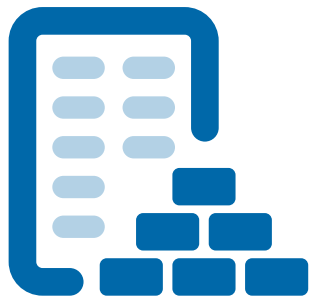
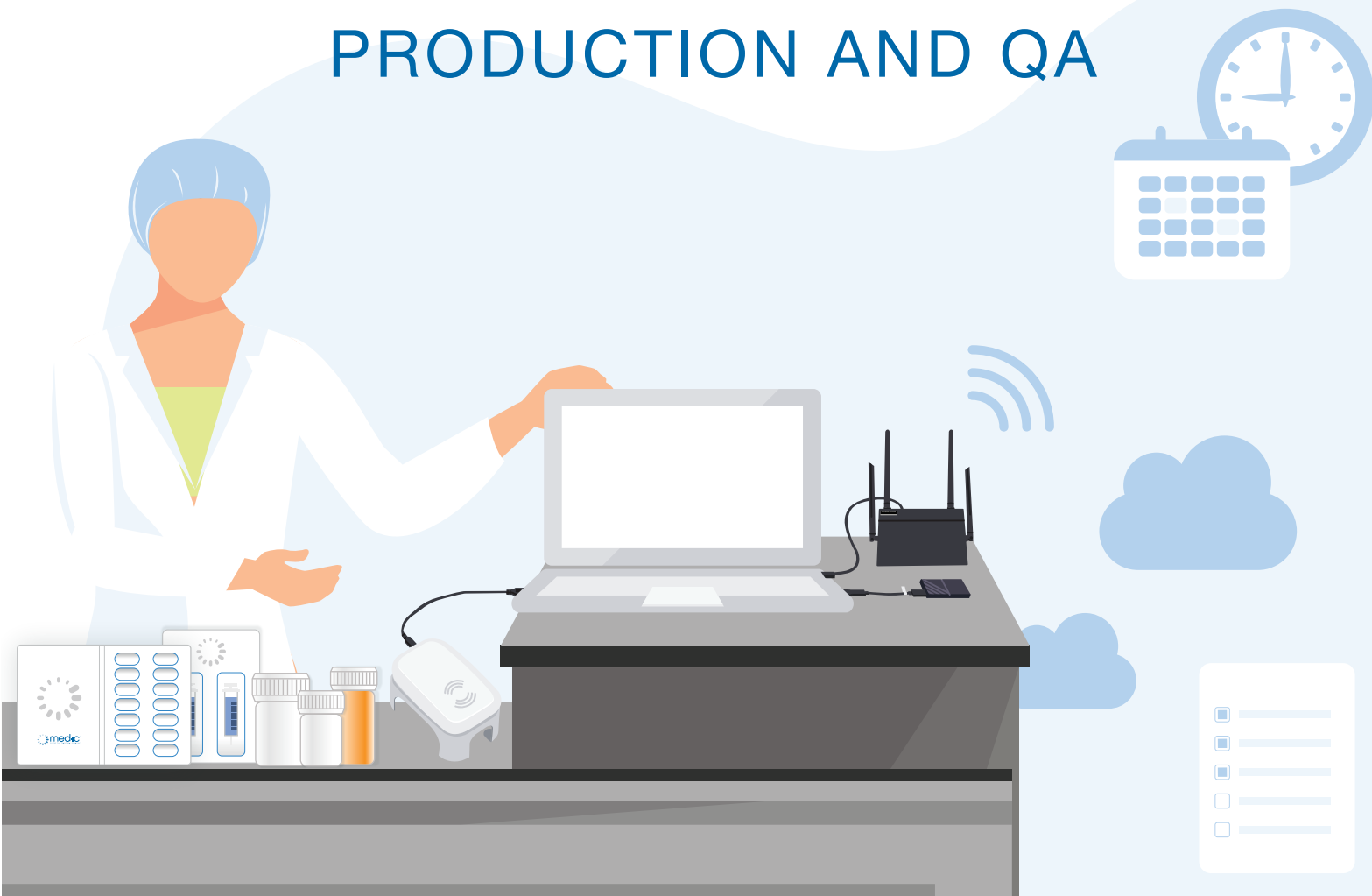




CERTISCAN[®]
ADHERENCE MATTERS



PRODUCTION AND QA





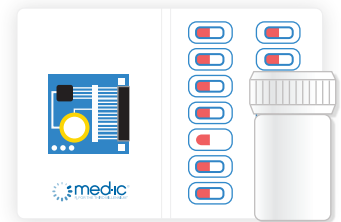
What is CertiScan[®]

The CertiScan platform combines smart packaging, apps, and analytics to give timely insights into patient medication trends, prompt behavioural interventions, and improved overall adherence - yielding **high quality dosing data and more effective research**. CertiScan's benefits extend to GCP activities, enabling decentralized and direct-to-patient scenarios, while also providing supply chain visibility and automating reconciliation tasks.

CertiScan for Smart Packaging Production and QA

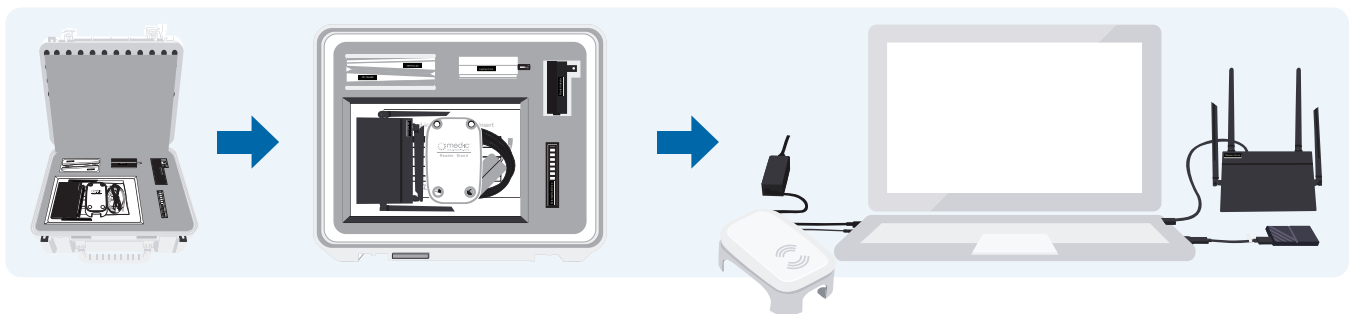
CertiScan Production and QA is a GMP-validated system used during the drug fulfillment and carding process to ready CertiScan smart packaging for use in a clinical trial. CertiScan Production and QA works seamlessly and comfortably within GMP packaging production environments using existing materials, processes and equipment. Production staff can be fully trained on CertiScan smart packaging in as little as a few hours. CertiScan specialists are available at all times for training and GMP production.

CertiScan Production and QA fully provisions and verifies correct CertiScan smart packaging operation, after which packaging can be distributed to patients to start the collecting of **high quality dosing data**. CertiScan Production and QA works with Med-ic[®] (a blister package with embedded electronics) and eCAP[™] (an electronic, standard threaded pill bottle cap) smart packaging.



Production and QA Kit

CertiScan Production and QA is provided as a kit comprised of multiple workstations and contains everything your staff needs to quality assure and provision CertiScan smart packaging.



Regulatory Compliance

CertiScan supports requirements for FDA 21 CFR Pt 11 and EU Annex 11



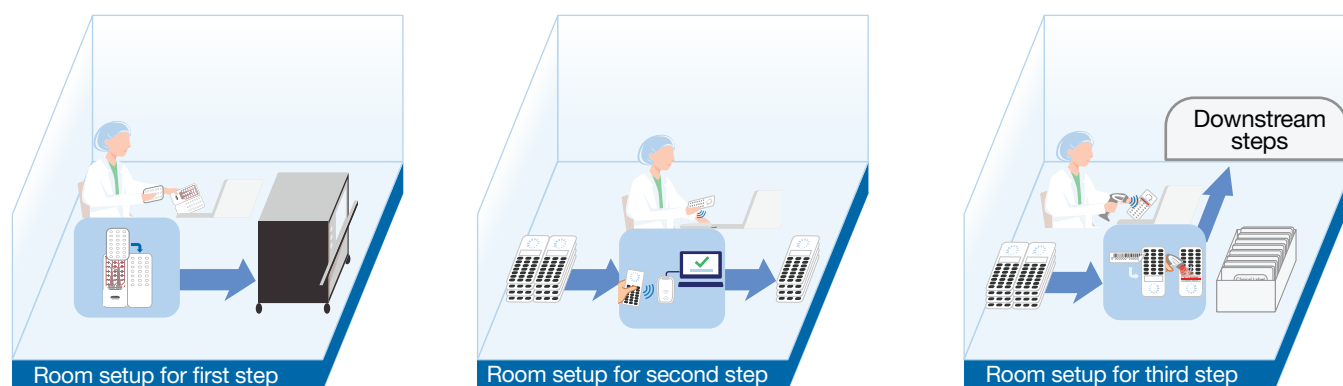


Workflow Details

CertiScan Production and QA organizes smart packaging work into jobs or lots with separate roles for line supervisors and operators. Work is then further divided and organized into 3 steps.

One or more workstations can be deployed at the same time in the same production room. Workstations easily network with each other to support any type of production workflow. There are two general workflow options (but mixed workflows are also supported).

- 1 Waterfall:** One (or more) workstations work concurrently on one production step at a time in the production room. CertiScan Production and QA is switched between steps when the entire lot is ready to move to the next step. **This workflow prioritizes simplicity.**

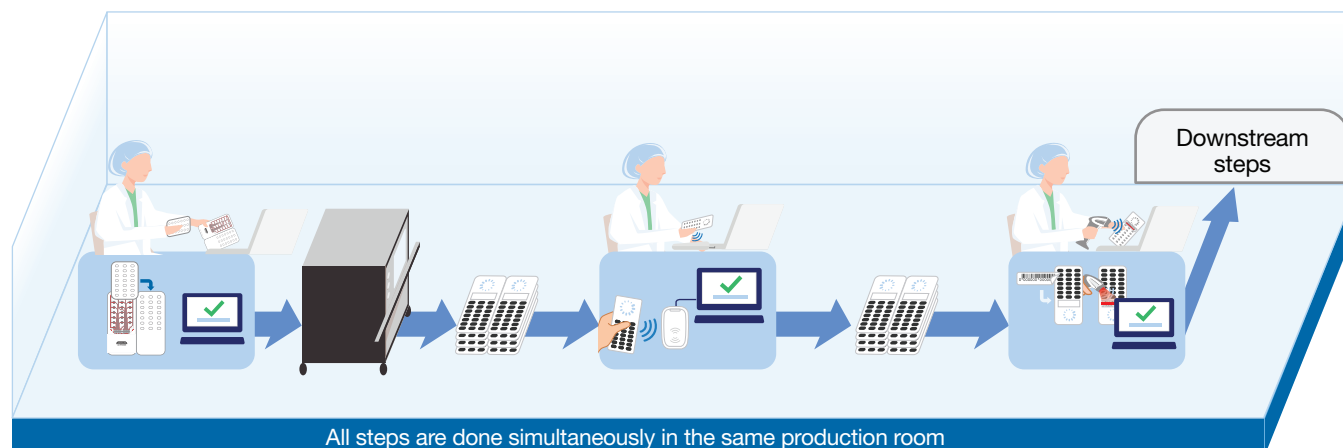


Pre drug fill/heat seal IQC: Packaging is confirmed to be fully operational before committing drug product to filling and heat sealing.

Post heat seal/drug fill QA: Packaging is verified to be fully operational after heat seal. Packaging will be fully provisioned and assigned all necessary study traceability information.

Verification: This activity is a 200% check on all packaging data before kitting and boxing occurs. After this, full reconciliation reporting can be done.

- 2 Pipelined:** Multiple workstations work concurrently on multiple steps at the same time, in the same production room. **This workflow prioritizes throughput.**



Features



Works with most blister, bottle or injectable packaging formats



Easy reconciliation and work management



Supports supervisor and operator role functions



Works with existing processes and equipment



Supports waterfall and pipelined work flows



Meets GMP regulations, FDA 21 part 11, EU Annex 11



Full suite of reporting



CertiScan Production and QA data can be used downstream to unlock additional value



Deployable on in-house IT infrastructure using customer-defined database





CertiScan Adherence Solutions

Taken altogether, CertiScan consists of 4 different technologies:



CertiScan Digital Adherence - An end-to-end platform combining smart packaging, apps, and analytics to drive timely insights, prompt behavioral intervention and improved patient adherence. *Refer to separate “CertiScan Digital Adherence” brochure.*



CertiScan Production and QA - A GMP-validated system used during the drug fulfillment and carding process to ready CertiScan smart packaging for use in a clinical trial.



CertiScan Integration - A suite of mobile SDKs and REST APIs to provide 3rd party access to CertiScan platform data and services which can be leveraged to build 3rd party apps and connect seamlessly with IRT, RTSM and EDC systems. *Refer to separate “CertiScan Integration” brochure.*



CertiScan Package Management - A set of tools and integrations to provide logistics and reconciliation opportunities from the dosing data you already have. *Refer to separate “CertiScan Package Management” brochure.*

Each technology can be used independently or together to provide value from smart packaging dosing data. Using them together will maximize the value of the overall solution. To learn more, email: adherence@certiscan.biz

