

## Case Study #1 Daw Tech Completes Extension of Ethical Pharmaceutical Products Pilot Plant for Rhodia Pharma Solutions

### Summary:

Daw Tech, a leader in controlled environment and cleanroom design, engineering, UHP and installation services was contracted to extend the scope of a pilot ethical pharmaceutical products plant for Rhodia Pharma Solutions (the former RHODIA Chirex).

### Situation:

Rhodia is a contract pharmaceutical manufacturer, specializing in Active Pharmaceutical Ingredients or APIs and Intermediates. Rhodia's Annan Pilot Plant was designed with future capacity for parenteral API, but began plant operation with a campaign of intermediates.

As manufacturing increased, Rhodia needed to complete the facility by building a class 10,000 cleanroom for a final product-offloading and a finishing suite located below the final stage filter/drier isolation equipment. As with all other manufacturing equipment on site, the new cleanroom and all its associated services needed to have hazardous area classification and cGMP criticality. While the initial design concept incorporated a traditional cleanroom construction, three additional issues were key drivers of the product design and construction:

1. Validation to standards approved by international regulations.
2. Ensuring that the new cleanroom fulfilled the area electrical classification requirements.
3. Maintaining the pilot plant's flexibility, so the plant could continue to produce multiple products.

The new clean room finishing suite was divided into several areas, designed with cascading pressure regimes and air flow rates:

1. The Offload Area: This area boasts two airlocks at the entrance and the exit. In addition, adjacent to the outlet airlock is a decontamination shower. Discharging into the Offload Area through the ceiling, is a high specification, Hastalloy pressure filter - dryer. This terminates with a 12-inch diameter, continuous liner loading head, which provides an accurate check weight and primary containment for offloading. The loading head and its controls were incorporated into the fabric of the clean room.
2. The Keg Handling Area: This area contains a special pass hatch for safe transfer of kegs through to the Offload Area.
3. Air Suit Change Area: This gray area acts as a safe change area for what is designated a single manning activity.
4. Dirty Change Area: This is where the operator leaves his outside wear prior to entering the Air Suit Change Area.

### Why Daw Tech

"Rhodia's pharmaceutical customers expect very stringent standards to be enforced," said Steve Revill, Senior Project Engineer at Rhodia Pharma Solutions in Annan. "The cleanroom needs documentary evidence of the quality standards achieved during each phase of the project, from design through construction to final commissioning and operation. Before selecting DAW for this work, a full engineering quality audit was carried out on the supplier.

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"At the conceptual design stage, Rhodia conducted a value engineering initiative. We were looking to find a solution that could not only satisfy all our operational requirements, but also provide a fully validated facility that was fully compliant with our technical specifications and keep our costs minimal. As we concluded each process, it became clear that Daw could meet our needs."

Rhodia Pharma Solutions and Daw Tech engineers worked closely together to satisfy the technical and documentation requirements of this facility, with the expertise of both parties playing a major part in the execution of a satisfactory project. Daw's commitment to supplying the CGMP documentation to demonstrate the quality of the build and validate it for its intended use was also critical to the customer.

The Daw Tech design managed to utilize the building's existing HVAC, or heating and ventilation system, which immediately reduced the installation cost by 30 percent. Daw's double HEPA filter Trox BOX design, allowed make up air to be discharged into the building envelope, as opposed to an external exhaust system, thus minimizing civil and ductwork costs.

"Daw Tech is known for finding creative ways to solve customers needs that often save the customer significant amounts of money," said Trevor Drummond, manager European sales, Daw Tech Europe. "Our work at Rhodia was no exception. In addition to the modifications in the HVAC system, Daw Tech was able to trim overall project costs by using modular, prefabricated construction, thus reducing establishment costs, and site labor charges."

The two companies also worked as an integrated team throughout the finalizing of the design and the part specification. The Daw Tech team extracted maximum advantage from Rhodia's extensive experience in the validation of facilities and equipment, while Rhodia relied heavily on Daw Tech's understanding of the fundamentals of cleanroom design and construction.

"We definitely faced some on-site challenges," said Revill. "One area that could have become a potential problem arose as we looked more closely at the electrical side of the design. The lights, drives and enclosures for the cleanroom both had to conform to Rhodia's explosion proof site standard and maintain cleanroom pharmaceutical integrity. However, the standard FFU was developed in order to meet the strict EXD ratings, which demand that no sparks are generatable. Daw Tech helped us design a solution that ensured that the Trox Box and Fan Filter Unit (FFU) met all the criteria."

### **About Rhodia Pharma Solutions**

Rhodia Pharma Solutions is a wholly owned division of Rhodia, serving the pharmaceutical sector. The company is a contract pharmaceutical manufacturer, specializing in APIs and Intermediates. It has research and development capabilities in the UK and the US, with two major manufacturing sites in the UK, Annan and Dudley.

### **About Daw Tech**

Daw Tech is a leading global supplier of controlled environmental solutions. Services include design and engineering, specialty contracting and UHP process systems expertise for the microelectronic and life sciences industries. Daw Tech's product portfolio includes architectural components for contamination control and containment, as well as systems for commercial applications.

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