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PHARMACIM®

COURBON

AUTOMATION AND DATA PROCESSING FOR INDUSTRY

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[www.courbon.fr](http://www.courbon.fr)

# Increase productivity and guaranteed quality



With 20 years experience in pharmaceutical and biotechnological industries, COURBON has capitalized its know-how in developing a MES software application in accordance with the strictest regulations and technical requirements on the market. PHARMACIM® drives, collects and diffuses data from the reception of the raw materials and packaged items to expedition of the finished product.

## A more motivated staff

Whether it is via the e-mail, via the web or on line, PHARMACIM® provides the right data to the right person. You therefore get quick user-friendly real time information which enables you to take the right decision at the right time resulting in a more responsible personnel and work teams that communicate more efficiently on a shorter time-basis.

## Quality improvement

In order to guarantee the best pharmaceutical safety, PHARMACIM® integrates all necessary functions to improve quality and decrease risks : in process control (IPC), systematic identification of material and items which are used, validation cycle of procedures, receipts, formulas.

## Cost reduction

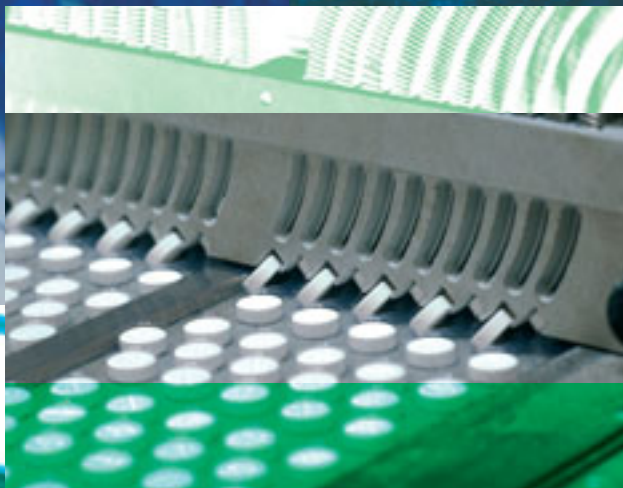
PHARMACIM® handles all the data minus the paperwork to guide you through to the production units and the logistic centres : less keyboarding data input plus automatic interaction between the systems (from PLC to ERP/LIMS). The advantages are instantaneous : no more rejects, less stock, less manufacturing and cleaning cycles, ...

## Productivity and output increase

By managing skills and schedules, PHARMACIM® guarantees an optimal use of the resources. Productivity gains are also positively influenced by the minimisation of machine stoppage thanks to the graphic analysis tools of assistance. Finally, good management of equipment and material flow control ensures an increase of productivity gains.

## PHARMACIM®

### A 21 CFR Part 11 compliance



## 21 CFR part 11

Developed according to GAMP standards, PHARMACIM® is also in conformity with the FDA regulations in regards to registration procedures (audit trail), electronic signatures and users management.

## Traceability

PHARMACIM® guarantees flows and batches traceability thanks to one single identification of the containers.



# PHARMACIM®

## A modular system

### Total electronic traceability from material reception to product distribution



#### Logistics - Flow management (PHARMACIM® FM)

Each handled item is identified upon reception so as to be able to efficiently keep track of the stock transactions. The organisation and the help tool in preparing the order-taking process enables PHARMACIM® to check product distribution while ensuring a total control of the clients' merchandise batches (BPD Conformity).

#### Weighing and dispensing (PHARMACIM® CDP)

Whatever the weighing method used, PHARMACIM® ensures material identification, weight control, production batch match ups, weighing instruments follow-up.

#### Scheduling (PHARMACIM® SC)

Genuine tool of simulation and decision-making tool, PHARMACIM® plans all the manufacturing and packaging steps. The Gantt chart allows a comparison between the forecasted planning and the realized one.

#### Production (PHARMACIM® PM)

In conformity with ISA S88 standards, PHARMACIM® drives, follows up, checks and ensures the production steps are carried out according to the pre-established and validated recipes and formulas. Any drift is pointed out, tracked and is the object of a commented decision (21 CFR part 11).

#### In process control (PHARMACIM® IPC)

The controls under procedure, the SPC analysis tools ensures a real-time follow-up in the product quality.

#### Equipment management (PHARMACIM® EM)

In all the workshops, during all the production steps, PHARMACIM® follows up and checks each equipment use.



#### Electronic batch record (PHARMACIM® DLE)

This electronic document is able to synthesize specifications and production (material assessments, equipment follow-up, anomalies, drifts). It facilitates the validation step and batch release. It is also able to do upward and downward retrievals.

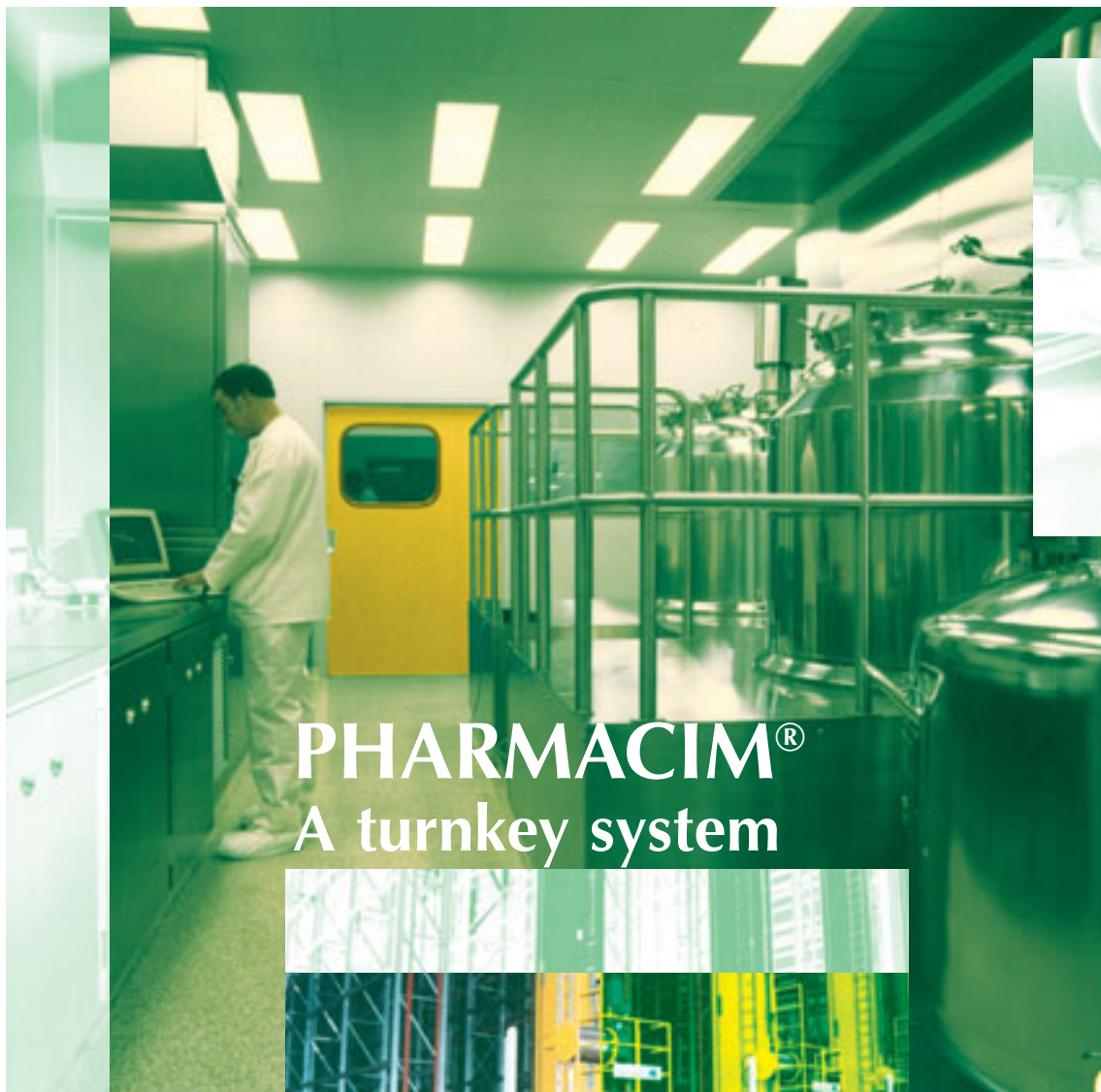
#### Performance management (PHARMACIM® SP)

The indicators and the reports ensure the performance measurement, the productivity follow-up, the assistance to new equipment reception, to the speed up in production rate, to maintenance (OEE, KPI),... in particular, of packaging units.

#### Label management (PHARMACIM® LM)

Everything is made easier : from the creation of gauges to label and stamps traceability. An interface graph guides the user throughout the whole creating process from label publishing to printing – all according to standards.





## PHARMACIM® A turnkey system



## A full control of pharmaceutical processes and constraints



### Project management

Our method as well as our experience guarantees you a perfect control of project integration while respecting your schedule deadlines and required quality from the specification up to the maintenance.

### Specification and system design

Our modular approach as well as all of our modelling tools guarantees a robust, easy to validate and adaptable system.

### Procedure analysis

Courbon has a solid know-how in batch processes (transfers, mixtures and cleansing - in liquid and pasty form). Our field of expertise also extends to galenic forms on the whole and to the entire production process from storage to distribution.

### ISA S95 standardized integration

Mastering current technology (PLC, OPC, RFID, bar code reader, ...), Courbon carries out turnkey systems : from the sensor to the ERP.

### Quality and regulation control

ISO 9001 V2000 certified, we use standardized documents and procedures for the whole of our processes. For example, each and every one of our Courbon experts working on pharmaceutical projects is automatically trained on regulatory constraints (21 CFR part 11).

### Validation tool

Our documentary system based on GAMP offers tools to help with system validation as well as standard regulatory audits.

### Training

Within the framework of the project or in addition to it, we also offer all the training necessary for operational teams.

### Maintenance and hotline

We also offer complementary to the integration project, preventive, adaptable, functional and changeable maintenance contracts. Moreover, our hotline has specialists and a helpdesk tool guaranteeing you the best service.