

Client:	Ipsen Biopharm Ltd	Validation Doc Number:			na	
Project:	Biotech Pilot Plant 2 (BPS2)	Validation issue:			na	
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Abstract

This Design and Access Statement (DAS) supports a full planning application by Ipsen Biopharm Ltd, for a new Biotech Pilot Plant facility in an existing building (Building 9) and consequential changes to add office accommodation in Building 55 at the Ipsen site in Wrexham.

This DAS statement is a short report accompanying and supporting the planning application. This report explains how the proposed development is a suitable response to the site and it's setting and demonstrates that prospective users can adequately access it.

Authors	Organisation & Responsibility	Signature	Date
Andrew Provan	eXmoor Pharma		

Approved By	Organisation & Responsibility	Signature	Date
Robert Haugh	eXmoor Pharma		

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DOCUMENT HISTORY

Version	Validation Issue	Reason for Issue	Date
A	n.a.	PLANNING PERMISSION	Dec 2014

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IPSEN BIOPHARM LTD.

Site Address:

Ipsen Biopharm Ltd
Ash Road
Wrexham Industrial Estate
Wrexham
LL13 9UF

- Development of new Biotech Pilot Plant facility in and existing building (Building 9)
 - Modifications to add office accommodation in Building 55
- Date Prepared December 2014

Applicant Details:

Ipsen Biopharm Ltd
Ash Road
Wrexham Industrial Estate
Wrexham
LL13 9UF

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1 Introduction

1.1.1 Applicant

Ipsen are a pharmaceutical company located in the Wrexham Industrial Estate, Wrexham.

Ipsen aims to be among the top 10 pharmaceutical companies in the world, in terms of profitability and growth.

Ipsen drugs are marketed in 115 countries with sales of more than €1.2 billion. Ipsen has approximately 4,600 employees worldwide.

Dating back to 1990, the Wrexham facility is dedicated to the production of biological compounds. Dysport® is produced at Wrexham. In addition to the manufacturing of existing drugs and product development, Wrexham also serves as the logistics platform for the UK.



1.1.2 Description of the development / site context

This design and access statement supports a full planning application by Ipsen Biopharm Ltd, for a new Biotech Pilot Plant facility in an existing building (Building 9) and consequential changes to add office accommodation in Building 55 at the Ipsen site, Wrexham.

The site lies approximately 4 miles east of Wrexham town centre and lies within the jurisdiction of Wrexham County Borough Council. Wrexham Industrial Estate covers approximately 550 hectares and in geographical terms is one of the largest industrial estates in Europe, it accommodates around 300 businesses, employing 7000 staff, and creates a livelihood for Wrexham and North East Wales. In addition to these businesses, there are ninety Local Authority houses and approximately one hundred private dwellings within the confines of the estate together with a number of retail outlets.

The site is operated by Ipsen Biopharm Ltd and is located within the blue line boundary (fig 1).

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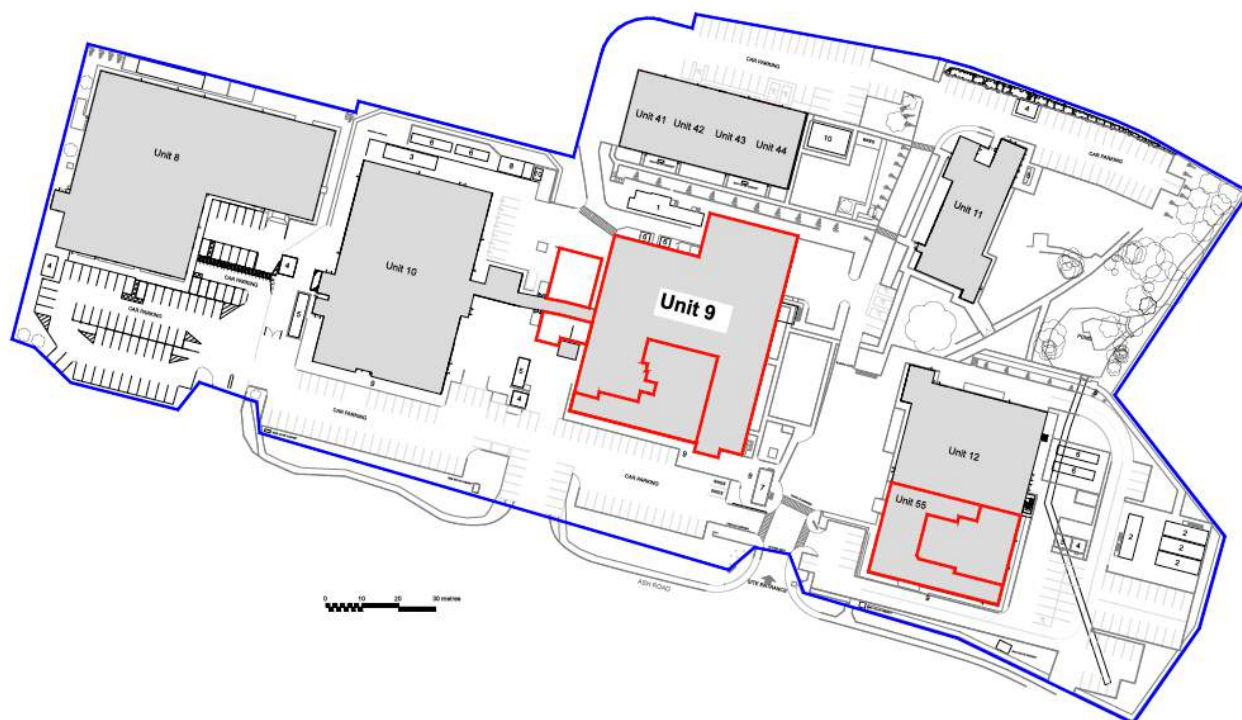


Fig 1. Site Boundary (blue line) and Development Location (red line)

The development is largely located within the envelope of the existing building 9. There is currently a large double height fallow space within building 9 into which it is proposed new cleanrooms and laboratories will the space at ground floor level and associated building services plant will be located at level 1 to form a new Biotech Pilot Plant (BPS2) facility.

In addition the proposed development will remove existing offices located at ground floor level and level 1 mainly to form the new laboratory space. These offices that have been removed to make way for BPS2 will be moved to the ground floor of Building 55 as shown in fig 1 above.

Externally there are minor changes. The east elevation of Building 9 will have some windows at level 1 replaced with louvres for the air handling units and it is proposed to lift part of the main roof with a small extension to the roof. The east elevation of Building 55 will have some windows at ground floor added.

Finally there are 2 new build extensions planned to the south of building 9 either side of the existing connecting link corridor. These will house the utilities required for the BPS2 development to the east of the link corridor and will house new cold stores to the west of the link corridor.

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Fig 2. Exterior view of the north face of building 9



Fig 3. Exterior view of the east face of building 55

1.1.3 Pre-application Consultation

A pre-application meeting was held between eXmoor Pharma and Wrexham County Borough Council (WCBC) Planning Department (Kevin Hughes) for advice prior to submitting the planning application proposals.

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2 Accessibility

This development will not increase the number of personnel at the site during normal operation. The facility is designed to provide the next phase of development to be used by personnel already currently using the BPS1 facility.

2.1.1 Site Access

Vehicular access off Ash Road will remain unaltered and will continue to be used for site access for both staff and for service vehicles, deliveries etc. The road has adequate footpaths either side to provide pedestrian access to the site. It is the intention that movement around the site and into the building will not be changed as a result of this development and as such will be accessible by persons of varying disabilities including wheelchair users.

2.1.2 Building Access

The existing buildings have a number of external access points, with the main entrances providing existing ramps / level access in compliance with the Building Regulations.

2.1.3 Part M Building Regulations

For the areas of building 9 that are not affected by this development the existing internal corridors and doors are to be retained and are therefore unaffected by the development.

Within the confines of the new development it is not expected that wheelchair users will be able to use the cleanrooms. This is due to the fact that the wheelchair cannot be suitably cleaned for the classified environment.

However where the new development is not a cleanroom door widths and circulation will comply with Part M of the Building Regulations.

In Building 55 where the offices are due to be relocated from building 9 there are no changes to the personnel entrance of the building and only minor layout changes internally. It is expected that a disabled person will have access to Building 55.

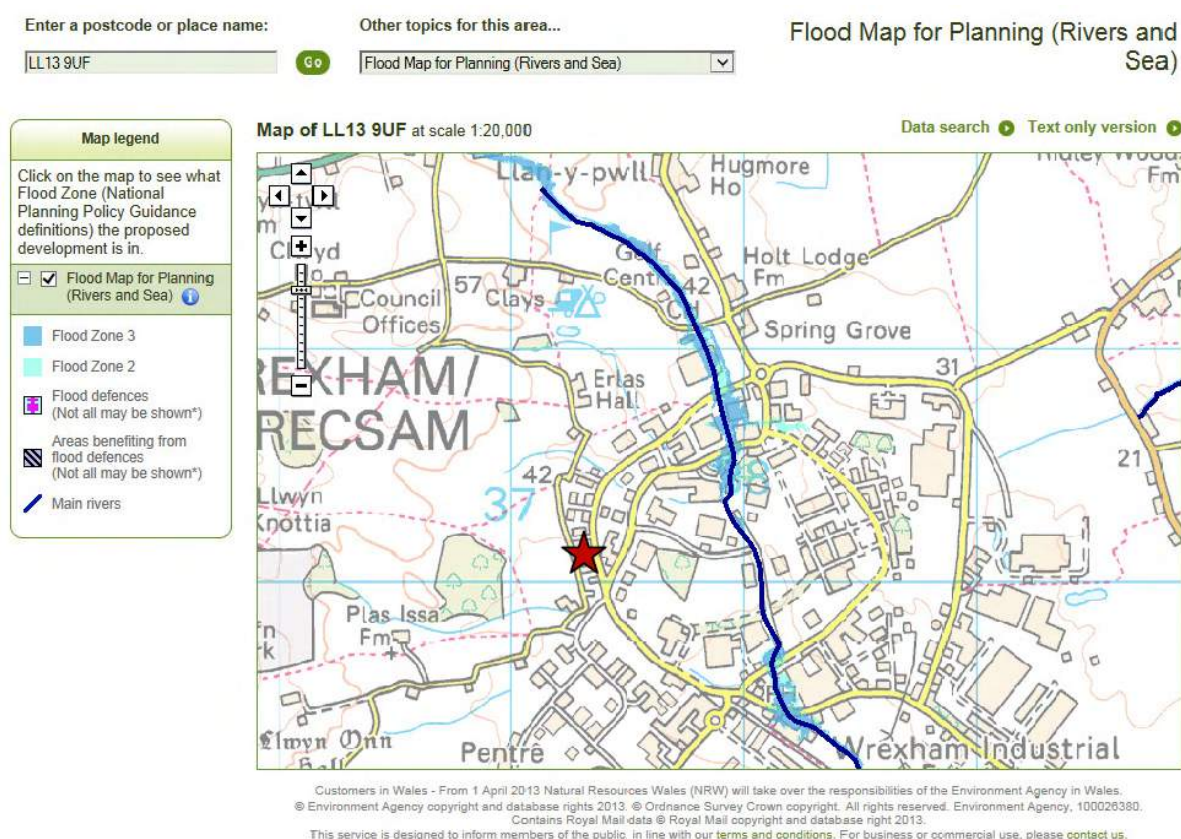
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3 Environmental sustainability

The proposed refurbishment scheme has been designed with sustainability issues in mind and to fulfill the current Building Regulations standards for a refurbishment project in terms of environmental sustainability.

3.1.1 Flooding

The map below obtained from the Environment Agency website, indicates the site is outside of the flood plain and that there is low risk from flooding from rivers or from the sea.

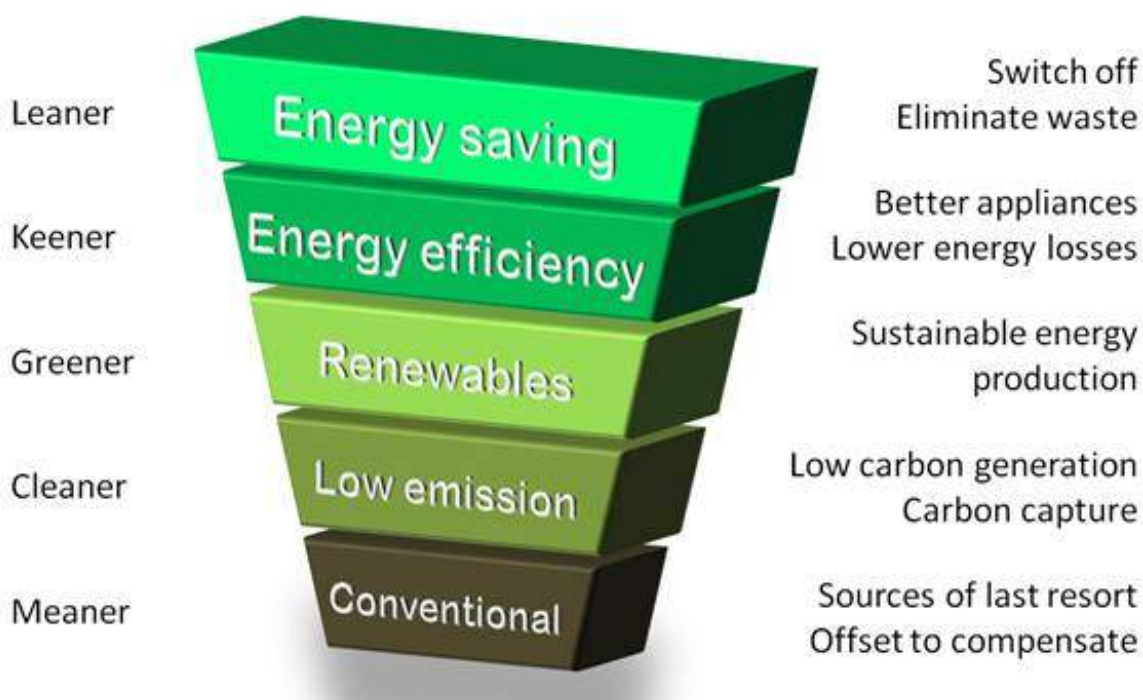


3.1.2 Energy efficiency

It should be pointed out that this development is a pharmaceutical facility that requires 100% fresh air for containment purposes at typically 30 air changes per hour that uses disposable single use technology. Opportunities for real energy savings are therefore limited, however, where at all possible measures have been taken as outlined below:

A multi-tiered approach has been adopted in the design and specification of the BPS2 project to reduce energy usage, and ensure that sustainability is built into the project.

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Multi-tiered energy efficiency approach used on this project

3.1.2.1 ENERGY SAVING.

Switch off HVAC and turndown over night

The HVAC system for the process will be run on a switch off basis where the HVAC fans and the chilled water and steam used for heating and cooling at switched off when the plant is not in use. For periods where the process rooms are in standby the HVAC will be capable of being turned down to minimise the energy being used.

Zoned HVAC and Recirculate where possible

Three different HVAC zones have been designed into the plant. This will allow recirculation of air, (and hence energy saving) into as much of the plant as possible. The process rooms, which require 100% fresh air for containment, have been minimised in space to ensure energy efficiency is maximised

Isolator Technology

The majority of the process is undertaken using closed process in isolators. This minimises the volume of air that is involved in the process, and hence the volumes of air that need to be filtered, heated and cooled.

Ambient Temperature Technology.

The majority of the process is undertaken at ambient temperature (20°C). This minimises the energy required for heating up or cooling down solutions. The WFI (Water for Injection) used in the process is generated by vapour compression technology, which is a very energy efficient process where 80% of the energy used in distillation is recovered and used.

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3.1.2.2 ENERGY EFFICIENCY

Reduce Cleaning

Conventional biopharmaceutical manufacturing relies upon significant quantities of hot water for Clean in Place of large stainless steel vessels and process plant. For every stage of the process where 100L of process fluid used, typically 1000L of water is required for cleaning and rinsing of the vessels and equipment, followed by steam sterilisation of the equipment ready for the next batch. For typical biopharmaceutical protein production of 5L final product solution, 140,000L of water will be used just in the cleaning of the equipment. All of this water needs to be piped onto site, to be purified (using deionisation technology), distilled (using significant energy) and then to be heated up from 20°C to 80°C, and finally, all of this water is then sent to drain, complete with cleaning detergents and caustic solutions. For the steam sterilisation, water need to be deionised, energy to boil it up and finally chilled water for cooling the equipment and HVAC prior to returning the equipment to process use.

For the BPS2 project, Ipsen have adopted technology to minimise the need for cleaning of process equipment, and hence reduce the large quantities of water, energy and chemicals used. Several studies have been undertaken to investigate the whole life cycle environmental impact of this approach, and it has been shown that lower environmental impacts compared to conventional bioprocessing technology in all impact categories studied.

Variable speed drives on HVAC plant

All the fans used in the HVAC plant will be energy efficient motors, with variable speed drives that are controlled automatically to match the heating and cooling requirements of the air flow in the processes.

Vapour Compression Still for Water for Injection

The WFI (Water for Injection) used in the process is generated by vapour compression technology, which is a very energy efficient process where 80% of the energy used in distillation is recovered and used.

3.1.3 Water efficiency

As described above for the energy efficiency section, process technology has been adopted to minimise the cleaning, and hence the water used. If the process were to be undertaken using conventional stainless steel vessels and pipework, it is calculated that 8,000L of water would be used for the cleaning of the equipment of each batch. Instead, this has been reduced to 200 L.

3.1.4 Surface water Run-off

No changes will occur to the amount of surface water run-off and existing drainage will be retained.

3.1.5 Materials

Durable low maintenance materials to match existing materials on site will be utilized to minimize energy use for external envelope elements.

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3.1.6 Waste

Waste generated during the construction phase will be recycled where possible.

Manufacturing waste will be dealt with on site in the same way as operated at present and will be treated where appropriate and made safe before disposal.

3.1.7 Efficient use of land

This development makes efficient use of land by re-utilising existing buildings. By doing so the impact on land use has been completely minimised. The development does not require any additional roads or pavements and does not have an impact on surrounding land. As the development will not employ any new personnel it will not have an impact on the parking requirements.

3.1.8 Pollution

It is not expected that there will be any pollutants generated either during the construction or in the operation of the facility. All discharges from the facility will comply with the current discharge consent on site.

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4 Character

4.1.1 Use

The intended changes are to build a new Biotech Pilot Plant facility largely within the footprint and boundaries of the existing building 9. Building 9 is currently in use partly as a research and production facility and partly as the site canteen. Note: A recent planning application has also been made to upgrade the canteen facilities on site **Planning Reference P/2014/0790**.

The offices that are make way for BPS2 in Building 9 are moving to Building 55, which is also part of this Planning Application.

4.1.2 Amount

The majority of works are contained within the footprint of the existing building 9. New extensions total approximately 250 sq m. The intended changes are shown in the diagram below:

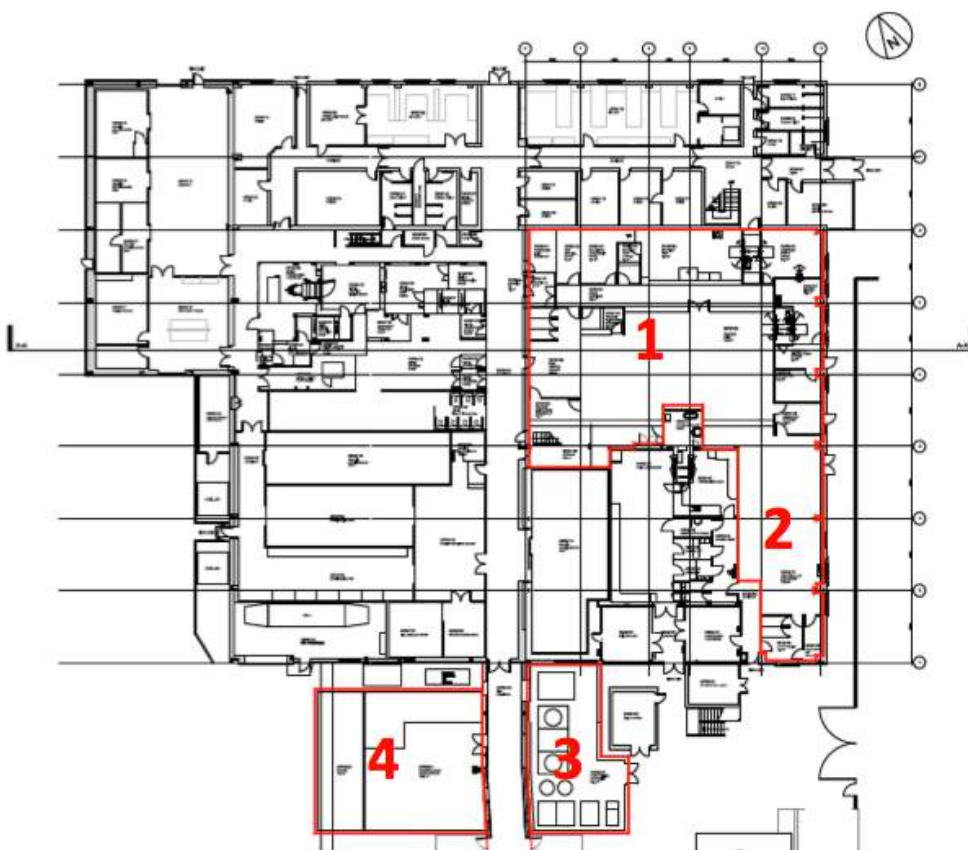


Diagram showing key development zones

With reference to the above diagram the following key development changes are proposed:

1. Conversion of double height fallow space within building 9 into research and production space and associated plant at first floor level.

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2. Conversion of existing offices at ground and first floor into laboratories and associated plant at first floor level
3. Demolition of small single storey lean-to structure housing existing laundry and then build new single storey extension to house utilities required for the new production spaces (90 sq m)
4. Build new single storey extension to house fridges and freezers (158 sq m)

In addition there are minor changes to the envelope of the existing building 9. At roof level an extension to the roof is required to house the new plant envisaged for the development.

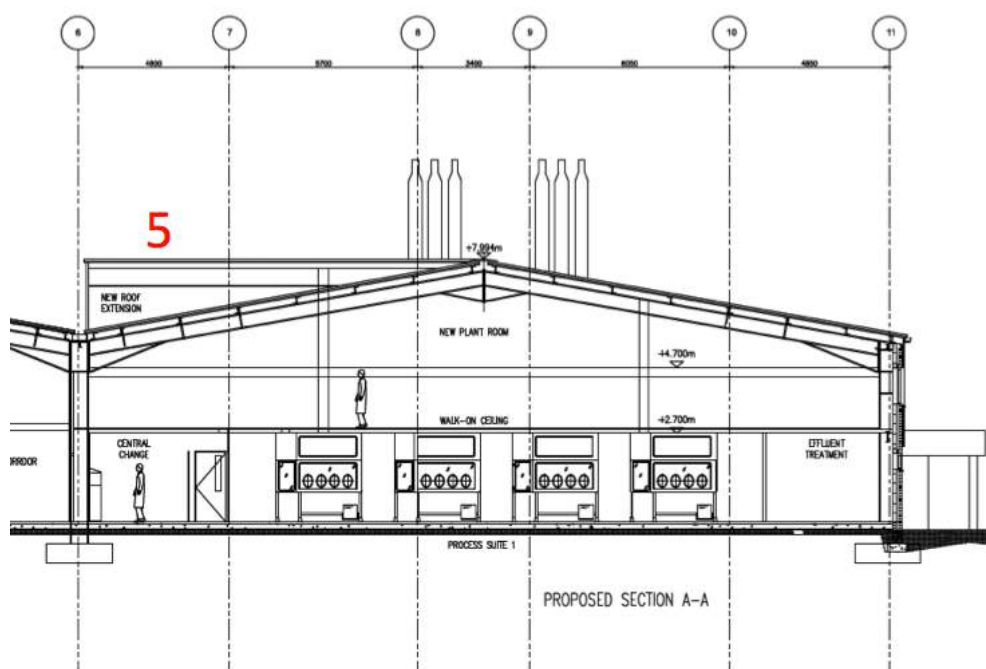
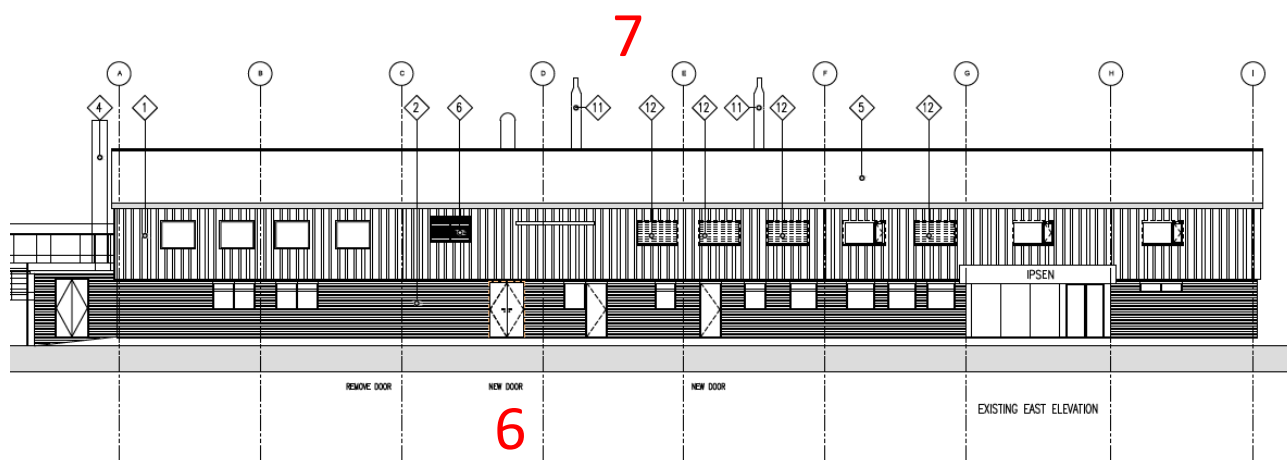


Diagram showing section through new roof extension

5. Roof extension to house new plant for BPS2 development.

There are minor modifications to the east elevation with the introduction of new doors and louvres in place of existing windows and changes to the roofline from all elevations in the form of new vent stacks from the proposed isolator extract flues which must vent at least 3m above the highest ridge point.

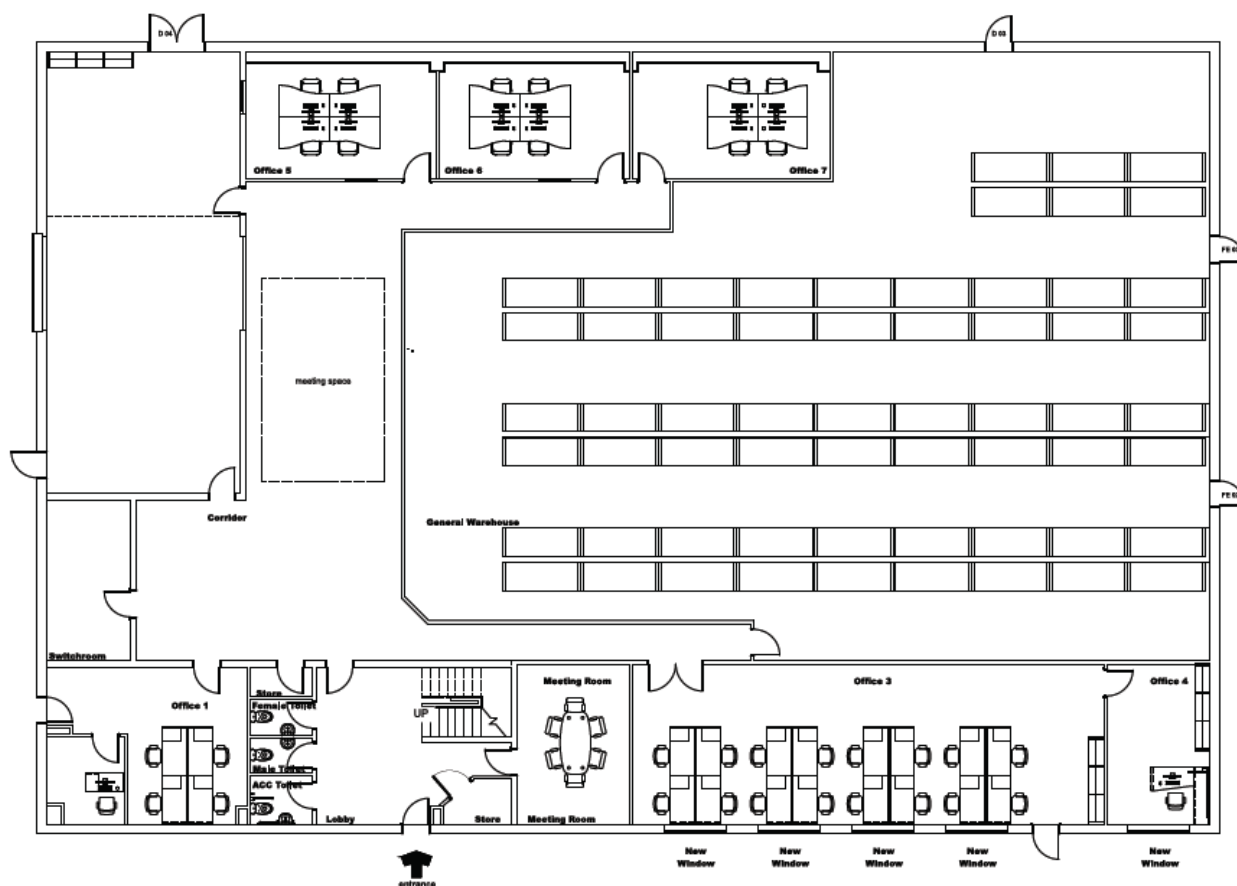
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6. New doors to east elevation and removal of a single door

7. New vent extracts at roof level

In addition, Building 55 is being partially converted into office space to accommodate the offices being removed in point 2 above. The new layout is shown below:



Proposed new offices in Building 55

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4.1.3 Scale

The alterations to the existing buildings are in keeping with the scale of the industrial estate and the site. The proposed works do not exceed the height of the existing buildings or surrounding buildings and therefore have minimal visual impact from the surrounding areas and Ash Rd.

New vent extract flues are located in the middle of the building 9 and will extend approximately 3m higher than the highest point of the existing roof. This is a Regulatory requirement.

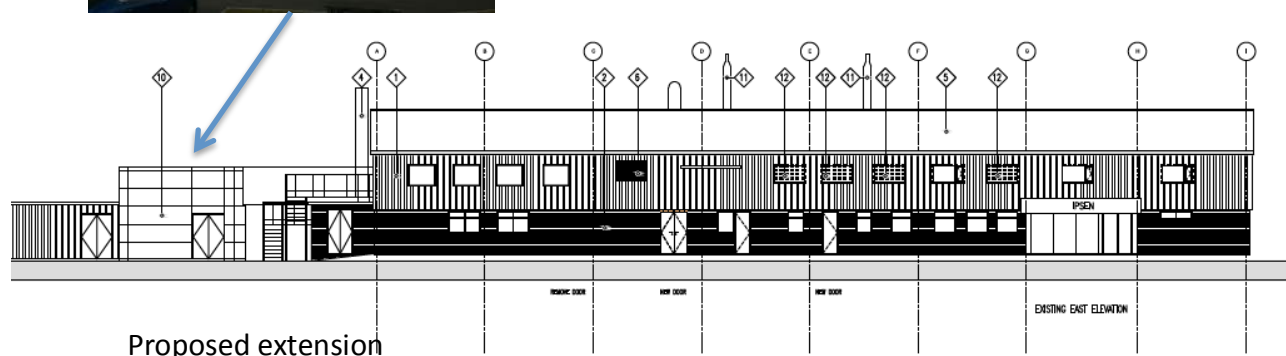
4.1.4 Appearance

The aim of the development has been to minimise works to the external envelope of the existing building 9. Minor changes to the existing building are explained in section 4.1.2 above.

The new extensions are designed with materials consistent with materials that currently exist on site. The new utilities extension on the east side of the connecting corridor in view of Ash Rd is clad with flat cladding panels consistent with panels currently found on the new building 12. This is to reflect the new modern image of the site.



Building 12 with flat cladding



Proposed extension facing Ash Rd – clad in flat cladding panels

Alterations to building 55 consist of 4 new windows to the east elevation.

4.1.5 Landscaping

The proposed works have no impact on any current landscaping. There are no proposed landscaping works as part of this scheme.

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5 Community Safety

Building 9 is positioned within the boundaries of a secure site currently operated by the Applicant Ipsen. There are no changes to the perimeter of the site, which might affect the community's safety.

Existing security fence lines and access gateways will be maintained and enhanced as required by the scheme ensuring that at all time the main boundary provides a secure perimeter to the site.

Due to the proposed refurbishment being on an existing industrial estate, no other impact on community safety is anticipated.

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6 Movement to, from and within the development

This development makes use of existing buildings (Building 9 and 55). As such the design has made use of an existing development. Access to and from the site for both buildings remains unchanged.

It is **important to note** that this development **does not** increase the number of personnel on the site. The new process suite and labs are for the use of the existing staff currently employed on site.

6.1.1 Access

Vehicular access off Ash Road will remain unaltered and will continue to be used for site access for both staff and for service vehicles, deliveries etc.

All forms of access to the site, whether these be vehicular or pedestrian, employee, visitor or delivery in nature, are controlled via a main entrance situated off the inner ring road on Ash Road North. The site does have two secondary entrances suitable for vehicular traffic, but these are reserved for emergency and contractor access only.

The site is ringed by a 2.8 metre palisade perimeter fence, and has a series of inner fences, which form fire safety and security zones. All employees are required to negotiate turnstiles in order to enter the main site.

6.1.2 Ipsen Travel Plan

Ipsen has an Employee Travel Plan, which has been in operation since 2005. The plan has been developed in conjunction with Wrexham County Borough Council (Highways and Asset Management Department) as well as a number of other organisations.

Ipsen are totally committed to being an environmentally responsible site, an undertaking reflected throughout the operation. Wherever technically possible and economically viable, Ipsen make every effort to minimise any impact that the manufacturing process might have on the local or global environment.

Every member of Ipsen staff is given a personalized Travel Plan and every individual is made personally aware of the travel options open to them.

6.1.3 Travel to site

Historically the majorities of people drive or arrive at site as passengers in a car share. This is somewhat understandable given the remote location of the site but Ipsen are committed to encouraging staff to find alternative methods of transport in line with the Ipsen Travel Plan and providing staff with realistic travel options. As such Ipsen are committed to:

- *Increase the use of alternative sustainable transport modes*
- *Reduce single occupancy car use*
- *Work with others to improve transport choices*
- *Ensure that staff are fully aware of the transport choices available to them*

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6.1.4 Travel by car

This development has no impact on the number of car parking spaces on the site. There is no intention to employ any more personnel as a consequence of building this development and as such will have no impact on the requirement for additional parking or the number of cars on site.

Notwithstanding the above, Ipsen already encourage car sharing with a number of incentives:

- Promote the benefits of car share, especially the financial savings that can be made, through the publication of suitable material.
- Provide reserved, on-site, car parking spaces for staff who car share.
- Provide an internal car share database, utilising dedicated software.
- Offer an emergency ride home service.
- Have a partnership with Wrexham Council and the Industrial Estate Coordination Unit
- Provide a number of incentive schemes that will make car share a permanent feature of company commuter travel.

6.1.5 Provision for cyclists

This development has no impact on the number of cyclists entering the site or the provision of cycle shelters.

Notwithstanding the above, the site already has cycle shelters that are conveniently situated in a corner of the Visitors Car Park under the observation of the security team. Cyclists (as with all other members of staff) are afforded ample, secure, locker space for the storage of helmets, gloves, clothing etc, and have the use of single sex changing areas.

In addition, Ipsen already encourage cycling to work with a number of incentives:

- Continually review the provision of on-site cycle facilities, including any requirement for covered, secure, parking and showering/changing facilities.
- Establish a company pool bike scheme.
- Discount purchase schemes for bikes
- Work with Wrexham Council to promote the provision and safety of Industrial Estate cycling routes.
- Provide road safety/Cycling Proficiency courses for those committing to regular cycle use.
- Stage a series of bike to work days.

6.1.6 Provision for pedestrians

The industrial estate is well served with public walkways and these are fairly well serviced and generally well-lit at night. However, given that the estate is situated some miles from any local residential areas, very few people are inclined to walk to and from work. On the site itself, all movement is by foot and access to building 9 is by foot. This development has no impact on the number of pedestrians accessing the site.

6.1.7 Public Transport links

Approximately half the personnel working on the site live with a 10 mile radius of the site which is

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within public transport travel distance to the site.

Wrexham County Borough is served by a good public transport system consisting largely of privately operated bus and train services.

National Rail services are available from Arriva Trains Wales, which runs regular travel between Wrexham's two main stations (Wrexham Central and General) and Chester, Bidston and Birmingham New Street where transfers to other elements of the national rail network can be made. Branch lines also run to the outlying areas of Chirk, Ruabon and Gwersyllt.

Of extreme benefit is a bus stop situated immediately outside the site.

To take advantage of the above, Ipsen work in close partnership with Wrexham County Borough to promote public transport links to and from the site as part of the Ipsen Travel Plan.