

# CASE STUDY

## Allergy Therapeutics

### Aseptic Plant Scale-up Project



#### The company

Allergy Therapeutics PLC (ATp) is a European based pharmaceutical company dedicated to continued allergy prevention. Allergy vaccination is a successful treatment that deals with the underlying cause of allergies and not just the symptoms! Allergy Therapeutics has a long-term commitment to the development of innovative therapies for allergy treatment and allergy prevention.

#### The project

Allergy Therapeutics PLC (ATp) launched a project to upgrade one of their manufacturing processes for the treatment of allergies. ATp have a sterile range of tyrosine based products which are used to de-sensitise patients who are allergic to known allergens especially Pollens.



Main Sterile Processing and Filtration Skid



Mobile SIP and Docking Station for Mobile Vessels



Set of Custom Designed Transfer Vessels



SIPOne™ Steam In Place System for SIP of Equipment and Vessels

#### The Project

Suncombe were awarded the contract for the detailed design and build of the 8 preassembled units that comprised the process. The equipment design incorporates semi automated operation by a bespoke control system, Clean in Place, Steam in Place together with the latest technology for the transfer of solutions between vessels including sterile filtration skids and metered control. Suncombe engineers worked as part of a team which constructed design and drawings, which integrated with the sites overall layout, to allow the precise location and position of the new equipment.

Extensive pre-delivery tests were carried out to ensure that, on delivery to site, the system could be reconnected and ready for operation without any hitches. Factory Acceptance Tests (FATs) included system documentation and certifications reviews, as well as full testing, including automation and dry run simulations and wet testing were carried out. The client then continued with the start of Process Qualification, prior to delivery to ensure the fastest transfer into production.

#### Suncombe Comments

Dave Adams, director at Suncombe, commented, "We were delighted to be part of this exciting project, scaling up an existing sterile process. We used our experience and expertise in sterile processing to develop equipment that was functional and robust and suitable for full validation to FDA and sector guidelines."

"The team we were a part of, worked incredibly well and contributed to the success of this complex project," added Dave.

#### Clients Comments

The project has been demanding and rewarding, the teams working closely together to overcome challenges throughout the life cycle of the project. It is hoped that this joint venture will be one of the first to be undertaken by the ATp, BPE and Suncombe. Rick Poland - UK Manufacturing & Engineering Manager

#### Our engineering

- 55+ years of Engineering Excellence
- Equipment manufactured in United Kingdom
- Designed and manufactured to CE, cGMP, PED, ASME, GAMP, ATEX
- In-house personnel for all disciplines
- Single point of contact for all aspects of a Project
- Full documentation and validation service
- Factory testing of all equipment