

Pharmaceutical and medical industry

Pharma industry is historically a big market for AOIP because of the ever rising level of performance and the very tight quality controls required by the approval bodies. It represents thus a priority for companies like AOIP that offer adequate precision instruments and guarantee performance and full compliance with standards.



Target customers

- ✓ *Per product type:* medicaments and generics, optics, prosthetics, homeopathy, blood collection, biotechnology...
- ✓ *Per activity:* laboratories, research and development, production and maintenance, administrations in charge of certification...

AOIP key-products to highlight

Data Acquisition

TM6640/50
FrontDAQ
PC10
Datalog 20/90/140
SA32

Calibration

Calys 50/75/100/150
PJ6301
PHP601/602
+Baths, ovens, dry blocks & humidity sensors

☞ Main installations to be controlled and/or monitored

- Air supply installations
- General production machinery
- Freeze-drying equipment
- Control sensors in storage rooms
- Centrifuges for blood plasma separation
- Reverse osmosis installations
- Steriliser and autoclave
- Environnemental control
- Refrigeration systems
- CO2 incubators
- Storage tanks
- Peristaltic pumps

☞ Key-issues of pharmaceutical industry

- Measuring temperature with high accuracy
 - Controlling temperature stability: average, maximum, minimum temperature
 - Controlling temperature homogeneity between sensors: deviation setting and deviation indication
 - Controlling humidity and pressure
 - Qualifying the climatic performances of the rooms
 - Detecting and troubleshooting possible temperature variations
- Storing results for audits and controls

✓ Our references on pharmaceutical market

- Novartis
- Glaxo Smith & Kline
- Aventis-Pharma
- L'Oral
- Sanofi-Aventis
- Biomerieux
- Aventis-Pasteur
- Chauvin laboratories
- Astra Zeneca
- Boiron Laboratories
- Maco Pharma



FDA Standard : 21 CFR Part 11

21 CFR Part 11 is a standard from the **Food & Drug Administration** in US, applicable since 1997. It specifies the way documents and electronic data should be correctly used in order to certify the reliability and safety of a system. The standard was set up **to minimise risks related to electronic processing of data.**

Key-rules for **pharmaceutical industry, medical operations, and cosmetics** are precisely defined in terms of system validation and safety, audit trail, operational control, documentation management, electronic signature and education.

The standard was set up to minimise risks related to electronic processing of data. For companies, having products complying with the standard means undisputable benefits:

- products with safe and reliable data monitoring
- no need to qualify each product for each new application

Which AOIP products comply with the 21 CFR Part 11 standard?

TM6640/6650
PC10
Datalog 20/90/140
SA32

when combined with
Visulog Pharma version
and Visulog Web

Calys150 and Datacal software

These AOIP products fully comply with 21 CFR PART 11: they create audit trails for all actions and events during a qualification.

The user is authorised to access to the systems through password and user ID given by the Administrator. Access Rights are also decided by the administrator. All the records are protected in a native format and can not be corrupted.

GAMP Good Automated Manufacturing Practises

The GAMP community was founded in 1991 by a core of pharmaceutical experts in the UK who were interested in meeting evolving FDA expectations for GMP compliance of manufacturing and related systems.

GAMP quickly became influential throughout Europe as the quality of its work was recognized internationally. GAMP has now become the acknowledged expert body when it comes to computer system validation issues.

AOIP and GAMP

GAMP recommendations are fully taken into account by AOIP when developing, manufacturing and selling new products dedicated to pharmaceutical industry.

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☞ Main applications

1/ Chamber monitoring for long-term samples and tissues storage

Need for temperature recording, storage of data and alarm system when temperature is beyond the authorized limit

For 10 thermal chambers:

1st solution: wireless data transmission

10 TM6650	150 €	1,500 €
10 Pt100	70 €	700 €
1 software Visulog pharma version	931 €	931 €
2 licences for Visulog pharma version	613 €	<u>613 €</u>
Total		3,744 €

2nd solution: wired data transmission

10 T2RN	290 €	2,900 €
10 Pt100	70 €	700 €
1 software Visulog pharma version	3,204 €	3,204 €
2 licences for Visulog pharma version	613 €	<u>1,226 €</u>
Total		8,030 €

2/ Climatic chamber characterization, respect of NFX15-140 or FDV08 601 standard

Qualification of temperature stability, homogeneity and humidity stability of the autoclave according to the must-have results edicted by the standard

If the chamber volume is below 2m³, characterization has to be performed on 9 temperature points.

1 PC10	1,977 €	1,977 €
9 Pt100	70 €	630 €
1 hydroclip probe	196 €	196 €
1 software Visulog pharma version	931 €	931 €
2 licences for Visulog pharma version	613 €	<u>1,226 €</u>
Total		4,960 €

3/ Monitoring incubators and ovens

Need to comply with the FDA Standard, real time data information on the monitoring computer, troubleshooting on the PC, storage of data afterwards

2 PC10 connected on RS485	1,977 €	3,954 €
20 Pt100	70 €	1,400 €
1 software Visulog pharma version	931 €	931 €
2 licences for Visulog pharma version	613 €	<u>1,226 €</u>
Total		7,511 €

