Projets Industriels/
Capital projects

References

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

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 sitefor 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

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
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
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
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.
FDA and EMA certification were achieved.

Reference Contact : Terry Simmons 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
tel + 1 570 236 28 81
Eric Latour, Le Trait Site Director. 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

Marc Bertaud 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 ingedient 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 Ingéniérie (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
Philippe was the client's Head of Project for Quality and Compliance

2.3 PHARMED / Casablanca Maroc (Galensiys). 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
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.

Architects : BRS Paris

Reference Contact : J.Darribère 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 Compnay : 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
+ 351 963 469 720)

2.6. ROUGINE TOLID / Iran (Galenisys) 2014 -todate

Revision of the concept and basic designs of the new solid doses factory green field project
Q&V of the facilities (on going)

2.7. SANOFI-GENFAR / Colombia (Galenisys) 2015

Redaction of the basic designs of the steriles workshops (3 ampoules + 1 eye drop). .

° alternatives of designs
° Estimation of the costs
° Scheduling

Detailled design : under discussion.
2016 : new Sanofi industrial strategy . Project cancelled.

2.8. CONGO-BRAZZAVILLE / Pointe Noire. 2017

Cost estimate of a green field project supplying several central-african markets.

Galenisys
Pharmaceutical Consultants

Audits FDA
Preparations
Mock inspections

References

2010 -> 2018

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.

8. 2017

8.10 Pfizer / Italy
Sterile behavior and preparation for inspection of the Catania site. 6 consultants from January to December.

8.11 Chanel / France
- Preparation of the Chamant site
- Preparation of the Compiègne site

8.12 Lonza / USA
Support to the site for preparing the inspection

8.14 MARTINDALE / UK
Support to the site for preparing the inspection.

9. 2018

9.15 MARTINDALE /UK
Support to the site from January to October

9.16.CHANEL / France
Double checking of Chamant.

9.17 LONZA / USA
Support local team. 4 auditors all year long

9.18 PFIZER / Taïwan
Sterile behavior observations and controls

9.19 HOSPIRA / India
Sterile behavior of sterile filling. Aurangabad plant

Galenisys
Pharmaceutical Consultants

Q & V
VMP

References
2010-> 2018

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

7 2016

7.12 CHANEL R&D / France
Q&V of analytical methods

8 2017

8.13 CHANEL Corporate / France
Q&V of analytical methods

8.14 SANOFI Winthrop / China
Support to cartridges filling validation

8.15 ALLERGAN / France
Sterilisation strategy

9 2018

9.16 CHANEL / France
Protocols for a TOC analyser

9.17 MACOPHARMA / France
Support to the validation of a new LVP 500 ml perfusion bag

Galenisys
Pharmaceutical Consultants

Regulatory compliance & APRs

References

2010 -> 2018

Regulatory compliance & APRs

1. 2011

1.1 CORMOVE / France
Support for development and registration of a medical device.

1.2HAYS / Germany
Study of the registation 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
HRA of one product

8. 2017

8.10 ALLERGAN
Sterilisation strategy

8.11 CHANEL
HRA for one product

9. 2018

9.12 MARTINDALE /UK
APR of 10 products

Galenisys
Pharmaceutical Consultants

Quality systems and supports

References

2010 -> 2018

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 . Penicillins and non Penicillins, day and night shifts. From November 2015 to April 2017

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

9 2017

9.13 PFIZER / Italy
FIT study

9.14 LONZA / USA
Evaluation of the systems vs FDA standards

9.15. CHANEL / FRANCE
Evaluation of the systems of Compiegne and Chamant vs FDA standards

9.16 MARTINDALE / UK
Evaluation of the Romford site and of the PFS workshops systems vs FDA standards
From October to December

9.15 DBV / France
Risk analysis of the project

10 2018

10.16 MARTINDALE /UK
NCR analysis
NCRs tabulation

10.17 PZIZER / China
Compliance of a aseptic filling line in Dalian site

Galenisys
Pharmaceutical Consultants

Due Diligence & Industrial Excellence

References

2010 -> 2018

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

8 2017

8.10 DBV / France
Risk analysis of the value chain. Supply chain

9 2018

9.11 SPE Capital /Morocco
Technical due diligence of a pharmaceutical company located in Morocco

Galenisys
Pharmaceutical Consultants

Audits

References

2010 -> 2018

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)

8 2017

8.15 SANOFI GmbH. Audits of CMO's in Russia
- First audit : sites of Dobrolek & Skopinpharm
- Second audit : site of Pharmastandart
- Third audit : site of Ufa

8.16 MARTINDALE / UK
- GMP status of Romford

9 2018

9.17 ITARUS / UK
- IT. System audit

Galenisys
Pharmaceutical Consultants

TRAINING

References

2010 -> 2018

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

8. 2017

8.18 CHANEL / France

- FDA training in 5 sites :
    - ° Compiegne
    - ° Chamant
    - ° Le Meux
    - ° R&D Pantin
    - ° Corporate Neuilly

9. 2018

9.19 PFIZER / India

- Training and coaching of sterile manufacturing at Dalian site

9.20 PFIZER IKKT / India

- Aseptic process improvement at Chenaï site from October to end of December