



# White Paper:

How Companies in Regulated Environments Can Leverage Mobile Technology

Video: MasterControl Mobile



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## Introduction

The use of smartphones and tablet computers has become so pervasive that mobile technology is rapidly transforming the workplace. Gartner Inc., an information technology research and advisory company, is forecasting that “by 2013, 80 percent of businesses will support a workforce using tablets.”<sup>1</sup>

What does this mean for your company? Flexibility is the greatest hallmark of mobile technology. Mobile devices offer access to information and connectivity to other people, anytime and anywhere. Your team members don’t need to be in front of a computer to perform their tasks. This kind of flexibility is particularly critical if your company’s employees and operations are scattered in various locations and require high team coordination; if a segment of your workforce travels or is out in the field; or if your operations require data collection in any way.

The consumerization of mobile technology has made smartphones and tablets better, less expensive, and ubiquitous. More and more employees use them not just for personal reasons, but to perform some of their work. In many cases, companies are forced to provide IT support for these employees. Those companies find themselves having to catch up with their employees who are leveraging mobile technology. Instead of viewing mobile technology as a necessary evil, many leading organizations see the trend as an opportunity. They are embracing mobile technology— as many of their employees have already done—by adopting it for the benefit of the entire company.

## Data Collection in Regulated Environments

Companies in regulated environments—those under FDA jurisdiction or bound by European Community directives and regulations, and those that adhere to ISO, European Union GMP, or other standards—have vastly different needs compared with other organizations.

Standards and regulations imply inspections, audits, and overall governance, and therefore, the need for compliance. Standards and regulations entail voluminous and rigorous documentation. They call for risk management and quality processes. In many cases, they require training on a regular basis. All of these things make regulated companies unique.

The requirements for these companies can be as varied as the regulations and standards they comply with, but there is one thing that almost all of them must perform: data collection. The most common way to collect data is through forms. Forms—whether electronic or paper—require input from the appropriate employee or researcher or customer or patient. They need to be secured, processed, reported, approved or acted upon. Data collected is ultimately used to trigger an action or to make decisions.

Companies that rely on paper forms typically track data using spreadsheets and store it in a database. This hybrid system is inexpensive, but also inefficient, less secure, and lacks the tracking mechanisms needed by regulated companies. Organizations that use electronic forms fare better in terms of efficiency and security, and they have the additional benefit of connecting their forms to other processes, such as document control, training, or change management. However, most automated forms-based processes require the use of a computer in the same location, such as an office, factory, or laboratory.

Mobile technology offers unique opportunities for companies that use hybrid and electronic forms-based processes. For the former, mobile technology is a great incentive for investing in a fully automated and connected system. Mobile devices are as portable as paper forms, but exponentially more efficient, more effective, and they have the added benefit of controlling forms-based processes and connecting them with other critical processes for compliance purposes.

For companies already using automated forms, mobile technology will significantly extend the usability of their system. In terms of compliance, mobile devices will help ensure that users outside of the office (researchers in the field, consultants, etc.) have the ability to access, review, update, or approve the latest documents wherever they are. In terms of overall cost, mobile technology means getting more mileage out of an electronic compliance system.

## Leveraging Mobile Technology: User Scenarios

Remote and field-based employees and other team members (such as outside partners) responsible for data collection, or whose work involves using forms, will greatly benefit from mobile technology. In addition, there are other segments of the workplace that are not directly involved in data collection, but can take advantage of mobile technology to boost productivity and enhance team coordination. Consider the following examples:

### Users Involved in Data Collection

- **Clinical Trial Investigators and Outside Partners:** Clinical trials and studies are typically conducted in various investigator sites. They involve collaboration between pharmaceutical or medical device companies (the sponsor) and outside partners, such as research institutes, contract research organizations, hospitals, and clinics. Instead of installing cumbersome and complex computers in every site, mobile technology offers a portable alternative. Doctors, nurses, and study coordinators will be able to collect and report site-related information that are usually submitted in forms, such as supply inventory and equipment requirements, easily and efficiently using mobile devices. This is particularly helpful in global studies that involve participants in different countries. For example, task coordination may be a problem for investigators and study coordinators involved in clinical trials in remote areas in Africa, where Internet connection is unstable. Mobile networks are more reliable and can serve as a great backup. As more clinical trials are outsourced in China, India, and other countries, mobile technology will become increasingly indispensable.

### Users Involved in Forms-based Processes

- **Plant/Manufacturing Floor Workers:** Many clean room and other manufacturing floor workers rely on paper forms or computer kiosks. However, contamination is a concern in using paper or bulky computers in clean rooms. Smartphones and tablets are more “clean room friendly” because they are sealed devices (without fans to move dust around) and they use virtual keyboards. Clean room workers who wear latex gloves will find it easy to use tablets like iPad. For other types of plant floor workers, the challenge lies primarily in efficiency because filling out and collecting paper forms and taking turns using computer kiosks require more time and effort. For example, in cold-temperature plant floors, it will be faster and more convenient for a worker to input data directly from an equipment into a mobile device compared with using paper forms, which would require extra work to transfer the data into a computer.
- **Transportation and Warehousing Staff:** Ensuring the integrity of products, especially medications and medical devices, during the process of transporting and storing them is critical to regulated companies. Such products may require controlled levels of temperature or special handling. Employees who are involved in the movement of these products across the supply chain need to record, monitor, and report information in a more efficient and secure way than filling out paper forms. Mobile technology makes inputting and collecting information along the supply chain—and overall product flow—more efficient.

### Other Users Who Can Benefit from Mobile Technology

- **Executives Who Travel Often:** Key approvals from executives in regulated environments are rigorous and constant. Traveling managers and executives can potentially delay the review and approval of key milestones and deliverables. With mobile devices, they can easily perform their reviews and approvals wherever they are.
- **Field-based Sales Staff:** Sales representatives require the latest marketing documents, design files and records, and client information when they are out in the field. It is critical for them to be able to provide any information the client needs in real time. With a mobile device, a sales rep for a new medicine can easily access the results of a clinical trial upon request by doctors, clinics, and hospitals. A medical device or medical equipment sales rep facing questions or concerns from a customer will be able to immediately report back customer feedback, perhaps using an electronic form, through a mobile device.

- **Remote Staff:** Manufacturers, financial institutions, and other businesses are increasingly outsourcing more of their work, making remote employees a growing segment of the workforce. For other companies, growth and expansion require hiring employees outside of the headquarters or relocating some employees to other states or even overseas. Mobile technology can bridge the physical distance between the headquarters and remote employees by increasing connectivity across time zones. Using mobile technology in conjunction with a laptop or a computer provides the remote staff additional channel for participating in compliance processes and for increased communication with headquarters.

### MasterControl Solution

MasterControl Mobile™ enables employees—from clinical trial investigators to traveling executives to sales reps out in the field—to be more efficient and effective no matter where they are. It allows users to access information from the MasterControl system using a variety of tablets and smartphones, including iPads, iPhones, and Android devices.

MasterControl Mobile is the portable gateway to MasterControl quality and compliance system, an electronic, centralized, web-based platform for all processes critical to regulated companies, including document control, forms-based and data collection, quality management, change management, corrective and preventive action, training control, audit management, product lifecycle management, bill of materials, supplier management, and submissions management.

MasterControl enables regulated companies to streamline processes, improve overall efficiency, and accelerate compliance. Using MasterControl Mobile in conjunction with the MasterControl system will extend all of these benefits to team members involved in data collection, as well as traveling, remote, and field-based employees.

Here are some of the benefits of using MasterControl Mobile:

- **Flexibility:** Users can access the MasterControl quality and compliance system anytime, anywhere using a mobile device.
- **Compliant Forms-based Processes:** MasterControl Mobile provides portable access to MasterControl's electronic forms-based system, which is designed to comply with regulations (such as FDA rules), guidelines (EU Annex 11), and standards (ISO, GMP, European GMP). The system provides features critical in regulated environments, such as time-stamped audit trail and reporting and electronic signature capabilities.
- **Save Time and Resources:** Users who spend significant time away from their computers can still quickly access the MasterControl system, which helps save time and money and avoids costly delays caused when approvals are needed from users who are not in front of their computers.
- **Immediacy:** Using MasterControl is not restricted to where the computers are, such as office or laboratory. Users will be able to access documents and task assignments wherever work is being done in real time—a clinical trial site, shop floor, clean room, or warehouse.
- **Enhanced Usability:** MasterControl Mobile extends the usability of the system anywhere outside of the headquarters or manufacturing plant, expanding the number of users who can benefit from the system.
- **Works with Multiple Devices:** MasterControl Mobile is designed to work with a broad set of smartphones and tablets. The same forms-based processes designed for use on the computer can also be used on mobile devices, with no required changes to the form.
- **Cost Minimization:** Going mobile helps reduce the costs of using outdated information in manufacturing environments, failing to capture quality event information, and giving outdated product literature to customers and prospects.

## Conclusion

Mobile devices are ubiquitous for a good reason. They offer flexibility unlike ever before. Tasks such as data collection; search, review, and approval of documents; launching non-conformance, complaints, and similar quality processes ; and retrieval of the most up-to-date documents and information can all be performed anytime, anywhere using mobile technology.

Companies should explore how they can use mobile technology to their advantage and how they can align it with their overall business goals. Consider using MasterControl Mobile as a tool for increasing flexibility and efficiency, optimizing employee performance and productivity, and strengthening team coordination in processes critical to compliance.

## References

1. “Gartner Reveals Top Predictions for IT Organizations and Users for 2011 and Beyond,” press release from Gartner Inc., Nov. 30, 2010, <http://www.gartner.com/it/page.jsp?id=1480514>

## Related Videos



[Customizing to Your Process](#)



[Creating a Paperless Process Using MasterControl](#)

## About MasterControl Inc.

MasterControl produces software solutions that enable regulated companies to get their products to market faster, while reducing overall costs and increasing internal efficiency. MasterControl securely manages a company’s critical information throughout the entire product lifecycle. Our software is known for being easy to implement, easy to validate and easy to use. MasterControl QMS and QEM solutions include quality management, document management/document control, product lifecycle management, audit management, training management, bill of materials, supplier management, submissions management, and more. Supported by a comprehensive array of services based on industry best practices, MasterControl provides our customers with a complete information management solution across the entire enterprise. For more information about MasterControl, visit [www.mastercontrol.com](http://www.mastercontrol.com), or call: 1.800.825.9117 (U.S.); +44 (0) 1256 325 949 (Europe); or +81 (3) 5422 6665 (Japan).



# MasterControl Inc.

## Corporate Headquarters:

### **MasterControl Inc.**

6322 S. 3000 E. Ste. 110

Salt Lake City, UT 84121

United States

Phone: 800.825.9117

Fax: 801.942.7088

[www.mastercontrol.com](http://www.mastercontrol.com)

## Asian Headquarters:

### **MasterControl KK**

AIOS Meguro Ekimae 5F

2-15-19 Kami-Osaki, Shinagawa-ku

Tokyo 141-0021

Japan

Phone: +81 (3) 5422 6665

Fax: +81 (3) 5422 6664

[www.mastercontrol.co.jp](http://www.mastercontrol.co.jp)

## European Headquarters:

### **MasterControl Global Limited**

First Floor North Wing

Matrix House

Basing View

Basingstoke

RG21 4FF

United Kingdom

Phone: +44 (0) 1256 325 949

Fax: +44 (0) 1256 325 289

[www.mastercontrolglobal.co.uk](http://www.mastercontrolglobal.co.uk)

### **Germany Office**

Mendelstrasse 11

48149 Muenster

Germany

Phone: +49 (0) 251 980 2140

Fax: +49 (0) 251 980 2149

[www.mastercontrol-global.de](http://www.mastercontrol-global.de)

Email: [info@mastercontrol.com](mailto:info@mastercontrol.com)