From Process to Culture: Build Research Integrity Through Design-Driven Compliance

YU Lan, WAN Kah Fei
Experimental Drug Development Centre (EDDC)

Introduction: Rethink Research Integrity

In today's dynamic research environment, real integrity isn't achieved through checklists, it's built into how we plan, decide, and work every day. It must be designed into daily practice, not added as an afterthought.

At EDDC, we adopt a design-driven approach that makes integrity intuitive, embedded, and shared, not enforced. Guided by **ISO 9001 principles** and **ICH Q10's Quality by Design (QbD)** framework, we've built systems that support good research practices from the earliest stages, including discovery and preclinical research.

Highlights

- Built a fit-for-purpose Quality Management System (QMS) tailored to research workflows
- Transformed SOPs into user-friendly tools
- Rolled out modular, role-based training for targeted learning
- Made compliance a byproduct of intuitive, well-designed systems

Common Pain Points in Compliance

🧩 When Processes Don't Match Practice

- 📄 SOPs feel disconnected from real workflows
- 📝 Too much documentation, too little clarity
- 👥 Unclear ownership in shared workflows

🧠 When People Don't Feel Equipped

- 🎓 Training is too generic
- ❓ Fear of getting it wrong discourages questions
- ⏳ Compliance activities are seen as extra, not integrated

🧬 When Systems Feel Reactive, Not Supportive

- 🧩 Uncertainty in authorship and credit
- 🚨 Oversight seen as reactive or punitive
- 🔁 Repetitive errors aren't addressed systemically
- 🤖 Lack of guidance for new technologies

Our Design-Driven Interventions

🧩 Co-Create Processes That Make Sense

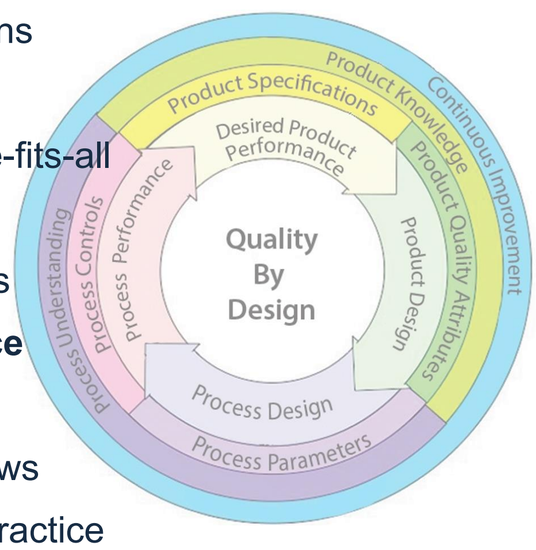
- 🤝 Engaged users before designing anything
- 🧭 Used design to make integrity intuitive, not forced
- 🗂️ Tracked changes with clear justifications

🧠 Equip People at the Right Time

- 📚 Delivered training by role, not one-size-fits-all
- ✅ Built checklists into daily workflows
- 💬 Created space for ethics conversations

🧬 Build Systems That Enable, Not Enforce

- ⏳ Designed a QMS that fits how we work
- 🔄 Replaced audits with risk-based reviews
- 🏅 ISO 9001 certified, grounded in real practice
- 🔧 Compliance flows from good design, not oversight



Culture Shift & Future Ready

Compliance Burden → Shared Culture of Integrity

💡 Colleagues' Insight

Make QMS Work in Practice

The ISO 9001 quality management principles have been instrumental in shaping *EARO's QMS. They've guided how we design our processes and ensure our service workflows are consistent and customer-focused. Our QMS software has been valuable for systematically managing training assignments and reminders, providing direct access to latest work instructions, and templates, streamlining SOP updates and notifying affected teams quickly.

QMS reviews, like our annual management review, allow us to evaluate performance, track risk mitigations, and drive continuous improvement.

**EARO: EDDC Academic Research Organisation, a fee-for-service initiate by EDDC.*

Embed Quality into Project Planning & Documentation

We have implemented structured processes to support consistent decision-making, ensure traceability, and improve project planning across the research lifecycle; including project governance, risk log, presentation materials and meeting minutes management.

We've also established supporting infrastructure to ensure high-quality documentation and records management; including centralised recordkeeping, electronic lab notebook (ELN), work instructions for grants, publications, and technical disclosure reviews, etc.

Enhanced SOP for Human Biomedical Sample Handling and Compliance Management

All human tissue samples are recorded and tracked using an electronic inventory system, ensuring full traceability. Personnel involved in sample handling have completed mandatory retraining aligned with the updated SOP.

To maintain compliance, risk based annual internal reviews and monitoring are conducted, with follow-up actions tracked to ensure proper resolution.

Future-Ready Research Integrity

As research evolves, so must our systems. Being future-ready means designing for **flexibility, awareness, and accountability**, especially in areas where standards are still emerging.

🧠 Ethical Use of AI and Automation

We've started conversations around responsible use of generative tools.

📊 Scalable and Adaptable Processes

SOPs, templates, and checklists are designed to scale across diverse projects.

🛡️ Proactive Risk Thinking

Risk logs and built-in review checks help teams anticipate issues early and take action before problems escalate.

🌐 Stronger Digital Foundations

Tools like ELN and QMS software enable real-time documentation, training, and traceable process oversight.

🌱 What Does Good Look Like in Your Setting?

Are your SOPs clear and usable in real-life work?

Are compliance activities integrated into daily work or added on top?

How is your organisation preparing for challenges like AI in research?

Acknowledgements & References

We thank our colleagues across EDDC for their contributions in shaping our quality practices, especially the EARO, and Project Management teams. Special thanks to those who shared user feedback and helped co-develop our SOPs, training modules, and digital tools.

Key frameworks referenced:

- ISO 9001:2015 Quality Management Systems – Requirement
- ICH Q10: Pharmaceutical Quality Systems
- Internal guidance and insights from QMS implementation and user engagement