GALENISYS PROJECT REFERENCES

Galenisys have carried out assignments for clients all over the world. Listed below are **some** recent projects in each of our Areas of Excellence:

Asepsis & Sterility Assurance
Qualification & Validation
Quality Systems
Regulatory Compliance
Capital Investment Projects

Asepsis & Sterility Assurance:

2018-20 USA Quality System and Aseptic processing 3 sites
Galenisys assisted with the improvement of Quality Systems, Aseptic activities, and Qualification & Validation programmes at 3 manufacturing sites for this major multinational client.

2020 United Kingdom Preparation for an FDA PAI
Full review of laboratory and site utility systems with a remediation plan (fully executed), and background support during the audit for an FDA PAI of the steriles manufacturing facility.

2019 Europe Steriles Audit (Vaccine) - Facility and Training Material
As preparation for a forthcoming FDA inspection, Galenisys provided the multi-national Pharma client with a thorough independent review of the readiness of the companys' key aseptic filling process, and personnel behaviour, with associated training materials & activity modules.

2017-2018 China Quality system and Aseptic Processes
Here we evaluated the pharma companys' Quality System & Aseptic Activities, and assisted with the design and implementation of improvements.

2018 India Review of Aseptic Processes and Systems
Galenisys team of five experts assisted in remediation of identified issues, and reviewed existing aseptic systems and processes in preparation for an FDA inspection.

2017 Asia Quality System and Aseptic processing
Galenisys evaluated this pharma companys' Quality System and Aseptic processes, defined an improvement plan, and assisted with implementation, especially operator & technician training.

2015-2017 Europe Review and Coaching for Aseptic Processing
A Galenisys team of six experts & project manager conducted a thorough review of all aspects of process, systems, and behaviour at a multi-national company site in preparation for an FDA inspection. Galensisy majored in the extended & detailed observation & coaching programme to improve aseptic area behaviour.

HQ/Siège 28, Rue Meslay, 75003, Paris, France.
Offices and Postal Address (Courrier) 11, Rue Notre Dame de Nazareth, 75003 Paris FRANCE
Tel Bur. : +33 1 45 55 44 14 Tel. Mob : + 33 6 32 32 99 27
Contact : info@galenisys-pc.com

SAS au capital de 70 000 € - N° TVA Intracom FR 70484296058 - SIRET 48429605800056 - RCS Paris B 484 296 058

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Qualification & Validation:

2020 Europe Cosmetic products Qualification
For this preminent cosmetics manufacturer Galenisys prepared Qualification Protocols to bring the facilities into compliance with FDA Regulatory requirements including those for personnel training. Concurrently we undertook microbiological contamination troubleshooting.
2019 Europe USA market entrant
As part of various multiyear assignments Galenisys established a validation & qualification programme to meet FDA PAI expectations for the flagship new product , and reviewed resulting reports.
2015 Europe Process & Analytical method validation
Galenisys assisted this Biotech company with process and analytical method validation of an aseptically filled biological product. We also provided process, environmental, & utility control procedures.

Quality Systems:

2020 Europe QC improvements
Microbiology Department. Laboratory management, analysis verification, coaching & personnel training.
2020 Europe Good Laboratory Practice
Guidance and Support for GMP approval of QC Laboratory, (pharma manufacturing site)
2019-20 Europe Biotech companys' packaging
As part of various multiyear assignments Galenisys prepared packaging materials specifications, and associated testing procedures, with implementation at the clients CMOs.
2019 Europe Auditing Quality Control
Audit and improvements report for QC & Microbiology Contract Laboratory.
2018 United Kingdom Review of Site Systems for FDA PAI
Galenisys undertook a full review of all site quality systems. & provided a comprehensive gap analysis plus a plan for remediation, (including the introduction of a multi-functional site management team). This was implemented with a Galenisys expert embedded in the organisation.
2016-17 Europe Quality System & Troubleshooting
Galenisys assisted with the improvement of this Blood Fractionation company's Quality System. We also provided solutions for various Quality and Manufacturing issues.
2014-15 United Kingdom Quality Assurance of CMOs
Galenisys assisted this medium sized pharma company in improving the management of their CMOs and Suppliers. We established Contractor & Supplier management processes and procedures along with detailed Quality Technical Agreements.
2014 Europe Quality Systems Improvements
Galenisys implemented Quality System and Batch Documentation improvements at this medium sized CMO, enabling the company to pass the following FDA inspection with no observations of non-conformity.

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Regulatory Compliance:

*Each of Galenisys other 4 Areas of Excellence are related in various ways to ensuring **Regulatory Compliance.** During our discussions with prospective clients, we provide the regulatory context of the proposed assignment scope. Our experience in different functions, different cultures, and different branches of the Healthcare Industry; has ensured that our assistance to clients in widely different assignments, are focused on providing the necessary Regulatory Compliance. Some examples of this follow*

2017-20 Europe USA market entrant
For this biotech company approval & USA marketing of its flagship development product was its primary objective. Galenisys various assignments were undertaken within an overall programme which we heavily influenced to ensure that key components of dossiers would meet requirements, and that its plant and CMOs would meet FDA PAI expectations.
2013 -15 Europe Returning an antibiotic manufacturing company to Compliance
Following FDA warning letters received by the client, Galenisys commenced a remediation programme with assistance in improving aseptic operator behaviour through observation. Training & individual coaching ensued. We also assisted with equipment & utility qualification, process validation, and the improvements to the site CAPA system. This Galenisys input was crucial to preparing for the follow up FDA inspection which raised no observations of non-conformity.
2014 Europe Implementation of process improvements
In this typical assignment for a biotech manufacturer, Galenisys advised on the necessary process improvements and monitored the resulting implementation to provide previously lacking process FDA Regulatory Compliance

Capital Investment Projects:

2020-21 Africa Major vaccine Project
Galenisys have been chosen to evaluate the capital investment requirements for a yellow fever vaccine manufacturing project at an existing vaccine plant, and we are closely liaising with the other project partners.
2018 South America New manufacturing facility
In this project management support was provided in a green field project. This included risk assessment of hormone product manufacture for concept design consideration of 5 sterile suites. The assignment also comprised GMP concept training, QC lab perfomance evaluation, key managers personal evaluation, & technical due diligence.
2014-15 Canada Design & Construction
The design & subsequent construction support- manufacturing facility for oncology products
2014 Europe Interim Site Management during construction
Galenisys provided an Interim Site Leader for a major sterile manufacturing plant employing c 400 people during a key remediation period, to ensure continued day to day management of the site, during a Capital Investment Project in preparation for a FDA GMP inspection.
2016 Europe Design, & Construction support prefilled syringe manufacturing suite