



ISOLOCITY

A QMS tailored for the life science industry.




Pharmaceutical

- Centralize documents in Isoloccity with customizable permissions.
- Access revision history for past document versions.
- Ensure FDA compliance with Isoloccity's adherence to 21 CFR Part 11 and Annex 11.




Natural Health

- Generate out-of-specification reports per lot/batch with recorded investigation actions and outcomes.
- Escalate issues to CAPA, non-conformance, deviation, and change control processes.
- Determine if a recall is necessary based on investigation findings.



Lab

- Set up equipment maintenance schedules by assigning templates and frequencies.
- Receive automated notifications for maintenance due dates.
- Document all maintenance activities within Isoloccity.



Medical Device

- Ensure supplier compliance and performance in Isoloccity profiles.
- Manage supplier certificates and documents within Isoloccity.
- Request and receive updates directly in Isoloccity.
- Comprehensive Medical QMS for ISO 13485, MDSAP, & GMP.

We solve problems



The inspection module helps ensure that products are **within specification** before release.



We have ready-made free SOPs which will help you obtain **FDA approvals** faster.



We own every line of code in our software, giving us better control. So with Isoloccity, your data is **100% secure**.



With Isoloccity's efficient customer support, **100%** of issues are resolved within just **19 hours**, ensuring your business stays on track without delays.

Award winning platform



Companies that have trusted us



Lean Data Management with our integrations



ISOLOCITY

Meet the **most recommended** QMS of 2024



Isolocity conforms to the requirements outlined in the ISO 9001 standard for QMS and cuts certification audit time by 50%



Isolocity is 3rd party GMP validated, i.e. it effectively supports GMP compliance for regulated industries, enhancing credibility.



Isolocity meets FDA's 21 CFR Part 11 & Annex 11 standards, ensuring compliance with regulations for electronic signatures and computerized systems.



Isolocity's is compliant with SOC 2, ensuring robust security controls and protection of customer data, fostering trust and reliability.



Training

- Drag and drop test builder
- Link documents for revision training
- Track training insights
- Automate by scheduling a repeat frequency
- Train employee groups
- Track employee certifications



CAPA

- Custom built workflows and routings
- Automatically triggered for issues or events
- Activity due dates and reminders
- Use for deviations, non-conformances, out of specifications, complaints and change control



Document

- Categorize documents, keep track of version history
- Set review frequencies with multi-stage approval
- Link documents with change control and training
- Create hierarchy for document with child-parent linking



Lot & Batch

- Generate your EMBRs using our template builder
- Track every batch to inspection/documentation from raw material to final production
- Recall defective products instantly and track specific problematic raw materials



Risk Management

- Mitigate risks and drive PDCA for improvement
- Built-in HACCP and PFMEA risk management report
- Prepare and adapt before any issues arise



Part inspection & SPC

- Input inspection records directly into your QMS and track all data real-time including SPC data and inventory levels
- Proactively re-calibrate machine before creating waste
- Re-order raw material before your product even comes out of production.



Supply Chain

- Isolocity supplier portal tracks certificates and progresses any related quality events.
- Enable supply chain traceability
- Automate supplier scorecards



Internal Audit

- Automate audits with our audit workflow builder
- Set up frequencies and drag & drop template builder
- Manage all your audits : internal, supplier, regulatory, etc



Templates

- Create inspection criteria while storing characteristic information for generating process and item inspection
- Revision controlled templates that follow 21 CFR Part 11 guidelines
- Clone existing templates for similar items and processes



Dashboard

- Centralized dashboard for your compliance management system
- Action items and visual management enable efficient navigation
- All your key metrics at one place for quick review