

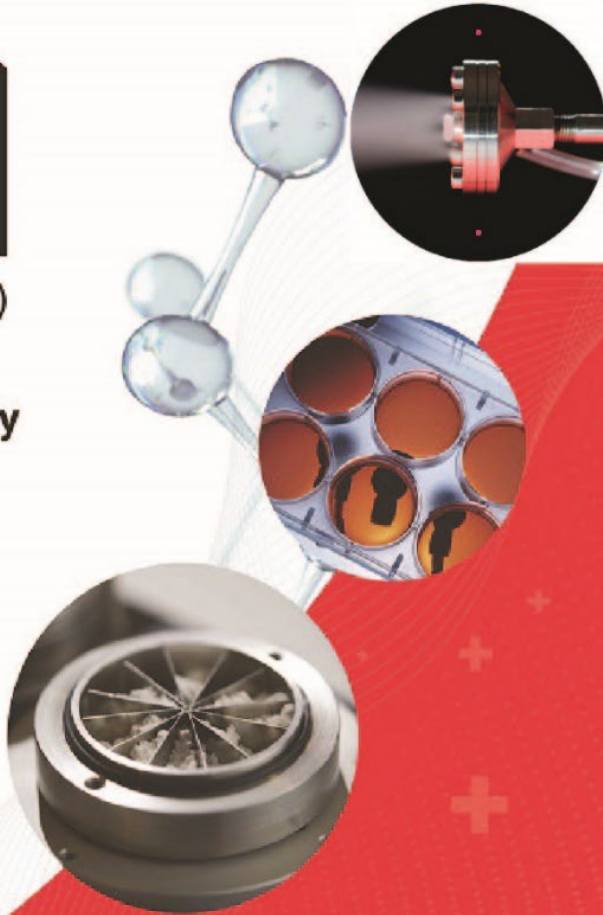
 **Inhalation Toxicology**

 **Aerosol Science**

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Inhalation Toxicology - Case Study T2

**Replacement of Competitor Supplied Inhalation
Exposure Systems at a Turkish
Contract Research Facility**

Problem Statement

A Turkish GLP CRO had decided it needed to offer Inhalation Acute Studies in support of 6-pack Toxicology work and after investigation of suppliers had selected a well-known European equipment manufacturer.

After a protracted period of validation and training work with the EU sourced equipment, staff at the facility were unable to reliably deliver atmospheres to the system.

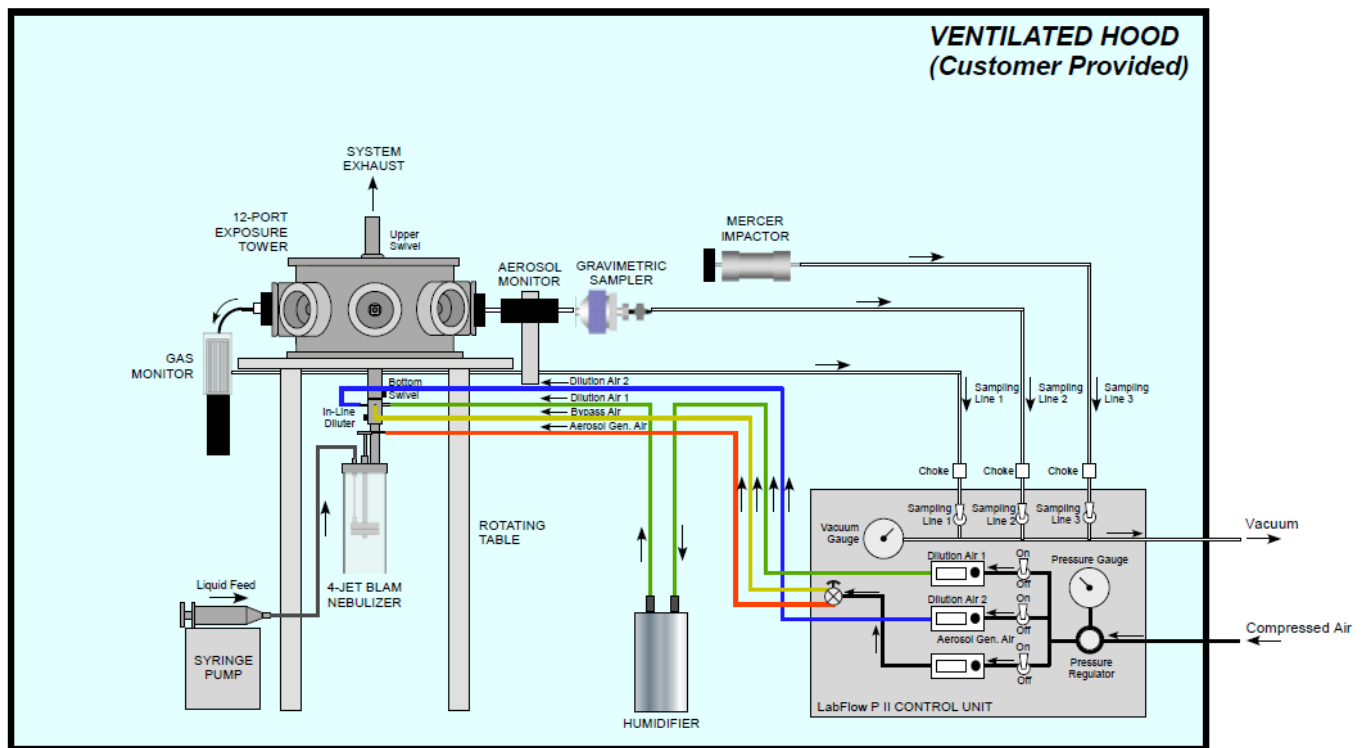
In the absence of appropriate support from the supplier, and with contracted studies scheduled, CRO management contacted CH Technologies (USA) with an aim of obtaining hands on training using the system they had received.

After reviewing the equipment, CH Tech scientists advised that the equipment sourced was unnecessarily complex and likely unmanageable.

After internal discussions CRO Management decided to replace the EU sourced equipment with a Directed Flow system and ancillary equipment from CH Technologies.

CH Technologies Supplied Equipment

The facility was supplied with CH Tech equipment including:



System Schematic

- A 12- Port Aluminum Nose-Only Exposure Tower
- Open restraint tubes for rats
- Manual Positive Pressure Control Unit
- In-Line supply air Stainless Steel Humidifier
- A Blaustein Aerosol Module 4-jet Low Flow Liquid Nebulizer
- Syringe Pump for Liquid Feed
- Gravimetric Open Face Filter Sampler
- A Mercer style Multi Stage Impactor
- CH designed Gas Monitor with Temperature and Relative Humidity Sensor
- A standard-traceable mass flowmeter for airflow calibration
- Casella MicroDust Pro Aerosol Monitor
- A Wright Dust Feed Mk II particulate aerosol generator (supplied at a later date)

Comprehensive system documentation and instruction information in addition to the direct face-to-face instruction.

General Description of the CH Tech Inhalation Exposure System

The CH Tech positive pressure Nose-Only Inhalation Exposure System delivered is a modular tower comprising a single 12-port, but expandable, exposure module.

System ports can be used to attach animal restraints, collect samples or can be plugged as needed.

The exposure tower was set up for rats but, equipped with alternative restraints and accessories suitable for a wide variety of species.

The system supplied was designed to operate under positive pressure, with open animal restraints and to vent directly into laboratory extract containments.

The system supplied is designed to freely vent, so chamber is only slightly elevated relative to atmospheric pressure.

The system is equipped with a BLAM nebulizer for generation of aerosols from liquid solutions or suspensions and with the potential future addition of particulate delivery from platforms such as the WDF Mk II or Palas RBG Pro.

Test article generators are designed to interface with a simple click lock mechanism.

An aerosol monitor, a gas monitor, a gravimetric sampler and a multi stage impactor provide the necessary measurements to characterize the test articles in use and exposure conditions, other monitors and sensors are available.

The data provided by the monitoring devices can be recorded and processed using the proprietary software of the monitoring devices. These records can be used for QA/QC verification and/or GLP compliance.



Client Outcome

As predicted based on numerous installations globally the CRO was able to qualify and begin operations with the CH Tech tower soon after the Engineering visit.

The facility has since conducted numerous successful OECD 403 studies and has since sourced and qualified additional equipment from CH Tech.

The original equipment inventory was returned to the European manufacturer and has likely been sold to another facility!

The adoption of the CH Tech (USA) modular exposure platform will permit the CRO the option of expansion to offer a broader range of study types in the future.



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