

## Audits

## References

2010 -> 2016

September 2016

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**No.Siret:** 48429605800015

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## AUDITS (suppliers & manufacturers)

### 1. 2011

#### 1.1 HELSIN BIREX / Ireland

Review of inspection data in a 3d party manufacturer.

#### 1.2 SEPRACOR / USA

3d party manufacturer audit.

### 2. 2012

#### 2.3 BIAL / Portugal

Suppliers audit.

#### 2.4 PREGLEM / Switzerland

GMP audit of a 3d party manufacturing site.

### 3. 2013

#### 3.5 OM Pharma / Portugal.

Audit of the IMPs documentation system at the Portuguese site

### 4. 2014

#### 4.6 HOSPIRA / Italy

Deviations investigations.

#### 4.7 VIROPHARMA / USA & China

3d party audits of Viropharma located in China

#### 4.8 LFB / France

Evaluation of 2 french sites specialized in blood derivatives

#### 4.9 VITTORIA / Portugal

GMP audit of the ointment manufacturing

### 5. 2014-2015

#### 5.10 SANOFI PASTEUR / France

Gap analysis of 24 buildings / 2 french manufacturing sites

## 6. 2015

### 6.11 ALBOURZ DAROU / Iran

Quality evaluation and gap analysis of PFS manufacturing

### 6.12 SOCIETE LAITIERE de RETIERS

Audits of the sites of Retiers and Bozzola (Italy)

### 6.13 ETHYPHARM / France

Audit of Delpharm

## 7 2016

### 7.14 OPTINOSE / USA

Audit of Nemera (France) and Hovione (Portugal)



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## Due Diligence & Industrial Excellence

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## Due Diligence and Industrial Excellence

### 1. 2011

#### 1.1 PHARMA 5 / Morocco

Evaluation of the strenghts and weaknesses of the Industrial Operations organization.

### 2. 2012

#### 2.2 AVENTIS-ZENATA/ Morocco

QC department perfomances evaluation.

### 3 2013

#### 3.3 COOPER / Morocco

Evaluation of the Industrial Operations management.

#### 3.4 SILVERBACK / USA

Benchmarking studies. Constraints for registering biological products in Finland

#### 3.5 POLYMEDIC / Morocco

Due diligence of the company

### 4 2013-2015

#### 4.6 PAREXEL / France

2 years assignment on site

### 5 2014

#### 5.7 ZENTIVA-SANOFI / Czech Republic

Analysis of the Industrial Operations departments performances

### 6 2014-2015

#### 6.8 HOSPIRA / Italy

Interim site management for 9 months

### 7 2015

#### 7.9 MARTIN DOW / France

Support for calculating the BP and establishing the dossier for buying the Meymac site

## Quality systems and supports

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## Quality systems & supports

### 1. 2011

#### 1.1 HELSINN BIREX / Ireland

P.I.P.

### 2. 2011-2012

#### 2.2 CATALENT / Belgium

Support to Quality project

#### 2.3 SHIONOGI / UK & France

3 P.I.Ps for 15 months for quality compliance

### 3. 2012

#### 3.4 CEPHALON / U.K.

Batch release process review

Management of toll manufacturers

### 4 2013

#### 4.5 GENZYME / Ireland

On site, investigation of products contaminations.

### 5 2014

#### 5.6 VIROPHARMA / Italy

Quality issues investigations concerning the development of a biological product

### 6 2015

#### 6.7 ETHYPHARM / France

On site quality support

#### 6.8 ALLERGAN / France

CAPA

#### 6.9 PIERRE FABRE / France

Review of sites quality plans and monthly reports of the quality units.

## **7 2015-2016**

### 7.10. WYETH LEDERLE . Pfizer / Italy

Coaching in aseptic techniques in the site of Catania . Penis and non Penis, day and night shifts. From November 2015 to December 2016

## **8 2016**

### 8.11 LFB. Alès / France

Corrective action plan and project management

### 8.12 ETHYPHARM Chateauneuf en Thymerais / France

Providing an interim Quality Manager from January to August



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## Q & V VMP

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## Q&V + VMPs

### 1. 2011

#### 1.1 SEPTODONT / France

Q & V of the premises

#### 1.2 SERUM Product / Libanon

VMP

### 2. 2011-2012

#### 2.3 PHARMA 5 / Morocco

Premises qualification protocols check

### 3. 2012

#### 3.4 MEDIPHAR / Libanon

VMP.

#### 3.5 ALFA Lab / Libanon

VMP

#### 3.6 STALLERGENES / France

Evaluation of validation reports

### 4 2013

#### 4.7 VIROPHARMA / Italy

Elaboration of the autoclave validation protocols

### 5 2014

#### 5.8 NORTHSTAR Healthcare / Ireland

Transport validation

**6**    **2015**

**6.9 ETHYPHARM / France**

Validations of 4 products.

**6.10 ALLERGAN / France**

Autoclave cycles validation

**6.11 ALLERGAN / France**

Qualification of Bio Indicators



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## Regulatory compliance & APRs

### References

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## Regulatory compliance & APRs

### 1. 2011

#### 1.1 CORMOVE / France

Support for development and registration of a medical device.

#### 1.2 HAYS / Germany

Study of the registration compliance of dossiers (6 products ) for the Algerian market

### 2. 2012

#### 2.3 BIOGARAN / France

Regulatory compliance for the transfer of 4 products.

#### 2.4 STALLERGENE / France

Support for the registration of a biological product.

### 3 2012-2014

#### 3.5 VIROPHARMA / Italy

Support to development and registration of a new biological sterile product.

### 4 2013

#### 4.6 COOPER / Morocco

Regulatory evaluation of the hormones production.

### 5 2013-2014

#### 5.7 ETHYPHARM. CET site / France

APRs reviews (14 products)

### 6 2015

#### 6.8 ETHYPHARM. GQ site / France

APRs reviews (8 products)

### 7. 2016

#### 7.9 ETHYPHARM .GQ

HHA of one product

## **Audits FDA Mock inspections**

### **References**

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## Support for preparing FDA audit

### 1. 2010- 2011

#### 1.1 CATALENT/ France

Support to a french site manufacturing steriles to improve the premises, documentation and ways of working to a level conforming to FDA regulation

### 2. 2011

#### 2.2 PAREXELL/ USA

Support for preparing a FDA audit in a US based facility

### 3. 2012

#### 3.3 BIAL / Portugal

Preparation and training for a FDA audit

#### 3.4 TRANSGENE / France

Gap analysis of a manufacturing facility for FDA compliance

#### 3.5 PEROUSE MEDICAL / France

Support to the site for preparing a FDA audit

### 4. 2012-2013

#### 4.6 CRUCELL / Ireland

GMP assessment for FDA compliance of all manufacturing processes

### 5. 2013

#### 5.7 PAREXELL / UK & France

Support to inspection preparation (CAPAs / APRs) prior to FDA inspection of a French based facility.

### 6. 2015

#### 6.8 PIERRE FABRE Cosmetics / France

Support to the Quality team for FDA site visit

### 7. 2016

#### 7.9 CHANEL

Mock inspections of Senlis / Compiègne / Pantin (CPV/CCP/R&D) / Neuilly

## TRAINING

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## TRAINING

### 1. 2010

#### 1.1 . ABIDI / Iran

- Principles of the Q&V for premises
- Practical example

#### 1.2 . SWISS Pharma / Nigeria

- QC management
- Water systems. Conception. Q&V. Maintenance
- Maintenance systems
- ICH Q9

#### 1.3 . CEPHALON / France

- Quality systems

### 2. 2011

#### 2.4. OUBARI / Syria

- Quality department organization
- Principles of Q&V
- Risk management
- Supply chain organization

#### 2.5. MERK SERONO / Germany

- Risk management

#### 2.6. LAVOISIER / France

- High potent drug management

#### 2.7. CEPHALON / France and USA

- Quality systems
- GLP
- Pharmacovigilence.

#### 2.8. IPSEN / France

- Quality systems

### 3. 2012

#### 3.9 PHARMED / Morocco.

- Project management

### 4. 2013

#### 4.10 GS2M / Algeria

- Principles of Validations
- Cleaning validation

#### 4.11 SHIRE / Holland

- GLPs & GCPs

#### 4.12 OM-Pharma / Portugal

- Training in IMP manufacture, packaging and control

### 5. 2014

#### 5.13 SANOFI-ZENTIVA / Czech Republic.

- Coaching and communication.

#### 5.14 LGM Pharma / Belgium

- 3 people / 12 months at Wavre factory for GMP coaching and mentoring

#### 5.15 GSK / Belgium

- 1 p / 12 months for GMP coaching and mentoring

### 6. 2014-2015

#### 6.16 PIERRE FABRE / France

- Quality and compliance in Europe
- Specific training to QP.

### 7. 2015

#### 7.17 ALLERGAN / Belgium

- Change control workshops

## Projets Industriels/ Capital projects

## References

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## Capital Project References

### Introduction

In reply to your request for references to capital expenditure projects in which Galenisys has been involved, please find a list below. The list contains projects performed by Galenisys, a company that has been in existence for 8 years, and projects that have been managed by the Galenisys team prior to the formation of the current company.

In every project, both before and during Galenisys, the team has always managed projects in the same manner

2

### 1. Projets managed by the Galenisys team (before the formation of Galenisys)

#### 1.1 ALGIERS / Algeria. 1996/1999

The Project consisted of the construction of a new manufacturing site for solid dose products in the Industrial Park « Oued Smar ».

The site was destined for Rhône Poulenc Saïdal

Head of the project : Eric Gruber

Engineering Company : SMIC

The project was completed within both project timelines and budget.

Reference Contact : Karim TAMIR. [karim.tamir@sotec-ind.dz](mailto:karim.tamir@sotec-ind.dz)

#### 1.2 LOURES / Portugal. 2001/2002

The project consisted of the refurbishment of filling and packaging facilities to bring them into line with European requirements (EMA GMPs)

Head of the project : Eric Gruber

Engineering Input, Supervision and Oversight : Guy Grognet / Gérard Philippot / Jean Ringard

Engineering companies : ERTEC et TELSTAR

The project was completed on time and in budget.

Reference Contact : Rui Martin [rui.martinho@generis.pt](mailto:rui.martinho@generis.pt)

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Please note that following the refurbishment the site was purchased by Generis.  
However, Mr Rui Martinho, who we propose as the contact reference, was present on the site in Loures during the refurbishment work.

### 1.3 TONGI / Bangladesh. 1999/2000

The project consisted of the design and construction of a manufacturing site for the production of solid dose and injectable forms of penicillins et de cephalosporins, to WHO requirements

Head of the project : Eric Gruber. Supported by Jean Ringard and Gérard Philippot

Engineering Company : APC (Australie)

The project was completed on time and in budget

The Reference Contact : Nayeem Rahman [nayeemR@a-p-c.com.au](mailto:nayeemR@a-p-c.com.au)

Nayeem was the Bangladeshi company Industrial Director and acted as the local project head. Currently, Nayeem is based in Australia where he has taken up a position with APC.

### 1.4 SINGAPOUR. 1999.2002

The project consisted of the design and construction of a new manufacturing site for the production of low molecular weight Heparin. The standards that were applied were those of the FDA(USA) and EMA (Europe)

Project Quality Compliance Head : John Orsato

Engineering : CRIT

The project was completed on time and in budget. EMA and FDA certification were received

Reference Contact : Mr Don Britt [brittdonb@aol.com](mailto:brittdonb@aol.com)

Don was the VP World Wide Quality of RPR at the time of the project.

Tel + 1 336 706 35 77

### 1.5 DAGENHAM U.K. 1993-1998

The project consisted of the design and construction of new preparation and filling facilities for an injectable anti-mitotic agent. The standards, applied to the project, were those of the EMA and FDA.

Project Compliance Head : Steve Biddulph assisted by John Orsato

Engineering Input, Supervision and Oversight : Gerard Philippot

Engineering Company : Jacobs, UK

The project was completed with a slight delay to the timeline but in budget.

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FDA and EMA certification were achieved.

Reference Contact : Terry Simmons [terence.simmons@hospira.com](mailto:terence.simmons@hospira.com)

Tel. + 44 7736 116396

Terry was production manager on the Dagenham site and intimately involved in the project. He is currently working with Hospira in Italy.

### **1.6. LE TRAIT/ France1998.2000**

The projet consisted of the design and construction of new sterile product preparation and filling facilities. The project required the implementation of two automatic filling lines for syringes. The project was for EMA and FDA approval.

Project Quality and Regulatory Compliance Head : John Orsato supported by Gérard Philippot, Will Brame and Steve Biddulph.

Engineering Company : SOFRESID.

The project was completed on time and in budget. Both EMA and FDA certification were obtained.

The Reference Contacts : Will Brame, [William.Brame@sanofipasteur.com](mailto:William.Brame@sanofipasteur.com)

tel + 1 570 236 28 81

Eric Latour, Le Trait Site Director. [eric.latour@sanofipasteur.com](mailto:eric.latour@sanofipasteur.com).

tel +33 6 07 16 34 95

#### **NOTE :**

S.J. Biddulph, G. Grognet, E.Gruber, J.Orsato, G.Philippot and J.Ringard are, today, all members of Galenisys

## **2 Projets managed by Galenisys (or by PharmEnergie, a Galenisys Subsidiary)**

### **2.1 MP5 / Creapharm. RIOM France 2009.2010**

The project consisted of the outline design of a 100% increase in the preparation and product filling facilities for sterile products. The standards to be applied were those of the FDA and EMA.

Head of the projet : Eric Gruber assisted by S.J.Biddulph

Engineering Company : Courbon Process (now, Akremi-AxePharma)

The project was completed on time and in budget. The project was not progressed due to company take over negotiations, at the time.

Reference Contacts : Maxime Laugier [maxime.laugier@carbogen-amcis.com](mailto:maxime.laugier@carbogen-amcis.com)

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Marc Bertaud [marc.bertaus@carbogen-amcis.com](mailto:marc.bertaus@carbogen-amcis.com)  
MP5/Creapharm were taken over by CARBOGEN AMCIS

## 2.2. SIO / Arras France 2008.2012

The project consisted of the renovation of workshops for the preparation, filling and packaging of an active ingredient for an injectable final product. In parallel, an FDA and EMA quality system was designed and implemented on the production site. The standards that applied to the project were those of the EMA and FDA.

Head of the project : Eric Gruber, supported by Steve Biddulph, Didier Thiot, Jacques Guillorit and Marie-Françoise Baudry

Engineering Company : Courbon Process Ingénierie (now, Akremi-Axe Pharma)

The project was successfully completed and EMA and FDA approvals obtained in 2013

Reference Contact :, Mr Philippe Boyot [philippe.boyot@adm.com](mailto:philippe.boyot@adm.com)  
Philippe was the client's Head of Project for Quality and Compliance

## 2.3 PHARMED / Casablanca Maroc (Galenisys). 2010.2012

The project consisted of the design and construction of a new solid dose manufacturing building. The design and early construction work were successfully completed but due to budgetary and strategy restraints, the project has been put "on hold" for two years.

Head of the project : Eric Gruber, assisted by Didier Thiot

Engineering Company : A.MSeffer

Reference Contact : Rym Bouazzaoui [r\\_bouazzaoui@hotmail.fr](mailto:r_bouazzaoui@hotmail.fr)  
tel + 212 6 61 40 68 63

Rym was the client's project leader and she is currently a director with Laboratoire Génération Santé

## 2.4 SEPTODONT / France (Galenisys). 2010-2011

The project consisted of the design of a refurbished facility to provide a 100% increase in product filling capacity for the manufacture (preparation, filling and packaging) of sterile injectables. The design included :

- The extension of the current facility to include a new filling line
- Additional preparation facilities

In addition to the above, the client requested the design of a new site layout with rationalized personnel and material flows.

Both outline and detailed project designs were completed on time and in budget

Head of the Project : G.Philippot , assisted by G.Grognet and S .Biddulph.

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Architects : BRS Paris

Reference Contact : J.Darribère [jdarribere@septodont.com](mailto:jdarribere@septodont.com)  
J.Darribere was the site director during the project

## **2.5. BIAL / Portugal ( Galenisys ) 2010-2011**

The project consisted of the outline and detailed designs of a green field manufacturing site for solid dose and injectable products to EMA and FDA standards.

Head of Project : Eric Gruber, assisted by Steve Biddulph and Gérard Philippot

Engineering Company : Courbon Process (now, Akremi-Axe Pharma)

The outline and detailed designs were successfully completed but no construction has begun due to the difficult national economic climate in Portugal.  
The project is on hold, for the moment.

Reference Contact : Guilherme Loureiro, [guilherme.loureiro@bial.com](mailto:guilherme.loureiro@bial.com)  
+ 351 963 469 720)

## **2.6. GENFAR-SANOFI / Colombia (Galenisys) 2014-2015**

Redaction of the concept & basic designs of 4 steriles workshops (3 ampoules + 1 eye drop) for human health and one sterile workshop for animal Health

- ° Alternatives of designs
- ° Estimation of the costs
- ° Scheduling

Head of project : Eric Gruber, assisted by Axe Pharma.

Work completed end of July 2015

Reference contact: Julio Varela +57 317 515 27 91. [Julio.varela@sanofi.com](mailto:Julio.varela@sanofi.com)

