# Entering a transitioning market with unshakeable quality credentials

KAZMIRA™

| | |
|---|---|
| **Industry** | Cannabis |
| **Regulations** | • ISO 9001<br>• FDA 21 CFR Part 111 (cGMP)<br>• Colorado, California, Oregon state regulations |
| **Uses Qualio for** | • Documents<br>• Training<br>• Events<br>• Suppliers |

## About Kazmira

Kazmira is a Colorado-based manufacturer of hemp-based cannabinoid products, including CBD oils, tinctures, topicals and edibles.

## The challenge

The cannabis and CBD market remains in a period of transition, teetering between legality and illegality on a state-by-state basis. In an immature market without widespread recognition, earning regulatory trust and proving quality with strong manufacturing processes is vital.

Kazmira operated a highly manual paper-based quality system supported by SharePoint and spreadsheets. Kazmira leadership felt that FDA cGMP requirements couldn't be met with this approach, and in early 2021 the company began the search for a digital quality system.

**96%**

Reduction in quality info retrieval time

**10 hours**

Saved every single week by ditching manual quality admin tasks

**99%**

Of employees have complete up-to-date training for their roles

"It looks good when we tell other companies that we have an electronic system and we're working in a compliant space with a compliant system. We really appreciate Qualio!"

**— Hanna Fanous**

Quality Assurance Supervisor, Kazmira



# The solution

Quality Assurance Associate Hanna Fanous began working with a consultant and former FDA auditor to pinpoint the optimal eQMS.

Qualio was identified as the system which best balanced price and usability and which could best allow Kazmira to hit their quality objectives.

With a structured validation, train-the-trainer and document migration approach, Kazmira could implement and begin applying Qualio quickly, transitioning to a fully digital quality platform within 4 weeks.

> *"The fact that Qualio offered everything all in one – events, CAPAs, complaints, documents – and getting in on that sooner before we grew much larger, made sense for us."*
>
> **— Hanna Fanous**
>
> Quality Assurance Supervisor, Kazmira

# The results

## Qualio gave Kazmira the control and visibility they needed for an optimal, cGMP-based cannabis quality system.

### Time saved for continuous improvement

With a lower time and cost burden for quality, Hanna and the Kazmira quality team are now free to focus on continuous improvement: accelerating towards **FDA 21 CFR 111 compliance**, ensuring colleagues are suitably trained, and strengthening their supply chain with better control of suppliers.

### Mature eQMS

Kazmira had a basic and limited QMS pre-Qualio. Their eQMS now encompasses:

- Over **500 version-controlled** quality documents underpinned by e-signatures and audit trails
- A rapidly growing library of **captured and resolved quality events**, from out-of-specification investigations to incident reports
- **Fully digital** training and supplier records with task reminders

### Customer and regulatory trust

Kazmira can prove complete control and compliance to their auditors and customers. **Spec sheets and Safety Data Sheets** can be quickly produced and shared from within Qualio to demonstrate product conformity with customers, while Hanna notes that...

*"Our auditor was really impressed and thought it'd take much longer to retrieve the information they asked for during the audit. Most auditors aren't happy if you have to go off for 30+ minutes to look for things!"*

### Paperless quality

Hanna replaced manual quality processes (like scanning paper training records) with a templated digital approach, **accelerating access to information** and allowing quality issues to be tracked in real time and closed out.