

PHARMACEUTICAL INDUSTRY

Sterile Forms in GMP environment

Innovative Solutions & Support



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TOGETHER BRING LIFE TO YOUR PROJECTS

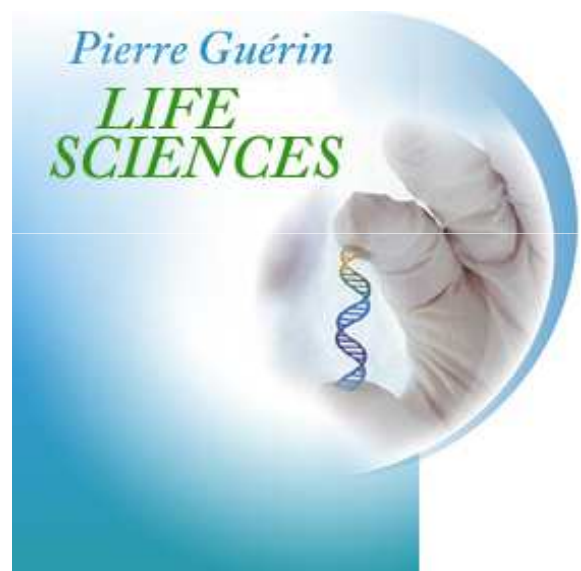
Pharmaceutical industry – Sterile forms Innovative Solutions and Support

PIERRE GUERIN provides you with the knowledge gained from more than 30 years in the design and manufacturing of equipment and process lines for the pharmaceutical industry. An expert for sterile forms in the GMP environment, PIERRE GUERIN brings you innovative and adapted solutions, incorporating excellence in quality, services and reliability.

At the heart of your process:

PIERRE GUERIN offers a full line of process equipment :

- Vessels for the storage of WFI and raw materials
- Formulation vessels with magnetic mixer
- Aseptic filling vessels
- Cleaning In Place Units
- Control system integration
- Turn-key formulation units for the GMP environment



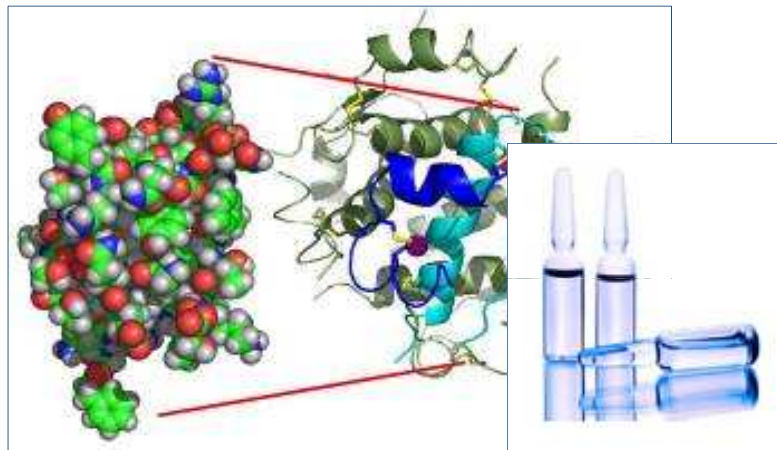
Our team is dedicated to your complete satisfaction:

At PIERRE GUERIN we take a full integrated service approach to ensure we meet your specifications from the initial quote through equipment installation and ongoing support Our turn-key solutions include:

- Process and equipment design in accordance with the highest standards (GAMP, ASME BPE, CFR, EHEDG, FDA, ATEX)
- Vertically integrated manufacturing of vessels and agitation systems, assembly, automation
- Detailed quality plan and project management, inspections and testing to support qualification
- IQ/OQ assistance
- Complete After-market Sales and Services

Process Expertise

PIERRE GUERIN knowledge related to the sterile forms extends from the raw materials storage through the formulation, the sterile filtration and the pre-filling storage. That compliments the expertise developed in the field of the biological forms where PIERRE GUERIN is also present at the heart of your process with a comprehensive range of Fermentors and Bioreactors from Research & Development to production scale.



PIERRE GUERIN has references for a numerous range of applications such as :

- Blood Derivatives (Factors VIII & IX, immunoglobulin, albumin, ..)
- Hormones (Insulin, Growth hormone, ..)
- Anti-cancer agents
- Microbial and viral vaccines
- Immuno-biologicals (Monoclonal Antibodies, Interleukins, growth factors, Interferon)
- Diagnostic products
- Parenteral drugs
- Nasals and ophthalmologic products

Storage and formulation vessels

The combination of our process and technological expertise with an extensive range of up-to-date design and calculation tools, is your assurance for quality and performance



Formulation vessels BIOVESSEL™



Mobile vessels BIOVESSEL™

Our range of standard vessels and services includes:

- Vessels for the storage of raw materials
- WFI storage vessels with minimum ferrite content (Capacities up to 40 000L or more)
- Mobile transfer vessels
- Formulation vessels, electro-polished inside down to 0.2 μm Ra, fitted with **PG-MAG™** magnetic mixer
- Aseptic filling vessels
- Comprehensive quality and test program (Including coverage and drainability tests) to support your qualification activities



Mobile vessels BIOVESSEL™

Mixing operations

We always have a solution to solve your mixing issues

PIERRE GUERIN designs and manufactures a complete range of agitators coming from the knowledge of MORITZ. For your most challenging applications, we offer you the support of our experts along with our testing capabilities either at your site or in our facility.



Three blades Agitator HTPG4™
for the mixing of fragile products



Heli Turbo Agitator HTA™ for
powder dissolution



Magnetic mixer PG-MAG™ for formulation
process and aseptic storage



2 or 3 agitation independent
movements for pastry products

Mixing operations

Transfer of liquids and pastry products, dissolving of powder, our experts bring you their support

The range of powder-liquid mixers POLYMEL™ and pumps PACKO™ complements the program of PIERRE GUERIN process components for transfer and mixing.



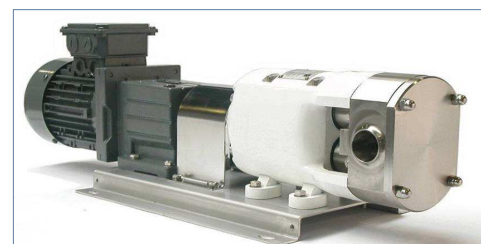
**POLYMEL™ with feeding pump
for pastry products**



**POLYMEL™ with hopper
operating under pressure**



**Centrifugal pump
PACKO™ EHEDG certified**

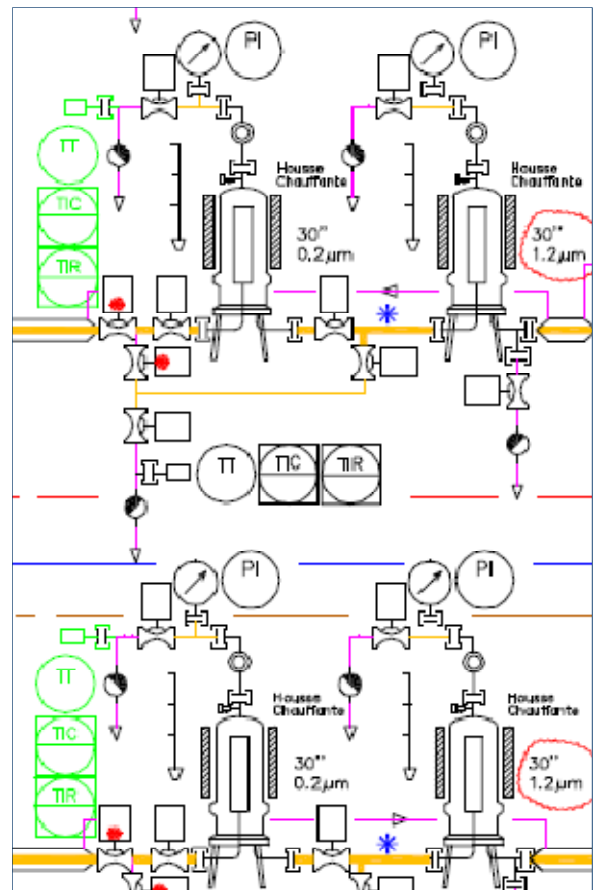
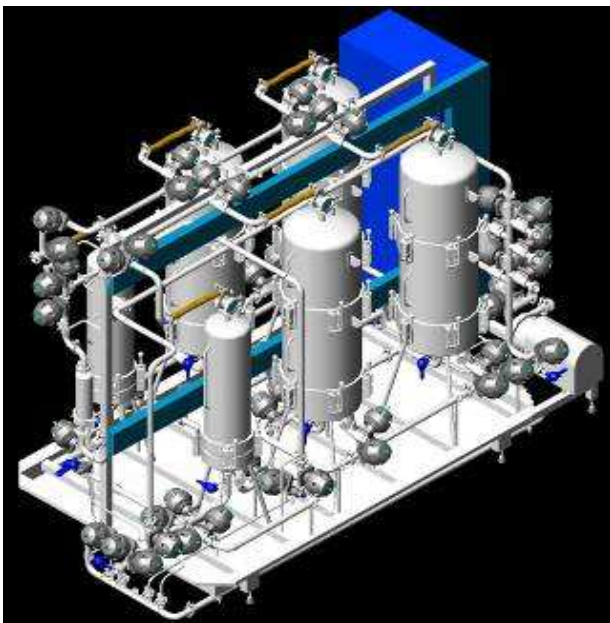


Volumetric pump PACKO™

Filtration Units

In partnership with your preferred filter cartridge manufacturer, we design your filtration units using original solutions for :

- Cleaning In Place
- Sterilisation In Place
- Integrity tests



Cleaning In Place

The principle of the Cleaning In Place technologies developed by PIERRE GUERIN is to optimise performance criteria, while respecting environmental constraints and minimising risk of cross contamination.

These units are designed to ensure the repetitiveness of cleaning recipes and the control of all cleaning parameters:

- Flow rate
- Pressure
- Temperature
- Contact time
- Detergent concentration
- Conductivity of the final rinse (for example in compliance with USP standards)

These systems also allow for a full traceability of the operations through a dedicated « Audit-Trail » module.



Automation

PIERRE GUERIN offers you specialization and expertise in numerous control system solutions gained through more than 20 years experience.

Programmable Logical Controllers (PLC)

- Simatic STEP 7 software for S7 300 and 400 PLC
- Unity Pro, PL7 PRO software for TSX Premium, Quantum and M340 PLC
- RSLogic 5000 software for ControlLogix® and CompactLogix® PLC



Supervisory, Control And Data Acquisition (SCADA)

- Intouch, IAS, InBatch
- iFIX, iBatch
- Factory Talk View, Factory Talk Batch
- WinCC, S7 Batch



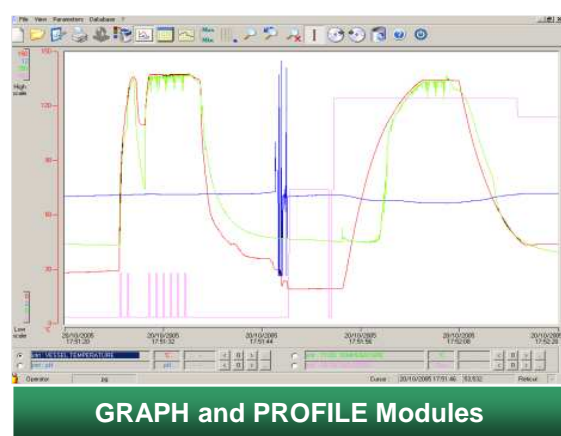
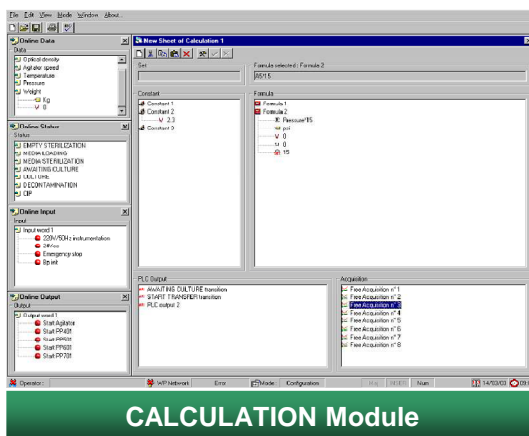
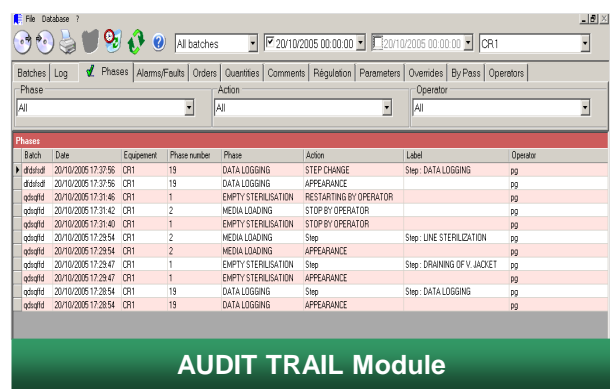
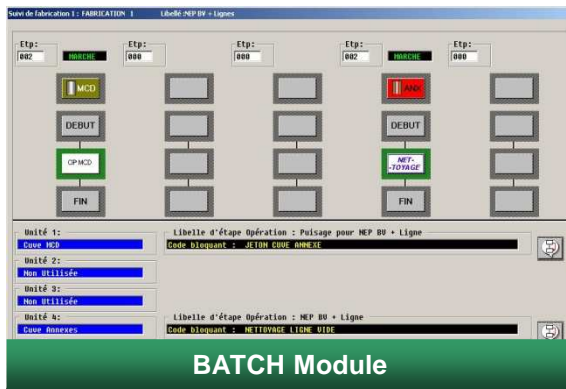
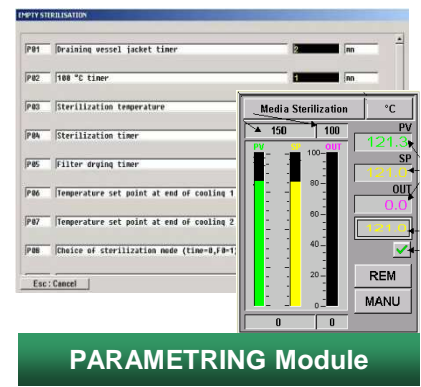
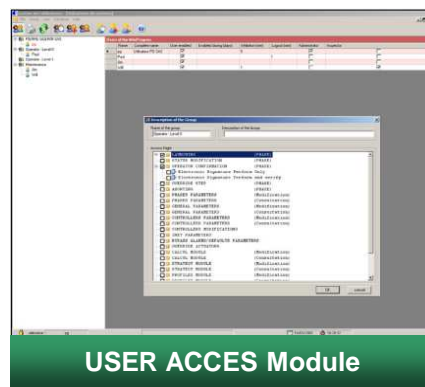
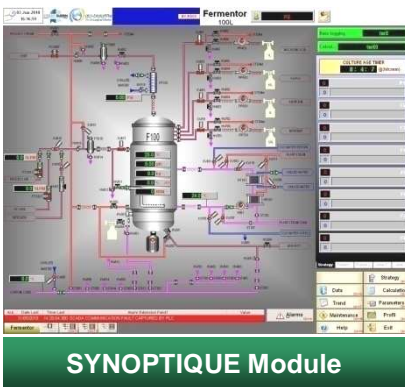
Digital Control Systems (DCS)

- DeltaV
- PCS7



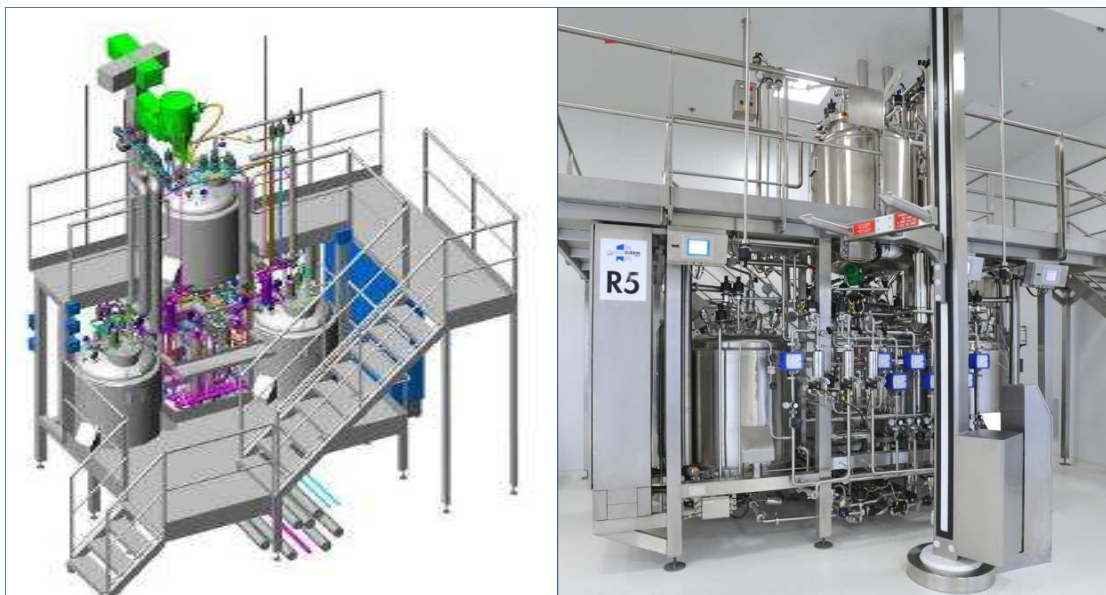
Automation

The control solutions developed by PIERRE GUERIN are designed to comply with the regulations and standards of the Pharmaceutical industries (GAMP5, 21CFR PART11, S88). In addition, they also offer an intuitive operator interface and a wide range of functional modules to suit your specific needs.

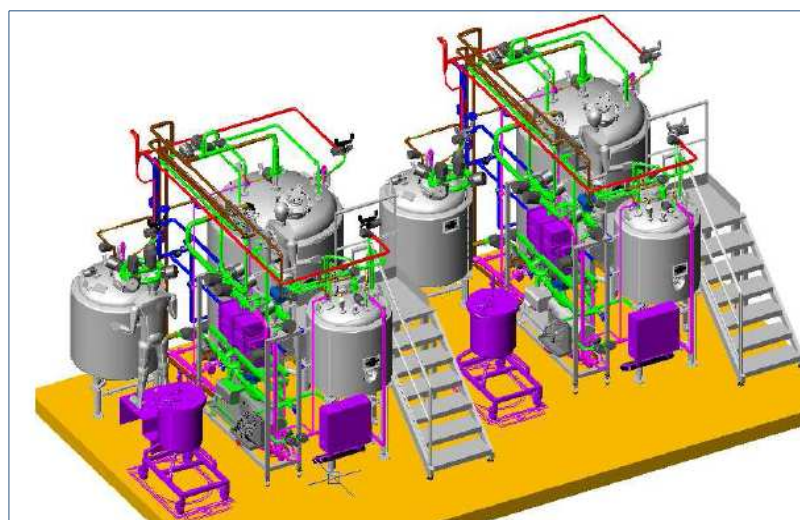


Our process and technological expertise to serve your turn-key unit projects

All over the recent decades, **PIERRE GUERIN** has become a major company in the design and manufacturing of turn-key units using a dedicated team of project & qualification engineers



Parenterals formulation units in super-skid design

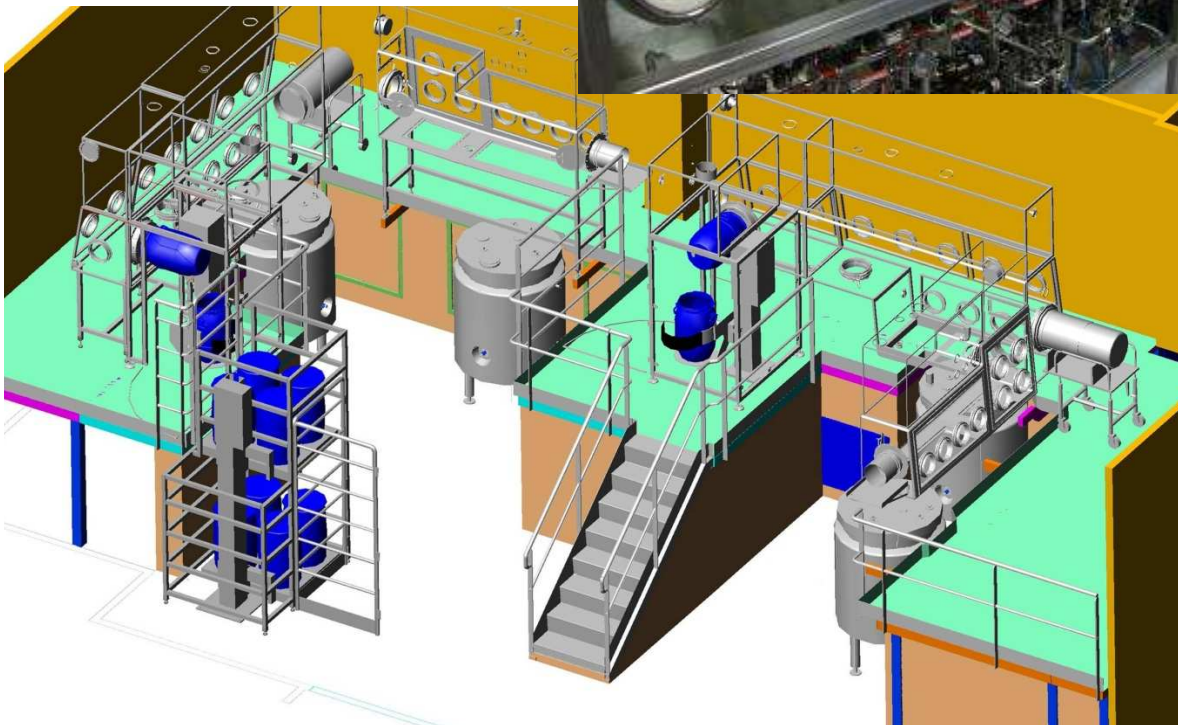


Turn-Key facility for the fractionation of human blood including 39 skid-mounted vessels

Our process and technological expertise to serve your turn-key unit projects

Acting as process integrator leader, PIERRE GUERIN may supervise the installation of complementary technologies such as isolators, fluid distribution, weighing units ..

Example of installation carried out in partnership with the GETINGE company for the supply of the isolators

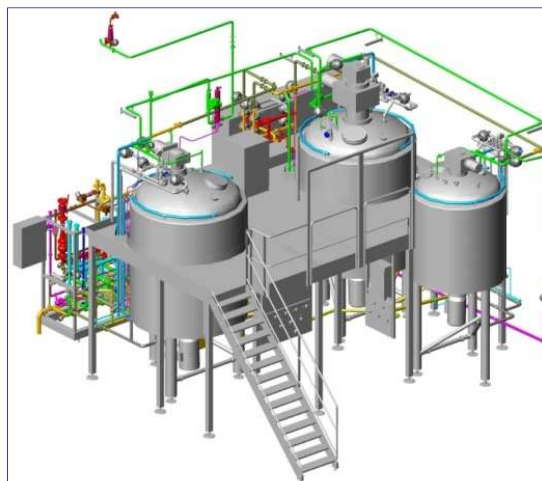
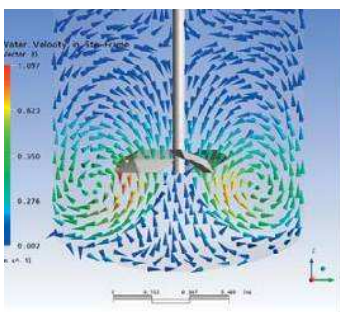
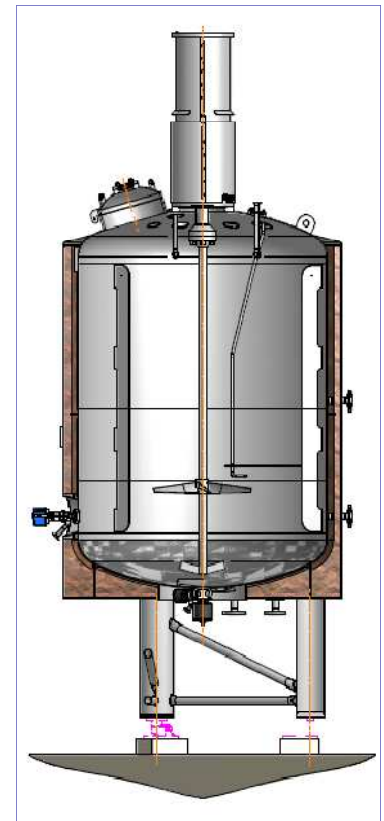
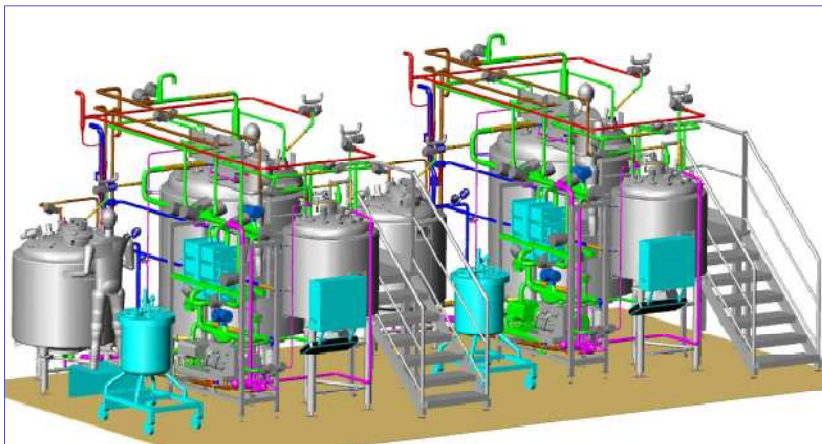


Turn-key unit for the formulation, sterile filtration and aseptic storage before filling of cytotoxic products

Design and Manufacturing

To meet the required process functionality and performance expectations and to achieve compliance with technical and regulatory specifications, **PIERRE GUERIN** provides you with:

- Expertise in design and manufacturing according to the highest standards (ASME BPE) and various construction codes (CODAP, ASME, ADMERKBLAT, BRITISH STANDARD)
- Advanced design and calculation tools including INVENTOR CAD system for full 3D design, SOLID WORKS for mechanical calculations, mixing and cleaning flow models
- ATEX experience
- Excellence in manufacturing and inspections : electro-polished finish down to $0.2 \mu\text{m Ra}$, controlled ferrite content, full material and welding traceability



Design and Manufacturing

Our industrial capabilities (390 000 h per year) and the vertical integration of our productions (vessel & agitators, piping assembly, wiring, automation, static & dynamic tests at factory with all fluids available) provides you with the assurance of:

- The highest quality equipment
- Effective project management
- On time delivery, fast installation and commissioning at site




Project Management and Quality Organization

From preparation of your initial quotation through product design, manufacturing, installation and support, the PIERRE GUERIN total-service approach ensures that your expectations are met or exceeded. Our internal processes were created to provide our customers with complete turnkey solutions of assured standards. They are supported by a thorough Quality Assurance System based on ISO 9001 but also the GAMP V5 for project management and automation development methodology.




The Bio-pharmaceutical projects are managed by a dedicated team using a comprehensive quality and test program (Project Quality Plan, Manufacturing and inspection files, FAT / SAT protocols) to support your qualification activities.

Project Management and Quality Organization

	Test & Inspection report (PV de contrôle) Thermal mapping with Kaye Validator (Cartographie thermique en cycle de stérilisation avec une centrale d'acquisition KAYE)		MI 12/174	
			Rev.	OR
		Date		10-AVR-2007
Client (Customer)	Project (Project)	Page		1/2
N° Projet PG (PG Project Nb)	Equipment (Equipment)	Instruction		MI 12/173



Action		Result (Résultat)		
		Pass (Conforme)	Fail (Non conforme)	NA (Non Applicable)
1	Configure Kaye parameters according to MI 12/173 <i>Configurer la centrale d'acquisition Kaye conformément à l'instruction MI 12/173</i>			
2	Perform temperature sensor calibration <i>Procéder à l'étalonnage des thermocouples</i>			
3	Place all temperature sensor according to approved P&ID <i>Positionner les Thermocouples suivant le P&ID approuvé</i>			
4	Run the sterilisation cycle Run the Kaye qualification phase <i>Lancer un cycle de stérilisation</i> <i>Lancer une qualification sur la centrale Kaye</i> Sterilisation phase number : (N° phase stérilisation) Acceptance criteria : F0 shall be more than 22 minutes for all sensors F0 ≥ 22 min pour tous les thermocouples (critère PG par défaut) Software project version : (Version projet client)			
5	Edit the configuration report, the calibration report and the qualification report <i>Imprimer les rapports de configuration, d'étalonnage et de qualification</i>			

	Dossier de traçabilité Cuve (Vessel Traceability book)		Revision :	C
			Date :	27-02-2007
			Page :	3/16
Client : (Customer)	N° de fabrication : (Series Number)		H1M60211-1	
Equipment : (Equipment)	CELL CULTURE BIOREACTOR	Capacité : (Capacity)	FE2200	
N° du plan : (Drawing #)		N° d'affaire : (Order #)		NA

Repère (Item)	Désignation (Description)	Matière (Material)	Fabricant (Manufacturer)	N° de coulée ou d'identification (Heat or Identification #)	N° d'annexe (Appendix #)	Nbre pages (page Qty)	Indice de l'annexe (Appendix revision)
1	LINER TH5 VIRGLE EP5	1.4404 EN 10028-7	OUTOKUMPU	41558-5	001	1	OR
2	HEMISPHERICAL BOTTOM FOND HEMISPHERIQUE DI 500	1.4435 EN 10028-7	OUTOKUMPU	451941	002	3	OR
3	BODY FLANGE BRIDE DE CUVE- COUVERCLE - FLAT COVER	1.4435 EN 10028-7	ISENBURGER GROBBLECH	491642	003	6	A
4	HEMISPHERICAL BOTTOM FOND HEMISPHERIQUE DI 525	1.4307 EN 10028-7	ACERINOX	6TL4	004	2	A
5	JACKET LINER DOUBLE ENVELOPPE TOLE EP2.5	1.4307 EN 10028-7	TKAST	0403388	005	1	OR
6	CIRCLE OF CONNECTION CERCLE DE JOINTION TOLE EP3	1.4307 EN 10028-7	TKAST	0570854	006	1	OR
7	SHEET JACKET CHICANE DOUBLE ENVELOPPE TOLE EP2	1.4307 EN 10028-7	TKAST	0572657	007	1	OR
8	ROUND ROND D10	1.4307 EN 10088-3	UGITECH	546011	008	2	OR
9	ROUND ROND D10	1.4307 EN 10088-3	UGITECH	546011	008	2	OR
10	SHEET COLLERETTE EP5	1.4307 EN 10028-7	OUTOKUMPU	50540	009	1	OR
11	SHEET COLLERETTE EP5	1.4307 EN 10028-7	OUTOKUMPU	50540	009	1	OR

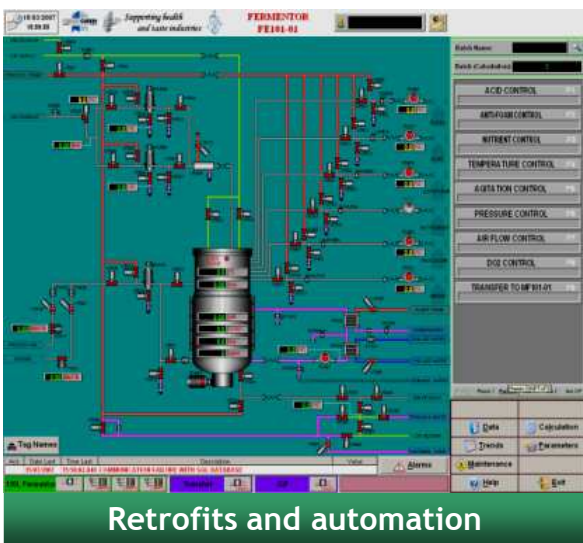
FAT Protocol



Traceability file

Customer Service

With PIERRE GUERIN, your Process Partner for 60 years, maximize your productivity while reducing cost of operation

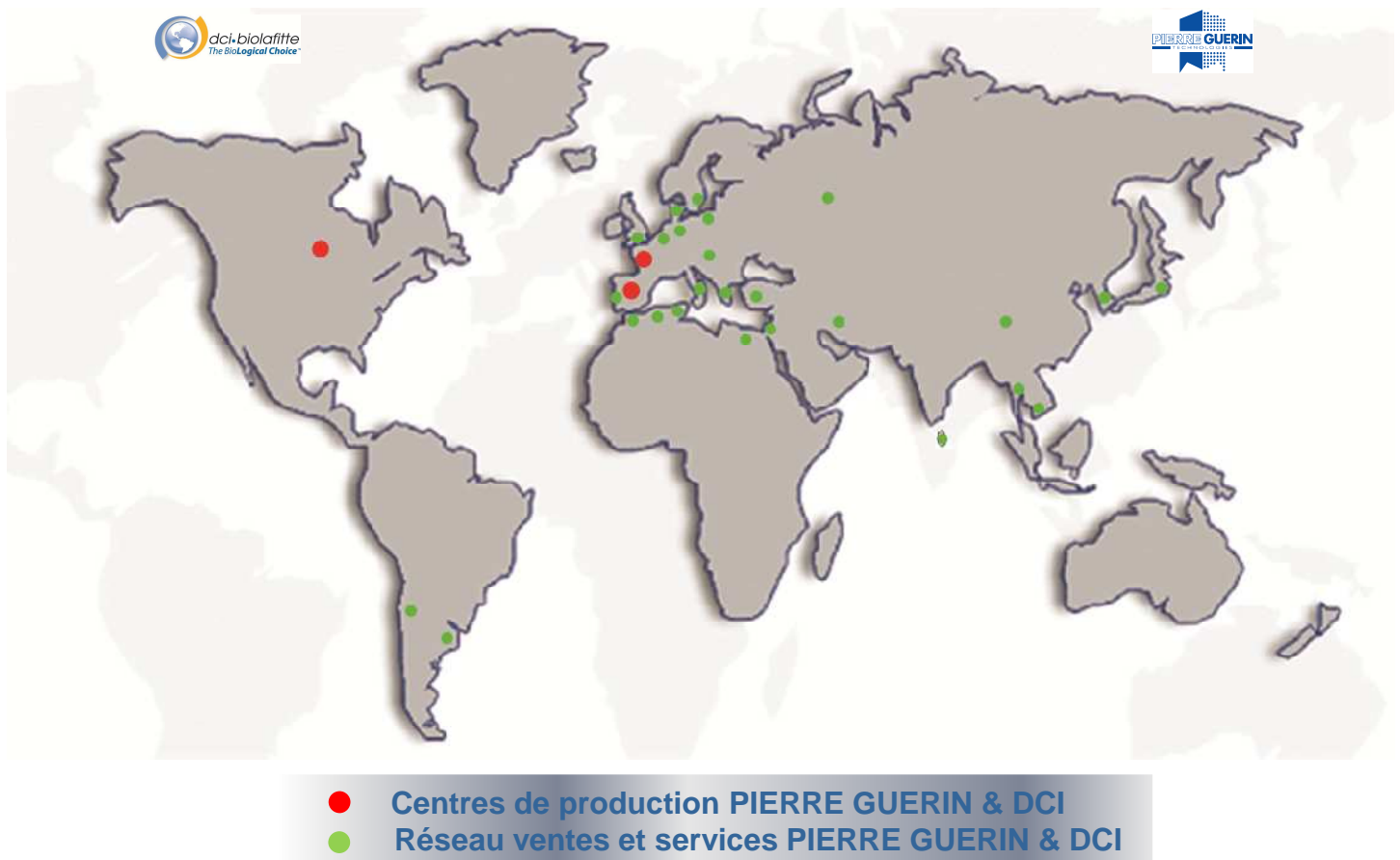


PIERRE GUERIN, a worldwide presence

Over several decades **PIERRE GUERIN** has supplied equipment to many of the worlds leading companies, Institutes & Universities through its extended **Sales & Services network**.

In Europe, our manufacturing units which are located in France and Spain, also serve Africa, Middle-East and Far-East.

Our Joint Venture **DCI-BIOLAFITTE** in the Unites States offers you similar manufacturing and service capabilities for the Americas.



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