"We look at our 6 EQMS modules like the quality Infinity Stones."

Laura Cox, Lead Responsible Person, CST Pharma

CST Pharma: Good Distribution Practice with EQMS



- UK's leading specialist in parallel import and export of branded pharmaceuticals and medicines
- Global supply chain to hospitals, pharmacies, wholesalers and clinical trial providers
- Licensed and regulated by the MHRA and the principles of Good Distribution
 Practice (GDP) and ISO 9001:2015



Good Distribution Practice guidelines



Chapter	Why we do it	How we do it
1. Quality management	Continuous improvement, consistent quality of distributed product	EQMS (all modules)
2. Personnel	Trained, responsible personnel, hygienic and compliant working	Training Records Manager, Document Manager
3. Premises & equipment	Safe, suitable and efficient operations	Audit Manager, Equipment Manager
4. Documentation	Traceable, standardised processes and procedures	Document Manager
5. Operations	Competitive advantage	Audit Manager, Issue Manager
6. Complaints/returns	Happy, satisfied customers, full control of product lifecycle	Complaints Manager
7. Outsourced activities	Qualified suppliers, protected supply chain, controlled contractual activities	Supplier Manager
8. Self-inspections (audits)	Identification of risks and opportunities, continuous improvement, preparation for MHRA inspections	Audit Manager, Inspection Manager
9. Transportation	Compliant containers, packaging, labelling, transport for special pharmaceutical conditions	Audit Manager, Document Manager
10. Specific provisions for brokers	Standardised, compliant and ethical broker relationships	Supplier Manager

EQMS in CST Pharma

- Introduced in 2019
- Modules:
 - Document Manager
 - Training Records Manager
 - Audit Manager
 - Issue Manager
 - Risk Manager
 - Equipment Manager
- Integrated system for embedded GDP
 - Spreadsheets and paper-based systems eliminated
 - Centralised source of truth for documents and training
 - Prompts and reminders for continued compliance
 - Complaint, return and recall management
- New audit and supplier/customer management processes planned for Phase 2





1 single source of truth: 50+ ways organisations use EQMS



Comply with global regulations and standards

- ISO 9001
- ✓ ISO 14001
- ISO 22301
- ISO 37001
- ISO 27001
- ✓ ISO 13485
- ✓ ISO 45001
- ✓ ISO 28000
- ✓ ISO 22000
- ✓ BS ISO 10001
- ✓ ISO 31000
- 🖌 ISO 14971
- ISO 50001
- 🗸 ISO 19011

- 🗸 ISO 41001
- ✓ IATF 16949
- ✓ BRC
- ✓ SMETA / SEDEX
- 🗸 HSE
- 🗸 CLP
- 🗸 FDA
- 🖌 MHRA
- 🗸 FCA
- 🗸 GDPR
- ✓ Modern Slavery Act
- ✓ REACH / HACCP
- 🗸 GxP

Control process & apply your methodologies:

- Document control
- ✓ Audit management
- Incident / accident management
- Supplier management / custom supplier portals
- ✓ Employee competence
- ✓ Risk management
- ✓ Gouernance best practice
- ✓ Inspection management
- ✓ NCR / CAPA
- Equipment maintenance and calibration
- ✓ SOP / policy management
- ✓ Customer feedback

- Lean Six Sigma / DMAIC
- 🗸 8D
- ✓ APQP / PPAP
- Privacy by Design
- 🖌 BI reporting
- ✓ Voice of Customer, NPS
- Data and record management
- War room preparation / inspection readiness
- Risk register
- Privacy by design
- Workflows / action-based triggers
- Demonstrate compliance

Why EQMS?

Qualsys

EQMS evolves with your business

- 1. Available in 15+ languages
- 2. Mobile applications
- 3. Free end users
- 4. Advanced permission controls
- 5. 8 configurable modules 'pick and mix' what you need
- 6. Easier, faster certification to ISO standards
- 7. Quick, systematic migration of your data
- 8. Microsoft Outlook integrations
- 9. World class best practice, 1-day-per-module implementation process
- 10. High levels of support
- Assisted validation journey compliant with FDA / MHRA GAMP 5 category 4 methodology

Good Distribution Practice every time

CST Pharma are the UK's largest international wholesaler and distributor of pharmaceutical and medicinal product.

The CST Pharma quality team work to the requirements of Good Distribution Practice (GDP) to ensure safe and timely delivery of product to hospitals, clinics, clinical trial providers, pharmacies and NGOs.

CST Pharma implemented δ EQMS modules in 2019 to cement GDP in a coordinated system managing:

- Documentation
- Training
- Issues and actions
- Risks
- Auditing
- Equipment and assets

qualsys.co.uk/case-studies/cst-pharma-good-distribution-practice/



3 recommendations:

- 1. Browse <u>qualsys.co.uk/case-</u> <u>studies/cst-pharma-</u> <u>good-distribution-</u> <u>practice</u> for more information
- 2. Review your existing systems: can EQMS save us money and harmonise group activity?
- 3. Request a custom demonstration of EQMS here: <u>quality.eqms.co.uk/eqms-</u> <u>software-demonstration</u>

