# Mikart CDMO Adopts TrackWise Digital® eEQMS, with Big Early Wins in Training and Document Management



Mikart, a recognized CDMO leader since 1975, provides pharmaceutical development, contract manufacturing, and packaging services to virtual and midsize pharma/biotech companies offering state-of-the-art technology and expertise. Mikart has a broad range of capabilities, including formulation development, clinical trial supplies, regulatory filing support, analytical development services, cGMP clinical and commercial manufacturing, and packaging.

In 2018, Mikart underwent a digital transformation initiative that included a fresh look at quality management system needs. Their stated goals included modernizing quality processes to meet and exceed current FDA and cGMP standards to better serve the current and future needs of their expanding client base.

## COMPANY OVERVIEW

**NAME:**
Mikart Pharmaceutical Manufacturers

**INDUSTRY:**
Pharmaceutical Manufacturing (CDMO)

**DISTRIBUTION:**
United States

**EMPLOYEES:**
200

**SOLUTION:**
TrackWise Digital
Audit Management
CAPA
Change Control
Complaint Management
Document Management
Training Management

> "Training Management has drastically increased efficiency at our company."

## THE OPPORTUNITY: Shifting Quality Processes from Paper-Based to Digital

Among the operational challenges Mikart looked to technology to address was to shift quality from being paper-based to digital, according to Brad Bryson, Director, Quality Operations. Too much time and human capital was being spent on routing documents for approvals and signatures – by foot – across their sites at their sprawling, multi-building campus.

Additionally, support for trainings, including safety and IT, were also paper-based and suffered accountability issues. Bryson said forms could be missed or forgotten at the bottom of an Inbox. Managers did not have Immediate visibility to their teams' completion.

**THE SOLUTION:** TrackWise Digital QMS with Integrated Document Management and Training Management

With the support of Mikart's management to advance their digital footprint, the company forged ahead with TrackWise Digital eQMS, Sparta Systems' cloud-based quality management solution to digitally transform core quality processes, including complaints, document management and training management.

All of Mikart's employees were easily onboarded to the system. TrackWise Digital's easy-to-use interface was an important factor in choosing the solution. Bryson said, since the digital system would be new to everyone, wide adoption was going to be critical to success.

> "Each manager has more visibility to what is outstanding in their department, from dashboards and email notifications that TrackWise Digital provides."

BEFORE TRACKWISE DIGITAL:

**OVER 10%**
outstanding training records

**2 – 3 DAYS**
for investigation routing and approvals

AFTER TRACKWISE DIGITAL:

**LESS THAN 1%**
outstanding training records per quarter

**1 DAY**
for investigation routing and approvals

## THE RESULTS: Instant Access and Approvals, Reduced Cycle Times and Greater Visibility

The TrackWise Digital's cloud collaboration capabilities were a clear win for everyone at Mikart. "A vast improvement!" Bryson was happy to share, especially regarding the significant turnaround in getting faster approvals on critical documents and training completions.

It would take two to three days to get an investigation approved, running a document from site to site, person to person. Bryson said, "In TrackWise Digital, it can go to everyone at once, throughout the buildings, even if they're working from home, or taking a business meeting in a different state."

Bryson used the example of a large department like Packaging. He explained that it was difficult for managers to stay on top of completion of trainings and often fell short in meeting standards and leadership expectations. Now, he says, "Each manager has more visibility to what is outstanding in their department, from dashboards and email notifications that TrackWise Digital provides."

Bryson reports that, before TrackWise Digital, Mikart had approximately 10% of their training records overdue or outstanding.  Shortly after implementation, and with successful training of all Mikart staff, that number of incomplete  trainings plummeted, Managers are now reporting less than 1% in outstanding training records at the end of each month, a stunning change.

TrackWise Digital's document management has solved key areas of inefficiency with the review and approval cycles for critical processes like investigations. Now, with a secure and central repository, accessible by mobile phone,  an approval process that could have taken 2-3 days now can take place in less than a day.

> "In TrackWise Digital, documents can go to everyone at once for review and approval electronically, throughout the buildings, even if they're working from home, or taking a business meeting in a different state."

### Get in Touch
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