

cGMP Batch Manufacturing Facility North Wales

Operate in-situ or Relocate

The facility offers a modern, flexible, stand-alone batch chemical manufacturing site providing capabilities for a broad range of cGMP processes, which is capable of adaptation and expansion.

Location

- ❖ Close to A55 expressway (Euroroute 22), convenient logistics for NW UK and Ireland
- ❖ 55,000 sq.m developed site
- ❖ Objective One/Tier One assisted area for government financial support

Manufacturing

- ❖ A comprehensive mix of multipurpose equipment designed for a wide range of cGMP and other fine chemical applications
- ❖ Well maintained plant with total capacity Ca 75,000 litres
- ❖ Multi-purpose batch reactors in glass and stainless steel
- ❖ Scale ranges from kilos to multi-tonne (100 L through 4,500 L reactors)
- ❖ 55 bar hastelloy hydrogenator
- ❖ Range of equipment for handling solids and liquids in flammable atmospheres
- ❖ Laminar flow-booths and finishing rooms with class 100,000 HEPA

Chemical development

- ❖ A 1,600 sq.m technology centre housing modern R&D laboratories, hydrogenation suite, hazardous gases suite, instrument and office areas
- ❖ Pilot plant & kilo-laboratory

Quality Control

- ❖ 500 sq.m dedicated facility sized for growth
- ❖ Segregated areas for wet chemistry, weighing and instrumentation
- ❖ Analytical development capability

Quality Assurance

- ❖ cGMP quality assurance system based upon ISO 9000
- ❖ ISO registration since 1991; ISO 9000:2000 since 2003
- ❖ Facility FDA and MHRA inspected in 2004 and 2006 respectively
- ❖ 24 audits by pharmaceutical companies in the past 5 years

Regulatory assurance

- ❖ Excellent safety record
- ❖ Excellent environmental performance
- ❖ Accredited to Green Dragon Level 4 standard (equivalent to ISO14000)
- ❖ Flameless thermal oxidiser

Materials handling

- ❖ 2000 sq. m warehouse capacity