The Austin Company
DESIGN | CONSTRUCT | INNOVATE

Austin Update

2020 / 2021

GW Pharmaceuticals

New Manufacturing Facility Handover

In the last update we described the progress of the GW Pharmaceuticals new manufacturing facility. We now are pleased to report that the facility has been handed over to GW as a world class leading facility to help GW further enhance their market world leading position in the development of plant-derived cannabinoid therapeutics.

Austin were initially approached to develop a concept design (Step 1a) for the new facility to accommodate GW Pharmaceuticals projected increased manufacturing capacity, which includes large scale extraction.

The preliminary design stage (Step 1b) was developed to include an additional 3No. large scale extraction units and further extraction capability as product demand was increasing. These designs were all integrated in Revit to provide a single overall coordinated model during the Detailed Design stage.

The facility layout was developed alongside specialist vendors and subcontractors, to ensure that all client requirements were integrated and delivered to the highest standard.

The facility was designed as an extension to the existing facility, over two storeys with a floor space of c. 3,570m^2, incorporating new capabilities and integrating these with no disruption to ongoing operations.

Construction completion was achieved in Q2 2020 and the further expansion of the small-scale production fully operational with the large-scale production anticipated to commence operations in 2021.

The project success has resulted in further expansion planned by GW Pharmaceuticals.

"The Austin Company provided the GW team excellent support throughout all the phases of the project and we are very proud of delivering this world class facility together."

Mr Manuel Loureda – Site Director

Managing Director's Update

What an end to 2020 and into 2021!

It is with great pleasure that I write this year's newsletter message. I am humbled and lost for words at how much our dedicated team of professionals have achieved.

It's easy to forget that Europe's biggest agenda for 2019/2020 was Brexit. We experienced some serious effects of this uncertainty, as this slowed the pace down towards the later part of the year. Once we began to see some clarity in UK's stance on Europe, we were unfortunately struck by the pandemic – what a challenge!

If the last 18 months have taught us anything, it is that we should cherish what is important to us. With this in mind, I would urge us all to continue to ensure we support the mental wellbeing of our families, our colleagues and ourselves. Being there as a support mechanism for each other is pivotal.

Moving forward I am keen to say a big thank you to our Clients for their trust in Austin during this unimaginable period and of course to our dedicated team of professionals who delivered some excellent assignments in order to support these clients, such as:

- We successfully completed and handed over three Construction projects.
- From March through to December 2020, we delivered more than 20 Concept & Preliminary design assignments with solutions on way forward with ±25% and ±10% costs respectively with implementation plans for each one to support our Clients' needs.
- We have subsequently been entrusted by our Clients to conclude the majority of the above projects by providing detailed designs, procurement, construction and commissioning services through to handover.
- This accomplishment has allowed us to recruit additional permanent staff which include Architects, Mechanical & Electrical engineers, Construction, Project and a Business Expansion managers.

I am also pleased and proud to note that some of the above assignments include supporting our Clients through expansion of their manufacturing facilities for the COVID vaccine.

I am very grateful to our Clients for their confidence in our team and for providing us with the opportunities during this inconceivable period. I thank each member of our team for their dedication, knowledge and positive attitude in delivering the requirements under such unthinkable circumstances.

If you have any facility needs, however small or large, present or future and/or would like to explore the services and experience our team has, please do give us a call on 01923 432 658 or email me at enquiries@austin.co.uk.

Prakash Davda, Managing Director

Once again, in recognition of everyone's efforts and commitments Austin have achieved the 12th consecutive RoSPA Gold award for their excellence in Health & Safety. This coveted accolade has been earned by demonstrating continued development and implementation of Health & Safety Management Systems that not only exceed legislative requirements but also promote Health and Wellbeing through the company's improvement programme. The company's ethos provides a solid foundation that shapes positive attitudes and high standards of Health & Safety throughout all our operations and within our supply chain.

Thank you to our Supply Chain for promoting Health, Safety and Wellbeing on all our projects, and we look forward to our 13th Award.

The University of Sheffield

The Centre for Nanoscience & Technology

Austin were privileged to support The University with a study for the replacement of fire-damaged cabinets within their Growth Laboratory of the Nanoscience and Technology Centre building.

Austin provided a detailed report following a site visit, which allowed an understanding of the requirements. As a result of the fire, 1No. Acid and 2No. Solvent cabinets had been damaged and needed to be replaced with like-for-like replacement cabinets which comply with current regulations.

Austin developed a specification for the replacement cabinets in order to allow these to be integrated within the building, along with new services, including power, waste, DCWS, purified water and nitrogen. Austin subsequently undertook the procurement process through to the management and technical review through the fabrication of the specified units and Factor Acceptance tests to confirm that the units meet the University's requirements prior to delivery to site.

Austin, upon arrival of the units, undertook a desktop study on site and checked that the unit configuration provided satisfactory operation in terms of airflow, containment and room pressures, allowing the University to undertake the complete replacement works including connections of all associated services.

Feasibility Study for new ICP and PECVD Nanoscience Room

Austin completed a feasibility study for the University which entailed the fit out of an existing fallow space to form a new ICP and PECVD Nanoscience room. The proposed Nanoscience room formed an extension to an existing Nanoscience cleanroom facility. An important consideration for the study was to minimise disruption to the existing cleanroom. The study confirmed the feasibility of the layout, optimal method/sequencing the construction and provided projected high-level costs and programme.

Multidisciplinary outline and layout drawings were produced to confirm space requirements within the layout of the room including all known equipment to establish efficient space utilisation. Austin reviewed current standards and service utility requirements, interconnections and potential new plant locations for the study. The report concluded with an indicative programme for the design and construction works.

World Leading Pharmaceutical Company

R&D Electrical Site Wide Infrastructure Upgrade

Austin were appointed to conduct a feasibility study for the upgrade and rationalisation of the electrical distribution infrastructure for this world-leading Pharmaceutical Company on their R&D site in the South East of England.

The existing HV/LV infrastructure and parts of the standby generation systems are aged and in need for replacement and upgrade. The upgrade works will provide resilience of supply; address future capacity; ensure compliance with statutory regulations; facilitate safe operation and ensure availability of spares and flexibility in use of the system.

The study reviewed the following concerns and developed options with cost estimates to address these:

- Age and obsolescence of plant
- Capacity and resilience issues
- Limitations to carrying out regular on-load generator tests
- Potential for operating the standby generators in a "revenue earning" mode
- Potential for implementing a power management system to allow best practice methods for monitoring and control of the HV, LV and generation systems. This will ensure safety in operation of switchgear, real-time data logging/trending and associated tools for improving maintenance

On completion of the study, it allowed among other things our Client to consider plans for the upgrade and rationalisation of part of the infrastructure specifically for Building 2 on their site.

Bio Products Laboratory

Fire Alarms Survey and Record Documentation Update

Bio Products Laboratory (BPL) has approximately 19 separate buildings on their Elstree site. Each of these buildings is fitted with a fire detection and alarm system that is linked to the site-wide system by either a hard-wired or radio link.

BPL invited Austin in October 2019, to assist in updating their record information to reflect correctly identified FACIE panels, device types, device locations and their addresses.

Austin worked with the site specialist incumbents and carried out detailed surveys which involved locating and identifying all devices in each building. This entailed triggering each device to identify its address and thereafter updating the associated record drawings. Where possible, the wiring type used was also recorded.

The work was carried out in phases during planned shutdowns beginning with the main production building (B27) followed by the rest of the buildings on site.

As a follow on Austin have been invited to provide a proposal to review the fire alarm systems in the ATEX hazardous areas (in B27) to establish their design, installation and maintenance parameters to adequately support the basis of safety documentation.

Building 27 Electrical HV/LV Infrastructure Upgrade

Bio Products Laboratory (BPL), engaged Austin initially to carry out a preliminary design with a ±10% cost estimate. This was followed by detailed design for the replacement of substations C&D at their facility in Elstree, which are critical to the production operations in Building 27. This is the first phase of a planned upgrade for the rest of the substations serving the site. Both substations are located on the service floor and are approaching obsolescence and capacity issues.

The design process required a detailed understanding of the existing and future demand profiles and an understanding of permissible shutdown(-s).

Austin addressed the above factors and delivered a design that included the following key features:

- Replacement substations C&D in weather resistant enclosures to be located on a new structural steel platform on the roof
- Replacement 110V AC UPS also to be located on the roof in a weather resistant enclosure
- Phasing strategies to allow integration of the new substations and migration of the existing loads with minimum disruption
- New access walkway arrangements on the roof for maintenance access

Austin are currently working with BPL on implementing the works on site by providing procurement, design and engineering support with Construction Management through shutdown periods to implement the requirements.

Pharmaron UK Limited

We are pleased to be working with Pharmaron on these two new projects.

Fleming Building Phase 2

Austin are pleased to be working with Pharmaron UK Limited for the Phase 2 design and fit out of new laboratory accommodation for their Process Chemistry group in Hoddesdon.

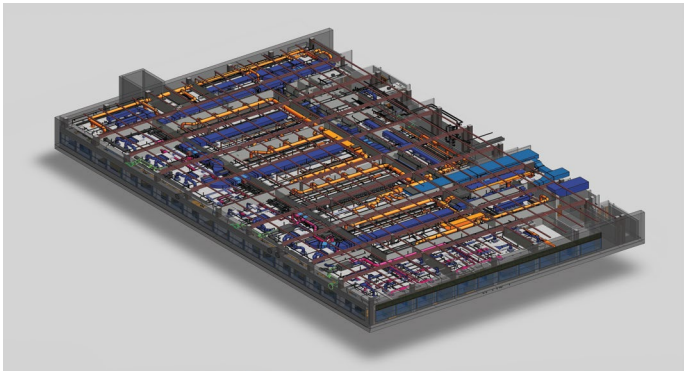
Pharmaron is a cutting-edge, fully integrated pharmaceutical R&D service platform supporting the life science industry. The company offers comprehensive services throughout the pharmaceutical R&D life cycle, with operations in China, the US and the UK. Their UK operations are home to drug discovery, process chemistry, API pilot plant, formulation development and GMP production on a 473,000 ft^2 site in Hoddesdon.

In May 2020, Austin were invited by Pharmaron to present a technical design and build proposal for Phase 2 based on the initial design. The project's aim was to emulate the provisions provided in Phase 1, whilst enhancing efficiencies through lessons learnt. Following successful presentations, Austin were appointed to commence preliminary design followed by detail design and soon after with construction for completion of the facility in Q3 2021.

The project commenced with a review of the initial design proposals with the Pharmaron stakeholder team to establish a robust basis of design. Austin proceeded to develop the agreed basis of design into technical detailed design documentation, incorporating the required services, equipment and building structure.

When the project is completed, the additional capacity will provide four new main laboratories, comprising 40 Fume Hoods with additional material sciences, smaller ancillary laboratories and office space.

The project will also identify potential future requirements and communicate these with Pharmaron, adding to the success and usability of the new facility, allowing Pharmaron to meet the growing demands and allowing them to meet their future commitments.



Pharm Ops Facility

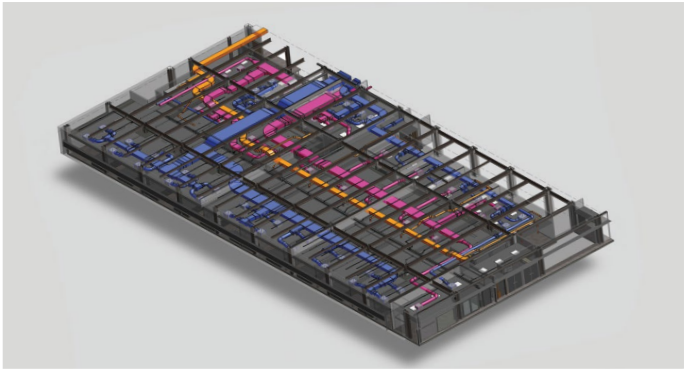
In addition to the new laboratory accommodation forming the Fleming Phase 2 project, for their Process Chemistry group, Austin are working alongside Pharmaron to provide design and build services for the re-start of the Pharm Ops facility housing analytical and formulation business functions.

Pharmaron's bespoke warehouse and manufacturing facility in Hoddesdon, has been identified as being able to accommodate the Formulation Development team and in addition, has been identified to provide Analytical Laboratory and further office accommodation.

Austin initially developed a concept design proposal and established high-level costings. The preliminary design provided further definition and basis for the technical design stage with a ±10% cost estimate. This is now into the detail design stage and construction due for completion in Q1 2021.

Crucially, the proposed upgrade/refurbishment will allow Pharmaron to meet MHRA requirements and current working practices to ensure a high degree of reliability.

The Project will provide building system changes to segregate floors and allow for future unimpeded expansion; formation of a new GMP/Grade D area; adaptions to existing offices and conveyor area; a new WIP Store, and adaption of existing primary packaging areas to create an equipment storage area.



Confidential Long-Standing Blue Chip Client

New ISO7 Cleanrooms

We are pleased to continue our 20+ years' relationship with this Healthcare Client and support their business function in Bridgend. Austin were invited to submit a proposal for undertaking a fast track remote concept study for the provision of new cleanrooms.

They are a leader in innovative solutions that help the food and beverage industries optimise the quality of their products to enable consumer protection. Their Food Safety facility in Bridgend is the development and manufacturing site for rapid hygiene testing and microbial screening products for use by dairy, food and beverage manufacturers and therefore is an important part of their operations.

They identified a need to redevelop the existing facility to allow the expansion of single shot products. This required adaptions to the existing facility to improve air quality so that product contamination could be minimised.

Austin's technical team met with stakeholders to understand the project brief and processes being utilised. A feasibility and concept study was submitted, which included options for consideration. The study provided a detailed assessment and evaluation of their requirements, which would best meet their needs. The study took in to consideration the existing facility in order to identify preferred design and engineering solutions and was provided on time along with a high-level estimate of the works and an outline plan.

Our Client's UK Central Engineering Manager noted – "The study was delivered with a virtual team which presented challenges for normal front end study work – nevertheless these were successfully overcome with good team work and collaboration."

Afton Chemical

Replacement of Laboratory HVAC for compliance

We are pleased to announce that Austin, in close coordination with Afton Chemical, successfully completed the replacement of their existing laboratory HVAC system for their facilities at Bracknell.

The design was completed in November 2018 and construction commenced in May 2019 with completion achieved in September 2020. The construction was undertaken in three phases, the last phase occurring during the COVID restrictions, all under work procedures confirming to strict HSE and COVID guidelines.

This challenging design and construction project involved the HVAC system being stripped out and new air handling units, ductwork and control installed. The new systems had to be designed around the existing electrical services and gases that had to be retained and involved extensive site surveys. In addition, the existing adjacent laboratories had to be kept fully operational, with minimal shutdowns, leading to planning of "break in" and shutdowns complex. This entailed detailed coordination and collaboration with the users.

The design solutions included new variable air volume systems for oven cabinets, local LEV extract systems and associated variable air volume supply systems for their fume cupboards.

Four independent HVAC systems were developed and located externally to the building for their laboratories, using intelligent variable air volume system to conserve energy. Enhanced acoustic treatment were employed with external extract stacks designed to be unobtrusive in order to minimise aesthetic impact.

The existing low temperature hot water and chilled water systems were enhanced with provision of new boilers, chiller and pumps. New bespoke oven extract cabinet systems were developed to protect the users and conserve energy.

The initial infrastructure works and first laboratory were constructed as Phase 1. After testing and commissioning of all services, containment testing of the fume hoods was undertaken and upon passing the test, the laboratory was handed over for occupation. After decanting the next area, works started seamlessly in Phase 2. Works continued in Phase 2 and the final Phase 3 in a similar manner with full occupation by the client in September 2020.

Walbury Oil Blending System

As a continuation of the working relationship with Afton Chemical, Austin were approached to provide the redesign and construction of one of the oil blending streams in the Walbury building. The installation was completed in November 2020, with successful test results announced in December 2020.

Afton test various oil formulations for engines. The oil blending area consists of five streams to test the efficiency of oils. After each test, heptane is used to flush any residual oil out of the system.

Austin, along with a specialist process partner, went through a period of R&D to design an optimum solution. The pipework had to be designed in such a way that after flushing the system, no residual heptane was left. Special pumps, valves and pipework material were chosen providing a smooth internal surface with no crevices or pockets for heptane to become trapped in. Additional features such as a safety relief valve had to be added.

After the design solution was completed and approved, Austin ordered the new pump, valves and specialist pipe fittings. Site adjustments were done to the pipe work, while maintaining the design intent to accommodate the installation within the physical constraints of the existing facility. This involved site measurements for pipework after equipment and valve delivery, part fabrication in the workshop and then taken back to site and fitted.

Kindeva

Austin are proud and honoured to continue our 20+ years' relationship with 3M and now through to Kindeva.

Update of Site Master Plan

Some two years ago we undertook the development of a Site Master Plan (SMP) for 3M Healthcare's pharmaceutical manufacturing operations in Loughborough, (now owned by Kindeva). The SMP informed outcomes of preceding audit and various stakeholder engagements led by Austin.

The SMP recorded the prevailing state of the facilities, equipment and established a development strategy for development of the requirements with a broad execution plan spanning over the coming years.

Since previous development of the SMP, the site has undergone significant changes in operations which necessitated a further review to reflect new and evolving business needs, operations and aspirations.

Kindeva therefore, invited Austin to update the existing SMP, which required exploration and development of a number of key aspects of the facility. This was undertaken in 3 stages:

- Assessment stage – to establish the current business requirements, objectives and to review the existing facility.
- Evaluation stage – to assess potential of the existing site to meet current business objectives, identify opportunities and constraints.
- Reconciliation stage – to develop the preferred strategy into an implementable set of development principles based upon agreed timelines.

The SMP was prepared to be workable, efficient, economical and flexible, whilst able to identify innovative solutions. It was intended to be an effective working tool to inform commercial strategic decision-making going forward.

Austin's collaborative work on the earlier SMP and long association with the site, provided the team with an invaluable and unique insight for adding value to this review and update of the SMP, which was successfully delivered to Kindeva in 2020.

Feasibility and concept study for the provision of new Production Office and Document Assurance offices

Austin are pleased to have worked with Kindeva to support their development plans by providing a feasibility and concept study for the provision of new Production offices and Document Assurance offices with the production building.

Kindeva identified a need to provide new office accommodation. A number of locations were identified and Austin supported the team in assessing feasibility and options.

Austin commenced with establishing a formal Statement of Requirement at the outset and progressed the feasibility and concept design study thereafter. The study aimed to provide a detailed operational and physical requirements assessment with recommendations on the most advantageous location(-s). The concluded study advised of the works required to the building fabric and services to implement the proposals with a high-level cost and programme.

Feasibility and concept study for the accommodation of a new Press & Breathe inhaler packaging line

Kindeva asked Austin to undertake a feasibility and concept study for the accommodation of a Press & Breathe metered dose inhaler packaging line, within their current site.

Remodelling part of the production facility allowed circa 300m^2 required for the equipment. The operational and associated physical requirements were considered in the identification of the location.

The primary aims of the study were to create a single open space by combining existing office spaces, store and inhaler function testing area, whilst establishing the operational and physical requirements for the equipment, as well as the work required to the building fabric and services.

An assessment was carried out of the utility/services requirements and existing HVAC systems to suit the new arrangement and to provide a CNC environment.

A high-level implementation strategy was developed along with an overview of the impact on implementation of ongoing operations. Austin provided an order of magnitude budget cost estimate in response to the concept design and implementation strategy.

This study provided Kindeva with all necessary information to make an informed decision regarding the remodelling.

GW Pharmaceuticals

WFE Expansion & Continued Collaborative Design

Austin have had a continued relationship with GW Pharmaceuticals over the last 7 years.

In 2020, GW Pharmaceuticals approached Austin to look at an additional extension to their original manufacturing and processing facility.

The Austin's interdisciplinary team provided a Preliminary Design and Engineering study with a ±10% estimate to allow them to take the project forward. The building extension includes a state of the art wiped film evaporator process to increase throughput and future flexibility. Austin are proud to have been considered by GW Pharmaceuticals for another challenging and important project.

"WE DO NOT LIMIT OUR CHALLENGES,
WE CHALLENGE THE LIMITS."

– The Austin Company –