UQMC
QMS Consulting Services

case study

eQMS Effectiveness Review

Urmi Quality Management consulting was contacted by a pharmaceutical CDMO to review and perform an effectiveness check of their recently implemented eQMS.

Challenges

- The eQMS software had been selected & implemented during the Covid pandemic to enable the company to continue manufacturing during the lockdown period. The implementation had been swift with little to no involvement of functions other than QA.
- Staff who had been responsible for implementation had left the organization & current QA employees did not fully understand the system.
- Complaints of the system been clunky & difficult to use were frequent
- QA and system admins had to continue to maintain manual levels of controls despite having an eQMS.
- Non-compliance issues around document management remained

Approach

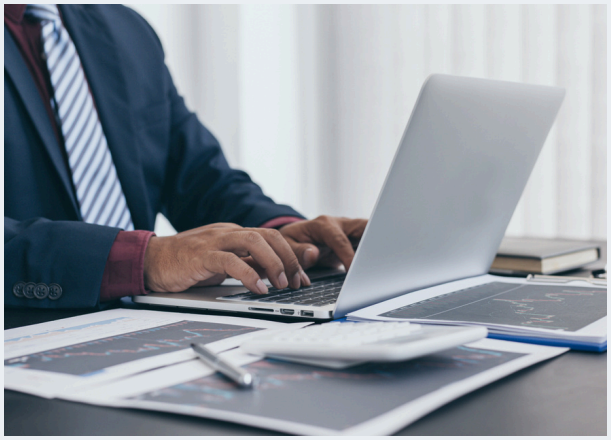
- A gap analysis of the implementation eQMS against PIC/s GMP guidance on Data integrity undertaken
- Process mapping of current document management process conducted with stakeholders
- Use of visual signs to highlight repetitive steps, non-compliance steps /Data integrity concerns
- Tailored training of all QA staff on regulatory expectations around document management & data integrity as well as the outcome of gap analysis & process mapping
- An action plan with short term remediation actions for compliance & long-term actions provided

RESULT

Increased understanding of regulatory as well as current business requirements around document management

Proactive identification of non-compliances and data integrity issues, that enabled the organization to put in remedial actions

Organization able to plan resources (human as well as capital) for changeover to a new eQMS for better compliance



Conclusion

Urmi Quality Management Consulting helped the organisation move from a fragmented, underutilised eQMS to a clear, compliance-focused path forward. By identifying regulatory gaps, mapping current processes, and delivering targeted training, Urmi empowered the QA team to understand and manage their system effectively. The result is a renewed commitment to data integrity, streamlined document control, and a practical roadmap for transitioning to a more robust eQMS—turning a struggling implementation into a foundation for future success.

+61 478816249 https://urmiquality.consulting/ Brisbane, QLD, Australia