

TELSTAR CONSTRUCTS A HIGH CONTAINMENT, MAXIMUM SAFETY, MODULAR R+D LABORATORY FOR MEDICHEM IN MALTA

TERRASSA, BARCELONA, SPAIN, October 30, 2014 /EINPresswire.com/ -- Telstar has successfully completed the construction and installation of a modular R+D laboratory and Kilo lab at the Medichem production centre in Hal Far (Malta) for manufacturing HPAPIs (Highly Potent Active Pharmaceutical Ingredients). The facility consists of a production room and a laboratory, both under negative pressure relative to adjacent rooms and the exterior to ensure user protection.

Telstar carried out the project management of this facility under an EPC (Engineering, Procurement and Construction) arrangement. The architecture, HVAC system, distribution of utilities and services, the provision of heating and cooling water, and the inside furnishings were included in the scope of this project. Telstar undertook the detailed and construction engineering phases, which relied on direct client involvement, the purchasing of materials and the construction, which required continuous supervision of materials quality and workmanship to achieve approval and validation of the facility.



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Modular design



The project has been developed under an EPC (Engineering, Procurement and Construction) agreement
Telstar

The modular laboratory has been built as a single structure that comprises nine rooms grouped in four areas: a production area, which includes two 15 litre reactors, a filter dryer and a micronizer; an R+D laboratory; a technical area (to house the air handling unit, hydraulic installation, electrical and control cabinets, vacuum system and so on) and, finally; staff changing rooms for entry and exit. The facility has been

designed and constructed to produce HPAPI's in a GMP environment and with containment levels of 40 ng/m³.

Unlike conventional construction, the modular approach enabled the entire system to be assembled and qualified in the Telstar manufacturing facility in Estonia. From the operational standpoint, this had advantages in terms availability, control and access to construction materials and manpower without relying heavily on the supply capacity in the client country. It has also resulted in considerable cost savings as a consequence of the limited time staff spent travelling and reduced implementation time on site. The modular facility was installed, commissioned and validated in its final location at the Medichem premises in Malta within one month. If conventional construction techniques had been utilised it would have taken six months to complete the project on the client premises. Finally, the modular design structure enables Medichem to easily modify the facility and even relocate it if required in the future.

High containment and maximum safety

The modular laboratory developed for Medichem in Malta fulfils the high containment and maximum safety specifications which are required when operators handle highly active ingredients. For example, air extraction from the rooms utilizes BAG-IN/BAG-OUT (BIBO) safe change filters, to eliminate the risk of cross-contamination and to protect the operator during filter changes. An emergency shower has also been provided at the exit, which the operator can use in the event of a hazardous spill. In addition, the Kilolab ATEX 3G classification for all the equipment in the room (including switches, push buttons, light fixture, power outlets, etc.) protects against explosions that are a risk when flammable solvents are being processed. Finally, Telstar has included in this modular laboratory an innovative system for distributing breathable air. Breathable air connection points have been installed in all the rooms so that, in the event of an emergency, the operator has access to a safe supply of air stored in cylinders installed outside the module.

Medichem

Medichem is an independently-owned API manufacturer, headquartered in Barcelona (Spain) with more than 40 years of experience in this market. The company, which has two FDA inspected plants (Spain and Malta) and 3 R&D centers located in Spain, Malta and China, has more than 250 people working at various locations (Spain, Malta and China) and delivers products to more than 60 countries (United States, the European Union and Japan among others).

Medichem is recognized for its broad pipeline of new products indicated for the treatment of diseases in many therapeutic areas, such as central nervous system, cardiovascular, gastrointestinal, ophthalmic, etc... Medichem has a sister company, Combino Pharm, which manufactures, develops and markets generic pharmaceutical products. Both companies also offer contract manufacturing services (API and FDF).

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