

Chong Kun Dang (CKD): Revolutionizing Pharmaceutical Quality Control with waters_connect System Monitoring

Discover how Chong Kun Dang (CKD), a leading South Korea pharmaceutical company, has transformed the operation of chromatography systems in their Quality Control (QC) Lab with the implementation of waters_connect System Monitoring.

CKD OVERVIEW

Established in 1941, CKD is one of the leading South Korea pharmaceutical company headquartered in Chungjeong-ro, Seodaemun-gu, Seoul. CKD manufactures and sells pharmaceutical products, including Ethical the Counter (ETC) drugs for hypertension, hyperlipidemia, and diabetes, as well as Over the Counter (OTC) drugs such as painkillers, digestive aids, vitamins in Korea but also exports around the world.

CKD's Cheonan plant is a state-of-the-art production facility equipped with automated logistics systems that handle everything from raw material weighing to the packaging and shipping of finished products. Since 2010, CKD has implemented advanced systems such as Enterprise Resource Planning (ERP), Quality Management System (QMS), Laboratory Information Management System (LIMS), Electronic Document Management System (EDMS) and Learning Management System (LMS) to maximize process efficiency. With this continuous investment in technology and infrastructure, CKD is leading the way as a representative of the pharmaceutical industry.

Waters™ Corporation met with Manager of CKD's QC testing support part, Yoon Jae-hoon to discuss insights gained during the project of waters_connect™ System Monitoring. Yoon has been with CKD for 11 years, serving in various roles within the Quality Assurance (QA) and Quality Control (QC) teams. His extensive experience includes Quality Management System (QMS), Risk Management, Quality by Design (QbD), Six Sigma, Validation, Instrumental Analysis, and Automation of Analysis.

"In my role, I am responsible for establishing test methods, managing test and storage samples, and analyzing chemical substances," explains Yoon. "I have also overseen the implementation of LIMS, Electronic Laboratory Notebooks (ELN), Visualization Dashboards, waters_connect System Monitoring, and advanced analytical instruments to ensure efficient analysis." Yoon's comprehensive expertise complements CKD's innovative energy and his commitment to reducing complexity and increasing operational efficiency required to maintain a world-class pharmaceutical quality control laboratory.

COLLABORATION WITH WATERS

CKD has had a long-standing collaboration with Waters Korea, known for providing excellent analytical equipment and professional support.

"Waters Korea has been a reliable partner, offering rapid and precise support in troubleshooting and maintaining services," says Yoon. "Their ongoing feedback and quick software updates have significantly improved the convenience and functionality of the system." This partnership has been instrumental in ensuring that CKD's QC operations run smoothly and efficiently, reflecting the importance of strong vendor and continuous collaboration in achieving operational excellence.

QUALITY CONTROL DEPARTMENT AT CKD

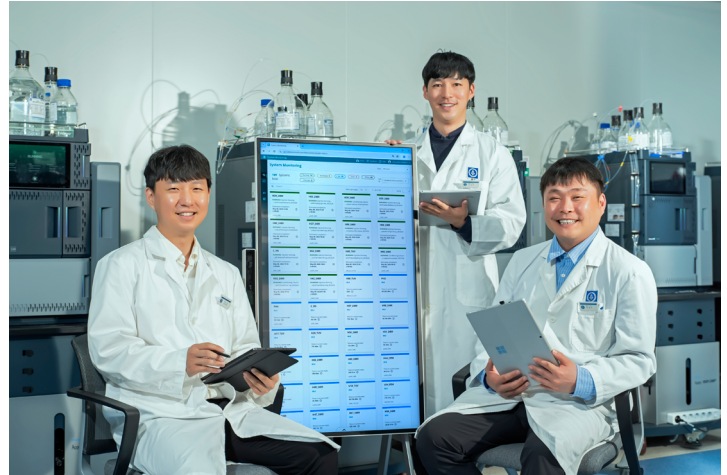
The QC laboratory at CKD conducts comprehensive analyses on various pharmaceutical dosage forms, including oral solid dosages, liquid dosage forms, injectables, ophthalmic solutions, anticancer drugs, patches, powder injections, antibiotics, and biopharmaceuticals. Utilizing advanced analytical instruments like high-performance and ultra-performance liquid chromatography and mass spectrometry, the lab operates an efficient smart laboratory environment.

“Our QC lab is equipped with cutting-edge technology and a team of highly skilled professionals, enabling us to maintain stringent quality standards,” says Yoon Jae-hoon, QC Manager at CKD. “We hold certificate of GMP approved by the Ministry of Food and Drug Safety (MFDS, Korea) and the Ministry of Health, Labour and Welfare (MHLW, Japan), and we have received ISO/IEC 17025 certification from the International Organization for Standardization.” These certifications assures that CKD’s lab operates under the highest standards of quality and reliability, critical for maintaining trust and compliance in the pharmaceutical industry.

IMPLEMENTATION OF WATERS_CONNECT SYSTEM MONITORING

CKD’s QC team recognized the need for a solution to monitor the operational status of analytical equipment like HPLC in real-time. After a thorough evaluation, the team decided to implement waters_connect System Monitoring in December 2023, and the full usage began in February 2024 through the installation and distribution process.

“HPLC is a critical analytical instrument in our lab, and managing it efficiently is directly related to productivity and quality improvement,” says Yoon. “We possess 62 Waters HPLCs and continue to invest in expanding this number. Given the large physical space of our lab, a real-time monitoring system was essential.” CKD’s implementation of waters_connect System Monitoring ensures that any issues can be quickly identified and addressed, work can be easily scheduled, and the laboratory can ensure their systems are operating at maximum efficiency, minimizing downtime and meeting the requirements as a tool to improve analysis efficiency.



Yoon Jae-hoon, QC Manager (left); Park Sung-won, QC Assistant Manager (middle); and Kim Jung-min, QC Manager (right), deploying waters_connect System Monitoring on a moving screen for a detailed view of their laboratory operations.



CKD are able to easily monitor their significant HPLC instrument fleet, including their Alliance iS HPLC Systems shown above, in real-time using waters_connect System Monitoring in their QC laboratory.

DECISION-MAKING PROCESS AND CRITERIA

The first step on decision to choosing and implement the waters_connect System Monitoring was driven by criteria of clear rationale including significantly increased laboratory efficiency, user convenience, system reliability, and maintenance with the full support of executive management. The decision on the first step was based on clear evidence and implemented with the full support of executive management. Waters supported the CKD team with their decision-making process by providing demo presentations and technical meetings focused on the waters_connect Cloud Platform, ensuring CKD were provided with all the information they needed to make a confident decision.



Implementing waters_connect System Monitoring at CKD was the result of the team's efforts, including decision making Quality Unit Director Im Na-young (left) and Cheonan Plant Director Byun Hyung-won (right).

"The decision was actively supported by our executive team, including CEO Kim Young-joo, Cheonan Plant Director Byun Hyung-won, Quality Unit Director Im Na-young, and Quality Control Team Leader Won Joon-young," notes Yoon. "Their continuous support and the efforts of the project team (QC Manager Kim Jung-min and QC Assistant Manager Park Sung-won), were crucial in this process." The involvement of senior leadership in the decision making process underscores the strategic importance of the initiative and reflects CKD's keen interest in technological advances in pharmaceutical laboratory operations and commitment to quality control.

BENEFITS AND IMPACT

Since implementing waters_connect System Monitoring, CKD has seen significant improvements in chromatography system's operational efficiency in their lab. The software allows for 24/7 real-time integrated monitoring of their extensive chromatography system fleet and has increased the response speed to equipment downtime issues and the efficiency of laboratory schedule management.

"Real-time checking has become possible from anywhere, at anytime, and we have set up dashboards on large monitors in the preparation area to monitor all HPLC instruments," says Yoon. "This has improved the efficiency of our analysis operations and allowed for continuous monitoring, contributing to productivity improvements." The ability to monitor equipment remotely ensures that the lab can maintain optimal operational status, significantly reducing delays and enhancing overall productivity.



CKD have benefited significantly from the implementation of waters_connect System Monitoring on large monitors in their preparation area, providing a dynamic, real-time view of their QC laboratory.



FUTURE EVOLUTION

CKD sees the benefit of waters_connect System Monitoring beyond their current implementation of the software. They plan to leverage the accumulated system data for statistical analysis and anticipate improvements in analysis efficiency and equipment utilization through integration with various programs.

“We expect to extend beyond basic monitoring of our analytical equipment remotely,” adds Yoon. “Keeping pace with AI, machine learning, and virtualization technologies, we look forward to further enhancing productivity and convenience.” These initiatives highlight the importance of CKD’s future-oriented approach and collaboration with Waters in driving innovation in pharmaceutical technology.

FINAL THOUGHTS

Looking ahead, CKD anticipates expanding the use of waters_connect System Monitoring to other analytical instruments, significantly increasing its utilization.

“We are grateful for the professional assistance from the Waters’ informatics team throughout the process,” concludes Yoon. “We look forward to continuing a productive collaboration between our companies in the future.” This collaborative approach is what has driven the development of waters_connect System Monitoring, continuous feedback from customers such as CKD is critical to ensuring Waters Informatics solutions remain focused on helping our customers achieve the scientific and business goals.



Waters and waters_connect are trademarks of Waters Corporation.
All other trademarks are the property of their respective owners.

©2024 Waters Corporation. August 24-12924 720008411EN Rev. A

Waters Corporation
34 Maple Street
Milford, MA 01757 U.S.A.
T: 1 508 478 2000
F: 1 508 872 1990
waters.com