





**Location**Santa Cruz,
California



Industry Non-Profit Research



## **Overview**

MAPS, a non-profit research organization, needed a controlled document system for quality management activities, as their old paper-based system presented a compliance risk and fell short with regards to facilitating collaboration. Since using Montrium's Quality Connect, the MAPS team can more easily demonstrate and maintain compliance with a cloud-based, centralized system for storing training documents and SOPs. "For SMEs and new companies just starting, Quality Connect is an excellent tool for them to track the progress of their business activities," says Maryann Böger, Clinical Systems and Quality Manager at MAPS.

## Challenge

MAPS began as a small start-up and has advanced to Phase 3 of their clinical trial. Initially, SOPs were insufficiently tracked, meaning adequate training was at risk, and something had to change. Growing from a team of 20, now up to 100+ employees having doubled in size in less than a year's time, the MAPS team drew up a cost-analysis, comparing three years of staying with the paper-based system with the ROI gained from moving to the cloud and purchasing a subscription for Quality Connect. Given the amount of time and resources consumed with paper-based processes, they determined the ROI would come within the first year.

## **Highlights**

**The customer:** The Multidisciplinary Association for Psychedelic Studies (MAPS) is a 501(c)(3) non-profit research and educational organization that develops medical, legal, and cultural contexts for people to benefit from the careful uses of psychedelics and marijuana.

**Challenge:** With more studies and personnel on board, the MAPS team needed a quality management system to manage the growing number of paper-based SOPs and training documents.

**Solution:** Since using Montrium's Quality Connect, MAPS has seen significant improvements in efficiency, productivity, and cost-saving measures.

"Quality Connect keeps us in perfect compliance. Its biggest advantage for us is its ability to organize SOPs and recognize any SOP gaps we need to fill. Directors and supervisors can quickly see the training status of their employees."

Maryann Böger
Clinical Systems and Quality Manager MAPS
Public Benefit Corporation

### Solution

Quality Connect has impacted the success of MAPS and its GCP compliance, proving to be a business-critical tool for their Phase 3 study moving towards a new drug approval. Having already had a good experience with Montrium's trial master file solution eTMF Connect, Montrium's attentive customer service and fast response time was a crucial element for a growing company like MAPS. "With their clinical study knowledge and experience developing technology, Montrium understands the nature of our work and what must be achieved behind the software," says Maryann Böger, Clinical Systems and Quality Manager.

# **Key Achievements**

- Onboarding used to be a very manual process that took a lot of resources. Now, Quality Connect's training management module, Training Connect, facilitates onboarding with ease.
- Reduced risk of failing an audit due to poor documentation
- Time savings and ease of creating, sending and updating controlled documents

"We've seen results in the form of reduced costs, time, and effort relative to training and documenting training. This was previously tracked with Excel spreadsheet training logs. Quality Connect allows one employee to manage the trainings and SOPs

Maryann Böger
Clinical Systems and Quality Manager MAPS
Public Benefit Corporation

### **Results**

### Streamlined Training on SOPs

- As MAPS is growing rapidly, Quality Connect facilitates training and re-training for each department and position in the system.
- Quality Connect helped update SOPs to account for MAPS's Phase 3 studies and train new staff to training profiles in a manner that would have been much more time consuming without them.
- MAPS uses Quality Connect to send live video training, and all MAPS employees are trained to the correct SOPs and controlled documents before starting their role in the study.

#### **Automated Compliance Controls and Reduced-Risk**

- When protocols and control documents are entered, they can be technically revised and quickly issued as training due to the integration of SOP and Training Connect modules.
- Quality Connect helps to facilitate authoring of SOPs and tracking a log of current/active SOPs and controlled document status for internal employees.
- Externally, contracted employees still must meet requirements and train on SOPs. Quality Connect can communicate tasks with these external organizations to facilitate compliance.
- Concerning IMP (Investigational Medicinal Products), MAPS faces complicated processes and requirements with shipping and labeling, having electronic SOPs means records are more accessible to manage and control.

#### **Productivity and Cost-Savings**

- Many employees are remote, some even working abroad. Quality Connect facilitates collaboration between these employees with electronic forms and intelligent workflows.
- MAPS can collect and create documents in less time and track everything without the time investment required by the paper-based system.

