intelligence, which lacks this intrinsic quality, this is our environment to thrive.
- As professionals, we're part of a larger ecosystem, and our actions ripple through it.

Quality Beyond a Buzzword

- Quality isn't an abstract concept; it's the bedrock of trust.
- Quality isn't a goal; it's the standard for success.
- When we prioritize quality, we build trust – the currency of professional relationships.

Bringing it all together

- Imagine an ecosystem—a delicate balance of species, processes, and environmental factors. Similarly, within organizations, quality depends on every team member.
- Let's embrace Quality and make it our way-of-living, weave it into our Culture – our distinctively human trait – as the Culture of Quality.

ICH E6(R2)

Quality by design



Proactively building quality into trial design.



Starting in the early planning stages.



Spanning operational and design groups.



ICH E8(R1)

The culture of quality

Importance of Culture in Clinical Studies

- ICH E8(R1) emphasizes the need for a supportive culture
- Encourages behaviors that sustain quality

Critical Thinking and Open Dialogue

- Values and rewards critical thinking
- Promotes proactive dialogue about quality

Moving Beyond Tools and Checklists

- Encourages innovative methods for ensuring quality



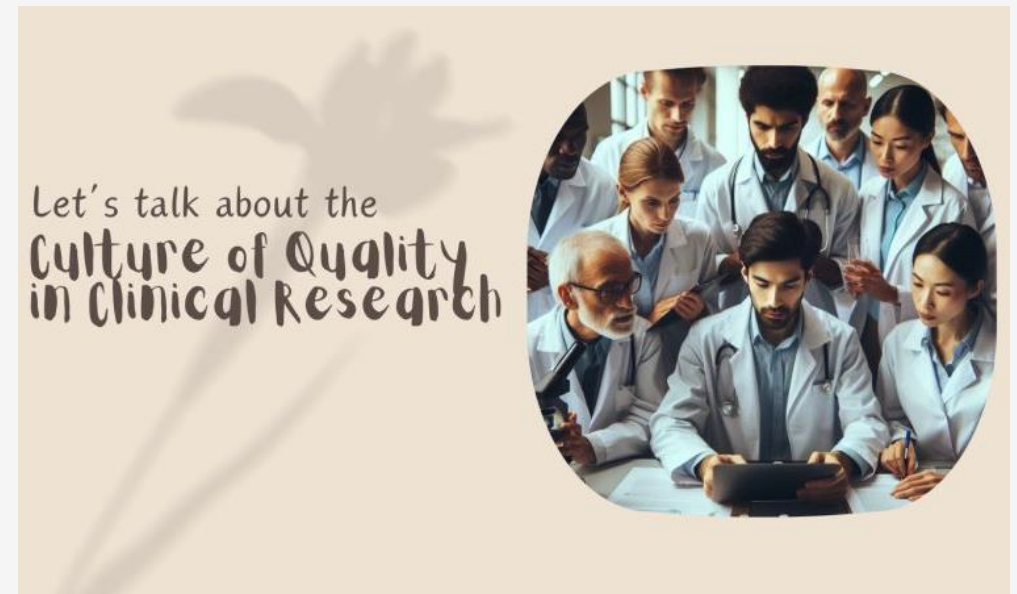
Draft ICH E6(R3)

Building on ICH E6(R1) and ICH E8(R1)

Highlights the regulatory expectation of a Culture of Quality into the operational aspects of the practices for clinical development

Builds upon, provides in-depth information and operationalizes the ICH E6 and E8 requirements

Reinforces concepts introduced in ICH E8(R1) which requires quality be managed through a Culture of Quality with human behaviors such as Critical Thinking and Open Dialogue.



The Culture of Quality

The layers

Quality Management System Framework

Risk and issue
management

Measuring quality

Management
review

Knowledge
management

Continuous
improvement

Robust
documentation

Culture of Quality Enablers

Leadership
Commitment

Employee
Ownership

Critical Thinking

Open Dialogue

Quality by Design

Patient Safety

Data Integrity

Quality by Design

Identifying Critical to Quality Factors

Study objectives are specific, scientifically valid and meaningful to patients.

Design and data sources meet objectives efficiently.

Operational feasibility is ensured without unnecessary complexity in study designs.

Compliance to the protocols is ensured without unnecessary data collection.

Patient and public health remains a priority.

Non-essential activities are avoided for trial efficiency.

Resources are directed to critical areas.

Quality by Design

Engaging Stakeholders in Study Design

Importance of stakeholder input early in the study design

- Includes patients and healthcare providers.
- Open to challenge by subject matter experts

Building Quality into the Study

- Involves clinical investigators and study coordinators.
- Getting insights into feasibility of enrolling participants.
- Assessing the relevance of study endpoints and settings.

Early Engagement with Regulatory Authorities

- Encouraged for studies with novel elements.
- Critical to quality aspects like patient populations and procedures, are discussed.



Quality by Design

Reviewing Critical to Quality Factors

Accumulated experience and knowledge supports determining necessary adjustments.

Periodic review helps address new or unanticipated issues.

Specific attention needed for studies with adaptive features during proactive planning.

Risk management is crucial (ICH E9 Statistical Principles for Clinical Trials).



Quality by Design

Ensuring Quality in Operational Practice



Feasibility assessment considering the study design, implementation elements and the impact on successful completion of clinical development.



Regional differences considering medical practice variations and patient population differences.



Qualified and experienced investigators/site personnel considering experience in conducting clinical studies.



Availability of equipment and facilities which are required for successful study conduct.



Leadership Commitment

Influencing Organizational Change

Set	the tone for quality by demonstrating commitment to excellence and high standards in every aspect of the work
Inspire	employees to prioritize quality
Support	the development of quality goals and align rewards and recognition with the quality goals
Empower	employees to identify and address issues promptly
Emphasize	that root cause analysis is needed to prevent recurrence and embrace a culture of continuous improvement
Adopt	blame-free environment to encourage open dialogue
Ensure	continuous learning, ongoing education, skill development across the organization staying updated on industry trends



Employee ownership

A sense of responsibility

Develop

a sense of responsibility

- Quality becomes everyone's responsibility.
- Everyone participates in maintaining and improving quality.
- Ownership extends beyond specific roles or departments.

Ensure

documentation for Quality Objectives

- Maintain records to support quality achievements.
- Document processes and outcomes to meeting quality standards.

Partner

with Quality Assurance (QA)

- Engage in open dialogue with QA teams.
- Seek opportunities to enhance critical thinking skills.



Open Dialogue

Overview

Accessing and exchanging data and information

- Ensure transparency and openness.
- Promote collaboration and understanding.

Leveraging diverse intellectual capital

- Utilize varied expertise and perspectives.
- Encourage innovative solutions and ideas.

Engaging the team

- Foster collaboration and trust.



Open Dialogue

Data access and exchange



Ensure data availability to the right team members.



Share data, knowledge, and information at the right time.



Ensure competency in analyzing data, distilling them into usable inputs before metabolizing and implementing in day-to-day actions.



Ensure user-friendly systems as these are essential for democratizing data.

Open Dialogue

Leverage diverse intellectual capital

Leverage diverse intellectual capital in a 360° manner including

- regulatory, Inspection, and Quality Intelligence.
- proactive exchange with stakeholders outside the organization.

The value of mastering intellectual capital for the team includes

- benefit from composite information from systems and intelligence databases.
- learning from each other and subject matter experts.
- effective management of quality risks and issues.

Open Dialogue

Team engagement

Early and regular discussions involving quality team members and the trial centers is

- fundamental to effective communication.
- critical for proactive risk identification and control.

Team transparency is crucial for mitigation as

- teams need support to work through risks and issues.
- applying across all functions and levels of an organization.

Forums for discussions within communities beyond team meetings for sharing

- effective risk controls.
- lessons learned sessions post-audit or inspection.

Potential strategies for engagement may include

- podcasts and interactive polling.
- breakout sessions and workshops.

Critical thinking

4 As of Critical Thinking

Answering the question

- for priorities previously defined.

Acting upon the answers

- so that the practice is action oriented.

Asking questions proactively

- with the cycle beginning again with new questions.

Analyzing the data related to the questions

- to ensure the process ends with meaningful activity.



Maturity Models for the Culture of Quality

The value

Quality performance systems and analytics models

- User-friendly systems to assess clinical enterprise health quality performance.
- Require data linking, normalization and standardization within the clinical development ecosystem supported by ML/AI.

Purpose of maturity models

- Self-assessment.
- Determine baseline for the enabler components.
- Identify necessary actions for quality performance improvement.
- Address deficiencies and develop competencies.

Benefits include

- Benchmarking growth and report progress.
- Properly document risks and mitigations.

The Culture of Quality in Clinical Research

Summary of the key points

Leadership vision and commitment

- Leaders in clinical development “walk the talk” on quality.
- Leaders emphasize the importance of quality when evaluating their teams.
- Leaders deliver credible and consistent messages on quality.

Clinical Research Team Ownership

- Everyone clearly understands how quality fits with their day-to-day work.
- Everyone feels comfortable raising concerns about quality violations and challenging directives that detract from quality.

Critical Enablers

- Encourage open dialogue, going beyond checklists or tools.
- Include patients, healthcare providers, and other stakeholders early in the study design process.
- Their insights can guide decisions related to study endpoints, patient populations, and safety measures.
- Foster a critical thinking framework : asking, analyzing, improving, acting, and iterating.
- It’s about nurturing an environment where team members can discuss, challenge assumptions and improve quality practices.

Final thoughts

Driving innovation

The Culture of Quality is not just about rules.

It's ingraining excellence into daily habits.

Open dialogue, critical thinking, leadership, commitment, and employee ownership are the key enablers.

To support operational implementation, we need a roadmap for cultural growth and initiatives at every level

This is where innovations starts.

The generated value touches sponsors, services, vendors, and first and foremost patients!



References

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