

Eisai Manufacturing Ltd

Multiproduct Blister Packaging Facility

Austin have been working closely with Eisai Manufacturing Ltd (EML) to deliver a new Packaging Facility at their EMEA Knowledge Centre (EKC) in Hatfield. The Project incorporates the fit-out of an existing ground floor fallow space of the extension building (built 2014), with a new 1st floor level section within the building and new external links between the existing buildings.

The facility was designed within the existing building envelope to provide a new secondary packaging facility for a multi-product blister packaging line, as well as new high Potency Packaging line to ISO8 standard to complement EML's existing packaging capabilities on site. Support areas include dedicated change rooms, offices, meeting rooms, canteen, and other ancillary spaces.

The main mechanical and electrical services for the packaging lines were installed at a mezzanine level with a walk-on deck that formed the ceiling to the production cleanrooms below to allow for routine maintenance access to the services.

The mechanical systems were installed within an operational plantroom and consisted of:-

- 2 No. new air handling units to serve the production/packaging areas, circa 3.6 m³/s each with duct-mounted humidification and dehumidification and HEPA filters.
- 1 No. new variable volume air handling unit to serve the new office accommodation and supporting areas – circa 2.5 m³/s.

- CO₂ sensor in all meeting rooms that modulates the air flow supply as necessary.
- 2 No. 550 kW steam to LTHW plate heat exchangers in a duty standby arrangement to provide heating for the new areas.
- 2 No. new hot water storage calorifiers at 300 L each to provide a 60% duty + 60% duty/standby arrangement.
- The existing site wide chilled water system was extended from the main header with a new branch, pipework and new duty/standby pump arrangement.

New electrical services for the development were tied into the existing building infrastructure for power, IT, fire detection, security access control and CCTV.

The Project was challenging due to the interfaces with existing operational areas, adjacent to the facility and the integration of the new packaging lines to provide seamless assimilation whilst other operations remained unimpeded. Construction challenges included the installation of a new steel frame and decking to create a first floor within the existing building envelope and accommodating break into the existing drainage systems.

Austin are pleased to announce that we successfully delivered the packaging facility in Q4 2021.

The success of the Project has come from Austin working closely with the EML Project Team and understanding EML's aspirations and commitments to meet stakeholder expectations.

Austin look forward to continuing the good relationship with Eisai and providing a first-class service on future Projects.



Pharmaron UK Limited

Formulation and Analytical Chemistry Laboratories

In the last Update we reported on the finalisation of the multi-option design phase for Pharmaron's conversion and adaption of their Pharm Ops Building. In this update we are very happy to report the finishing of works on site for the analytical chemistry and laboratories, formulation suites and associated office space. These works included additional building enabling works, upgrading of the process utility systems and the new BMS systems. All of which have been designed, refined and constructed by The Austin Company.

Completion of the works has been on time and on budget as agreed by Austin as part of the Step 1b – preliminary design stage. Detailed design and engineering were completed during the initial phases of construction, with the overlap of the works allowing for the early start and completion of the works. This has allowed Pharmaron to be in place and starting the validation, quality assurance process ahead of normal. The Austin Method® has been developed and utilised to facilitate rapid delivery of highly complexed facilities. Our structure as a design house with construction management capability, out strips both the design & build, and traditional contract models, maintaining the quality, cost, and delivery speed required by our clients.

Our delivery of Pharmaron's Pharm Ops building was strengthened by Austin's continuing commitment to the progressive development of our BIM capabilities. The success of highly complexed facilities is also testament to Austin's open and continual dialog with our clients and the stakeholder teams.



Pharmaron UK Limited

Biosciences Laboratory Expansion

Last year Pharmaron approached The Austin Company to look at options for the siting of an expansion to their Biosciences unit. A number of options were reviewed with the users, and the final decision was to utilise an unused level of an existing office building.

The project looked to redevelop the unused area in to a mixture of laboratory and support service functions, addressing new and modern office space.

The footprint of the building is almost square and relatively deep. Light penetration was a concern as the objective of other projects within the facility has been to incorporate as much natural daylight into the space as possible. Utilising full height glass internal walls to the laboratories has allowed shared light and deeper light penetration, as well as being helpful in visually linking office and laboratory space.

The proposed design has been to maximise the use of glass wherever possible, giving varying levels of visual depth to the project, maximising the interconnectivity of the spaces and allowing as much shared natural light as possible into the heart of the layout.

Austin commenced with the detailed design at pace, modifying their normal process in order to suite the client's extremely rapid business case model. One of the challenges of the project was the level of mechanical extract and ventilation required in the compressed space of a building designed originally for office space. The increased level of mechanical extract required to manage well designed laboratory spaces needed to penetrate the main structural deck of the first floor and a new plant deck was added to the building's flat roof area. With the amount of equipment now on the roof, acoustic banked screens were introduced to the roof in order to minimise any noise bleed reaching the perimeter of the site. Extensive acoustic surveys were undertaken and the practical and elegant solution was accepted by the planning authority as the last of the conditions cleared in order to undertake the design.

Part way through the construction phase Austin had to respond to a



change in the client's business needs. As the science changed, so has the design. Austin worked tirelessly to adopt the new functions of the required design, modifying the construction plan and implementation schedule in order to keep the build process underway, whilst adopting and altering the overall design. Austin pride itself on its skill and agility to respond to projects. If it's the ability to modify and adjust a design to suite the clients need as in this case, or to provide cost certainty at concept design, Austin are always proud to rise to the occasion.



Confidential International Client

Laboratory to Support CRO Expertise in Oncology, DMPK, Drug Discovery and Pharmacokinetics

The Austin Company were approved by our international client to develop new laboratories for their tenant, a contract research organisation (CRO) to support, expand their function and expertise in CNS/ oncology/ respiratory, DMPK, drug discovery and ADMET/ pharmacokinetics.

The CRO occupied part of the first floor area in the R&D building that is owned by our client, a global pharmaceutical organisation.

The Austin Company was initially appointed by our client to design state-of-the-art laboratories for the CRO tenant to replace their existing laboratory area within the R&D building; the landlord wanted to consolidate their own R&D activities, and this required providing an alternative space for the CRO on the ground floor level.

Upon completion and approval of the design study, Austin were subsequently appointed to undertake the construction and commissioning of the new laboratories.

The project presented an opportunity to consolidate Cell Culture, GxP Bioanalysis and non-GxP (General Discovery) as separate but adjacent spaces that are also visually connected. The scope included a separate Formulation laboratory.

The project includes fixed and mobile laboratory benching, ceiling-mounted service droppers, fume cupboards, MBSCs and high-efficiency LED lighting.



Utilities include a dedicated power supply from a generator-backed supply, water services, laboratory gases, including nitrogen, compressed air, and vacuum which were all piped from the existing infrastructure within the R&D building. A new CO₂ and O₂ monitoring system interfaced into the existing fire alarm and new BMS outstation.



The ventilation system involves connecting into the existing building system providing fume cupboard extraction and tempered supply fresh air to the laboratories, with ceiling-mounted cassettes and corresponding external condensers, to provide duty standby cooling mode of operation.

The project was completed on time and within budget to a finish which both the client and tenant were very satisfied with.

Our client's Senior Director noted at the handover *"The Austin multidisciplinary design and construction team worked with us in a collaborative manner as a true partner from the time we started the Feasibility study through to handover of the completed facility to meet all ours and the CRO's expectations on quality, cost and time."*

Trinity College

Cleanrooms Technical Advisor

Trinity College Dublin (TCD) invited Austin to provide a consultancy proposal for engineering support to support their project at St. James Hospital in Dublin.

TCD were undertaking the construction, commissioning and handover of a 100m² cleanroom suite at St. James's Hospital and had identified a requirement for Specialist Cleanroom Engineering expertise.

Austin provided support to TCD on matters such as whether the facility complies with Health and Safety requirements; on alignment with the design intent and compliance with EU GMP requirements which permit it to be operated as a GMP facility.

A key part of this assignment was to confirm that the documentation provided by the contractor meets the scope, detail and quality requirements identified by TCD and meets good engineering practice.

Austin completed a detailed review and provided observations on the documentation provided by TCD and others. This included testing and commissioning data protocols, O&M manual compilation and training and handover approach.

Austin established a robust basis for the evaluation of the documentation and the facility and the observations provided allowed for close out of any potential gaps, inconsistencies or incorrect interpretations.

As part of the role, the Austin team visited the facility to review its alignment with the design intent and other agreed baseline documents, including the evaluation of actual testing and commissioning data and recorded their observations on a compliance schedule.

Austin developed a master compliance schedule through the project, which provided a consolidated list of observations and comments that was subsequently used to as the reference document for signing off the Technical Advisors "Opinion of Compliance" certificate.

Kindeva

Combined Heat and Power System

Kindeva is a pharmaceutical contract development and manufacturing organization (CDMO) that is using its expertise, vision, and capabilities in developing drug delivery products whilst remaining committed to achieving its sustainability goals.

As part of Kindeva's sustainability plan they are exploring the potential benefits of procuring a combined heat and power (CHP) system.

Kindeva appointed Austin to assist it in providing engineering design support for the procurement of new CHP system at its Loughborough site. This would initially use natural gas as fuel but would be capable of using partial or full hydrogen in the future.

The scope involves the compilation and assessment of the necessary energy consumption data, current and future tariff data for gas and electricity, space planning options, tie-in options for electricity, heating and cooling networks and the preparation of a performance specification that would be used for procurement purposes.

If the project progresses, the next stages will involve working with the successful CHP vendor and Kindeva to provide the engineering designs for structural support, mechanical, electrical and public health services for incoming gas service, tie-ins for the LTHW and CHW networks and the interface with the electrical network.

If installed, the system will function as a prime supplier of electricity to the site with the heat generated used for reducing or replacing reliance on gas-fired boilers for low temperature heating and also to supplement the cooling system by using an absorption chiller.

Therapeutic Inhalation Development

Kindeva, a pharmaceutical contract development and manufacturing organization (CDMO), is using its expertise, vision, and capabilities in developing products for inhalation drug delivery, microstructured intradermal delivery and transdermal drug delivery.

Austin was appointed by Kindeva to carry out a feasibility study on the remodelling of part of their production building at the Loughborough site. This was to accommodate filling lines and a batching area for producing a new generation of pressurised metered dose inhalers (pMDI) that would use very low GWP propellant gases.

The process will use HFA-152a or HFO-1234ze, supported by appropriate R&D facilities. These propellant gasses have respectively 90% and 99.9% lower GWP than P134a, the greenest propellant used in the industry currently.

Austin worked with Kindeva in developing spatial options to fit the batching plant and the filling line together with supporting areas.

The design study involved the demolition of internal walls and the strip out of existing services followed by a remodelling fit-out exercise that included the consideration of equipment and services that would be energy efficient in use and where required be compatible with the relevant hazardous area designation.

The design also included the potential for re-using the existing air handling plant located on the plantroom floor above.

The challenges that lie ahead in the next stage of the project include

Confidential International Client

Automated Warehouse Expansion

Austin were appointed to carry out a feasibility study on the expansion of the existing warehouse facilities.

The scope involved creating a new 6000 pallet automated storage and retrieval facility using a 'cladrack' construction methodology. 4500 pallets were to be part of an environmentally controlled 2° to 8°C temperature whilst the rest were to be maintained at ambient temperatures.

The existing warehouse area required to be brought up to cGMP standards by introducing an additional MAL between the warehouse and the staging area. The new warehouse floor area had to be raised to allow for dock levelling and use of articulated lorries. An internal conveyer system allows for mechanised movement of pallets to and from the high bay warehouse area to the staging areas.

The racking system includes automated cranes and other horizontal movement transportation to link with the conveyer system.

Austin and the client's teams, worked together to develop an overall scheme for the integrated automation and warehouse.

The scope extended to review the areas for future expansion of packaging facilities with additional lines and expansion of the QA/QC laboratories.



working with multiple process engineering specialists, incorporating the specific requirements of DSEAR risk assessments and identifying capacity issues with the existing services plant.

Austin completed the feasibility study and submitted a report at the beginning of January 2022.

Kindeva has since commissioned Austin to take the project to the Preliminary Design stage.

Managing Director's Update

Partners in Growth

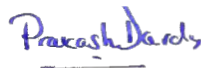
It is with the greatest pleasure and delight that I am able to report another exciting year at The Austin Company. This achievement has only been possible due to the abundance of support provided by our clients, supply chain and our staff's dedication and enormous personal efforts to overcome challenges as they appeared in order to make it another successful year for all of us.

In the last update we noted that the UK office is aligning with our US and Japanese colleagues and as we get to know each other we are finding considerable synergies and resources that we can exchange and develop for the good of our staff and for expanding our offerings to our Clients, here in UK and elsewhere around the world. Our global turnover is in excess of \$16bn with staffing of circa 20,000 worldwide.

This year in our office we have continued our work with Pharmaron, Eisai, Kindeva, GSK, Afton Chemical and also reacquainted our relationship and offerings to Pfizer and BP amongst others.

2022 has been a challenging year and no doubt 2023 will be even more challenging given the uncertainties in the market and economies. Nevertheless, we will remain focused, overcome complications as they arise with support from our clients and supply chain whilst maintaining agility to ensure that we service our clients' needs in the most efficient and professional manner in order to achieve their goals.

I thank you all for your support and look forward to 2023 with enthusiasm and positivity.



Prakash Davda
Managing Director



2022 RoSPA

5th President's Award and 14th consecutive RoSPA Gold Award for Austin

We are happy to announce that this year Austin earned their 14th consecutive RoSPA Gold Award and 5th President's Award for continuously pursuing excellence in Health & Safety within the work environment.

The RoSPA Awards scheme is the longest-running of its kind in the UK, and receives entries from organisations across the globe, making it one of the most sought-after achievement awards for health and safety worldwide.

Austin prides itself on excellence in its Health & Safety performance.

RoSPA Award is a fantastic accomplishment, and we thank all of our teams and supply chain who champion and drive up Health & Safety quality standards every day, throughout all of our projects.

