

CASE STUDY

Ioi Integration of instruments

IPC/QC off-line checks in pharma packaging lines

Needs

- Fill Data Integrity gaps respecting compliance with *GMP Annex 11* and *FDA 21 CFR Part 11*
- Summarize and report the measurements results
- Access data remotely

Challenges

- Move from a traditional paper-based process to a digital system for acquiring and processing data
- Implement a platform fully compatible with legacy instruments and existing systems

Inpharmatic solution

- Ioi CORE Module
- Ioi IPC Module

Results

- GMP/FDA compliance
- Data summaries and reports
- Remote access to data
- Data security
- No paper
- Time saving

Background

The bio-pharmaceutical company of this case study has a strong focus on research and is present in 70 countries with 47.000 employees.

The Data Integrity gaps highlighted by the Authorities in the primary and secondary packaging lines prompted the company to implement a solution to digitalize the old instrument of the production department.

According to EU and US manufacturing regulations, in the pharmaceutical industry the data management has to be centralized and must include reporting, analysis and traceability. This is difficult to achieve with a paper-based working method. The data review is complicated too, as well as being a time-consuming activity highly subject to human errors.

We started by implementing Ioi - Integration of instrument in one of its sites, near Rome, in order to perform the IPC (In-Process Control) sessions electronically and in compliance with pharma regulations. Ioi has been introduced in two departments, specifically in 5 stick sachet packaging lines and 1 liquid packaging line.

IPC consists of checks performed during production processes to monitor and adjust the process. The purpose of the IPC is to ensure that the drug conforms to defined quality criteria and to prevent and detect mistakes during manufacturing.

Delivery & GoLive

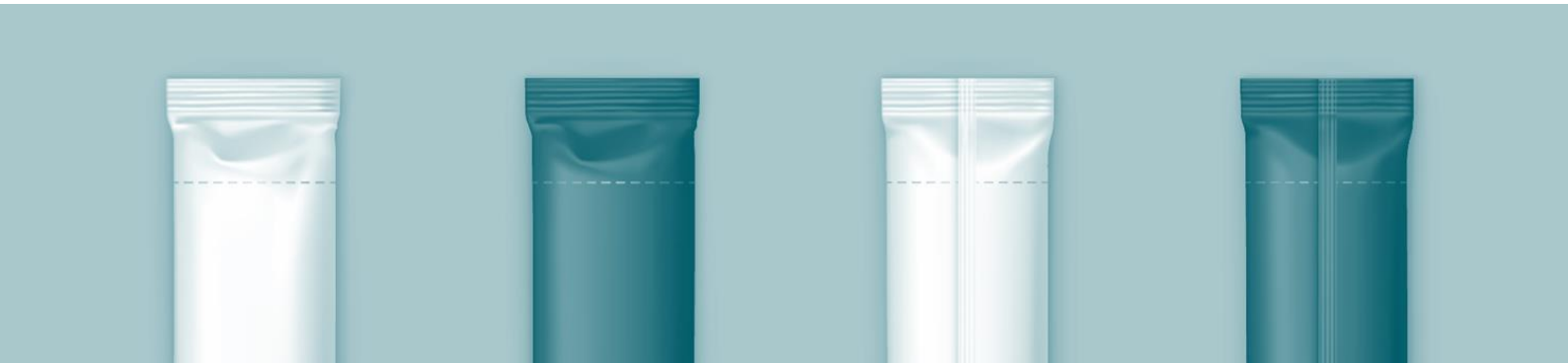
The whole project (installation of CORE Module + IPC Module, including Test Environment, integration of 8 instruments, training, configuration and validation) lasted 5 weeks.

CORE Module performs acquisition and processing of data, review and approval of measures, and creation of reports. IPC Module is designed for managing off-line checks on the production line. Through this module it's possible to set up a sampling recipe/method by selecting a set of parameters, tare type, alarm and blocks. At the end of every IPC shift or session Ioi provides a complete set of reports, control charts, Audit Trails, Electronic Logbook and the possibility to carry out the Electronic Review with electronic signature.

We started with the implementation of a pilot project on a single packaging line. After a phase of evaluation by the customer and adaptation of their standard operating procedures to accommodate the new system, they decided to extend Ioi to other packaging lines.

8 instruments were integrated in the Ioi platform:

- 5 scales
- 3 checkweigher





Results

The collaboration with the customer's Business Technology Solution department was positive, as Ioi IPC Module responded to their automation and compliance need.

Currently, 70 users are performing IPC with Ioi. They have executed around 80.000 measurements in less than 1 year.

The main advantage is for sure the coverage of the Data Integrity gaps they were suffering from. With Ioi they avoided replacing legacy instruments, making them compliant with Data Integrity. The internal QA Auditors are definitely satisfied because the system improves compliance and data security.

They had significant benefits in every step, from the acquisition of measurements with the instrumentation to the final review of the IPC results.

The company also improved the efficiency of packaging lines and operators' activities by removing all paper-based processes. The laboratory staff do not have to handle the receipt and annotate the printout anymore. They feel very comfortable thanks to the out-of-range warnings and the timer between samplings.

Last but not least, the Area Supervisors can now review the IPC results remotely from their desktop, even remotely. In particular, they found the review by exception very easy because Ioi summarizes the out-of-range results

Future developments

The positive experience with this project, resulted with customer now evaluating the extension of Ioi IPC Module to packaging lines in other sites.

Currently, an interface project between MES and Ioi is underway, now nearing completion. This will enable to start IPC sessions directly from the MES with which the customer manages production orders by automatically downloading context data in Ioi and selecting the instrument to be used.



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