



**Creating solutions**

**Consultants  
to the  
Pharmaceutical  
Manufacturing  
Industry**



PHARMACEUTICALS - BIOTECHNOLOGY - HEALTHCARE

# Foster Wheeler Pharmaceutical Consultancy Services

The Pharmaceutical Division of Foster Wheeler in the UK comprises an integrated team of over forty technical specialists, many with a pharmaceutical operations background, with experience in all aspects of pharmaceutical operations.



Our members are well-known in the industry and contribute to many business initiatives, including ISPE, Britest, Parenteral Society and IChemE.

We have developed an in-house Knowledge Management System giving our specialists access to their combined knowledge and experience - anytime, anywhere.

We understand our clients' needs, develop close relationships, adopt a flexible approach and provide a completely confidential service.

We offer a totally professional service for the pharmaceutical industry characterised by:

- State-of-the-art experience
- Specialist advice at short notice
- Independent and impartial guidance

## Our services include:

- Business relocation studies
- Site master planning
- Benchmarking studies
- Feasibility/concept studies
- Compliance audits and validation master planning
- Standard designs
- Process simulation/process optimisation
- Process/technology design reviews (e.g. materials handling, containment, cleaning, and equipment selection)
- Regulatory compliance guidance
- Operational consultancy
- Capital investment modelling
- Architectural/layout studies
- Training



# Site Master Planning

We are internationally recognised as a leader in site master planning. We have developed an extremely successful and well-respected method of executing this work, and have prepared studies for many of the leading pharmaceutical and biotech companies.

Every site master plan is unique, ranging from a simple study to optimise the location of a single new building, through to a major study to assess the future development of a large, mature pharmaceutical site.

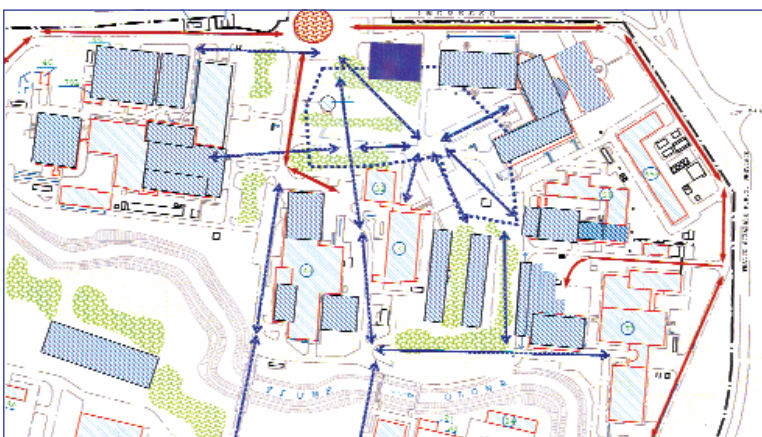
Each plan is therefore tailored to suit the particular project, using appropriate techniques from our proven portfolio of methods.

We can call on the specialist resource within the Pharmaceutical Division to generate footprints of pharmaceutical buildings and optimise materials and personnel flows.



## Our site master plans:

- Demonstrate a sound understanding of the existing site
- Meet an agreed business plan
- Identify all potential solutions
- Prioritise alternatives against agreed criteria
- Challenge perceived restraints to test validity
- Meet regulatory requirements
- Provide a clear, cost-effective plan that is well researched but simply and effectively presented
- Incorporate state-of-the-art technical solutions



↔ Principal External Vehicular movements  
 ↔ Principal Pedestrian movements

--- Campus Zone

# Compliance/Validation

From our background in design, construction, commissioning and validation of facilities to meet European and FDA expectations, we have an extensive database of knowledge of the application of GMP/validation for the pharmaceutical industry.



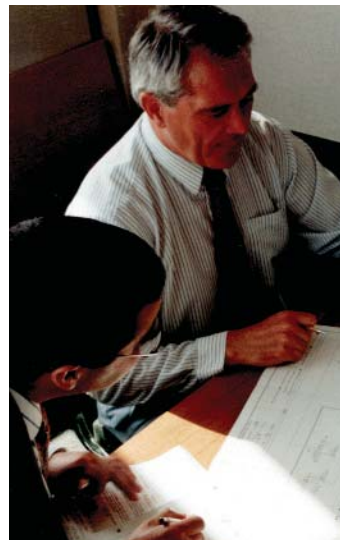
Foster Wheeler's compliance and validation team helps the pharmaceutical industry achieve compliance with international regulatory bodies. We provide detailed services to meet international GMP requirements for FDA, EU and MHW and other regions.

We have proven experience that the application of risk management and the integrated approach to commissioning and qualification to projects delivers clients' expectations for quality, safety, schedule and cost.

Our commitment to the industry is demonstrated by our involvement with the development and application of the ISPE Baseline Guide for commissioning and qualification. We have delivered substantial benefits by applying these approaches to recent projects.

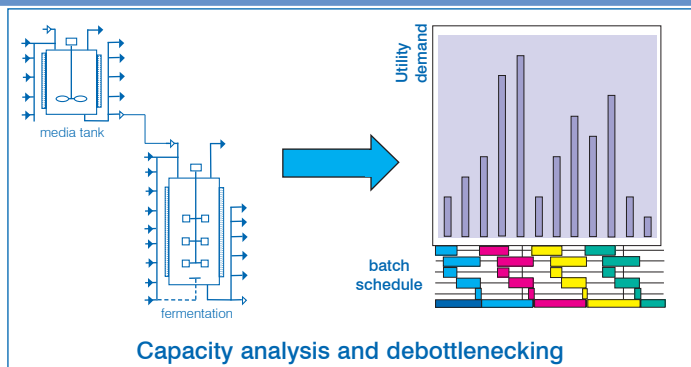
## Consultancy services in GMP/Validation include:

- GMP audits of existing facilities with a view to upgrades
- GMP training
- Audits of validation systems and procedures
- Retrospective validation (process plant and computer control systems)
- GMP statements
- Validation master plans and planning
- Baseline qualification practices (impact assessments, risk assessments)
- Documents for regulatory authority facility review submission
- Independent design GMP reviews
- On-site, 'hands-on' equipment validation
- Integrated validation/maintenance plans
- Regulatory guidance
- Good document practices



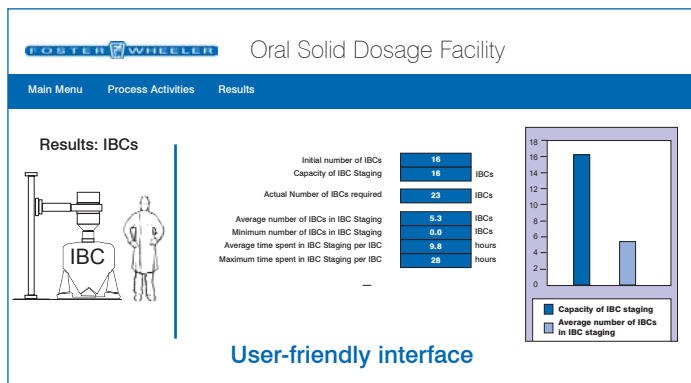
# Process Simulation

Our process simulation capability involves using both proprietary packages and modelling simulation packages developed by Foster Wheeler.



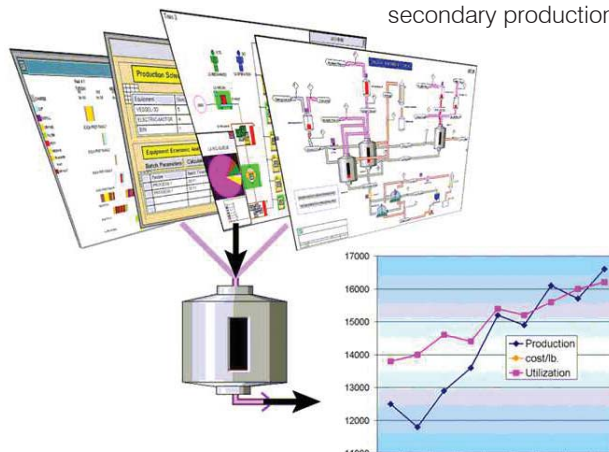
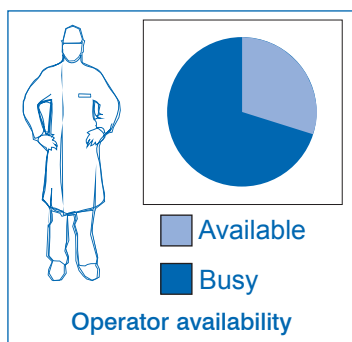
## Simulation is used to:

- Debottleneck processes
- Optimise plant capacity
- Reduce capital and operating costs
- Schedule complex processes
- Perform 'what if?' analysis
- Maximise equipment utilisation
- Assess resource requirements
- Size utility systems
- Assess environmental emissions



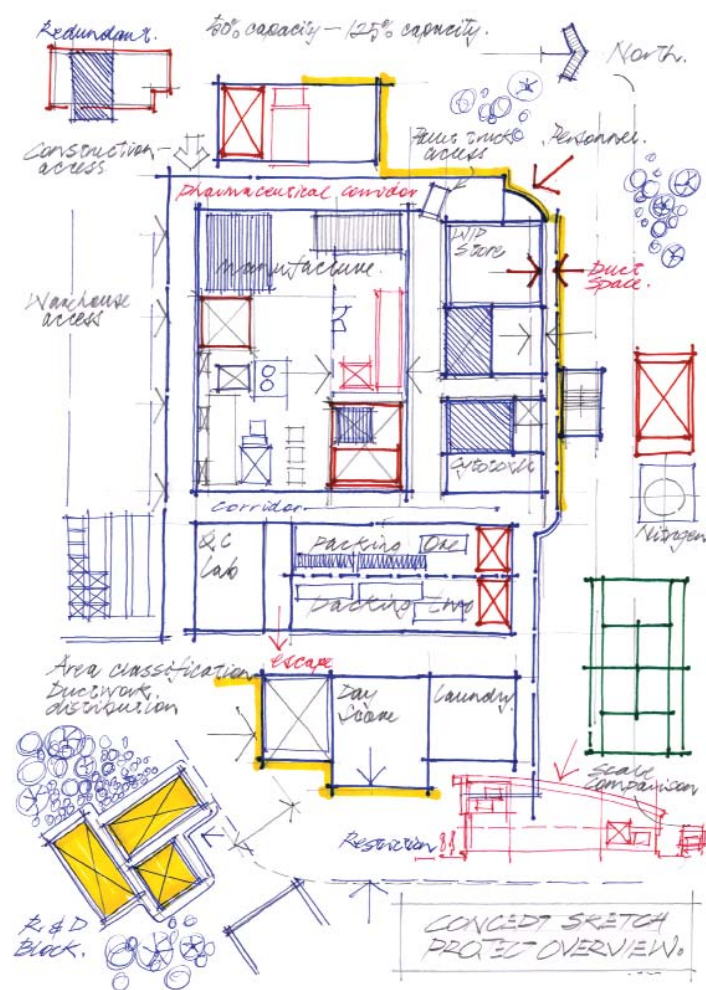
Process simulation is a valuable tool that can be used to assess how a manufacturing operation performs and quickly evaluate the effects of changes to input parameters.

Our Pharmaceutical Division has a dedicated Process Modelling and Simulation Group with experience of a wide range of simulation tools and techniques. Our simulation expertise has been applied to pilot plant, bulk API, biotechnology and secondary production processes.



# Layout Development

Foster Wheeler's Pharmaceutical Division provides consultancy services to the pharmaceutical industry. A well-conceived layout is one of the most important factors in controlling project cost. Decisions made at the concept stage of the project are critical. Our structural approach to layout design has been tailored to the identification of the optimal design of plant layout.



Foster Wheeler has the specialist skills to quickly identify layout solutions for all types of facility design. Irrespective of the size and scale of the project, our dedicated layout specialists are on hand to identify, through the most appropriate means, design alternatives that reflect our vast experience in all fields of pharmaceutical design.

We offer state-of-the-art 2D and 3D CAD designs as well as hand-made concept drawings to visualise the embryonic design. We are particularly experienced in conceptualisation techniques for small projects in this respect, ensuring commitment to detail and efficiency of effort.

# Process Architecture

The integration of architectural aspects into plant design is key to the overall success of any facility. In recognition of this we have within the Pharmaceutical Division a dedicated team of architects who have an in-depth awareness of the industry's requirements.



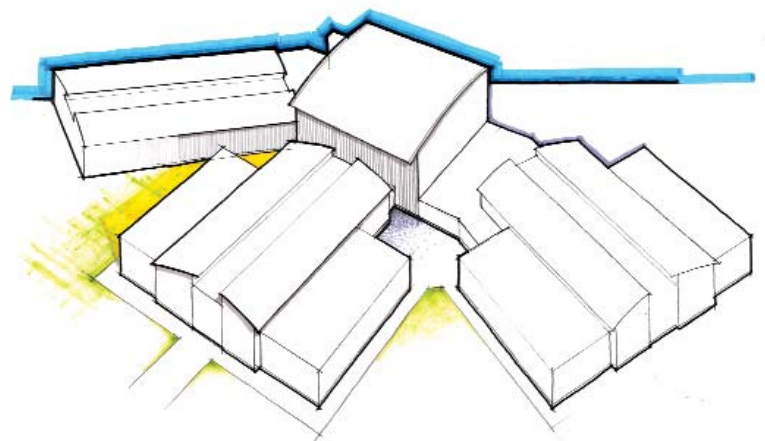
## We can offer a range of services in the early stages of project design comprising:

- Existing building surveys
- Input to master plans/site evaluation
- Negotiations with local authority planners
- Input to layout design concepts
- Room data and area categorisation
- Building envelope studies
- Outline finishes schedules
- Preliminary material selection/specifications
- Hand drawn perspective images
- Computer generated 3D models
- Photo-realistic images
- Access to library of standard details
- Building regulations input

In the preliminary stages of design our architects work as part of the core team developing a project layout and developing the concept design of the facility in line with the client's philosophy for the building while at the same time incorporating GMP and other regulatory requirements.

Foster Wheeler architects have a wide range of experience in the design and construction of pharmaceutical manufacturing facilities including API, secondary, biotechnology and R & D.

They provide innovative, aesthetic solutions while meeting the challenging demands of clean room design and specification. All this is achieved in a multi-discipline environment of which they are a key part.



# Active Pharmaceutical Ingredients

We have experience with a large number of API technologies and offer services to cover every aspect, from high technology sterile production to conventional synthetic chemistry API's, together with all the supporting services.



## We provide specialist advice and consultancy on :

- Reactor design technology
- Large and small scale materials handling
- Containment
- Centrifugation and filtration operations
- Drying technology
- Multi and general purpose design
- Novel design for specialist operations
- CIP, COP and associated systems
- New and upgrade facilities
- Problem solving and 'brainstorming'
- New technologies

Foster Wheeler has extensive knowledge of a range of procedures to ensure safe plant operation. This knowledge can also be used to test the plans and designs of its clients.

Foster Wheeler can offer these services on a standalone basis providing independent expertise in many different areas.

## Reviews and studies for :

- HAZOP
- COSHH assessments
- COMAH assessments
- Hazardous area classification
- ATEX compliance
- SIL review
- Concept design review
- Front end packages review and optimisation
- Value engineering
- Risk management

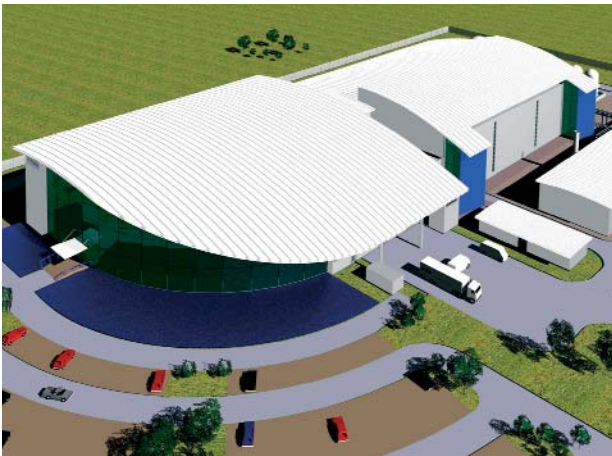


Technologies for API's including Grignard reactions, Birch reductions, chiral preparations and separations, halogenation, alkylations, ozonolysis, condensation reactions, carbanion reactions, Friedel-Craft reactions and many others.

# Biopharmaceuticals

Foster Wheeler's team of biotechnology specialists brings together the expertise, innovation, industry knowledge and commercial awareness to serve this key sector of the pharmaceutical industry, predicted to grow significantly over the next five years.

Our team brings a flexible approach to problem solving and understands the complexities of producing biopharmaceuticals within a regulated environment.



This experienced team offers a wide range of biotech consultancy services including:

- Sterile and hygienic engineering
- Manufacturing strategy
- Advice on scale up from laboratory to pilot plant
- Technology transfer / contract manufacturing
- Feasibility and front end design studies
- Multipurpose facility design
- Overall process and fill finish design
- Bioreactor design (including scale-up studies)
- Purification design
- Media and buffer preparation
- Utility system optimisation studies
- Cleanroom operation and design
- GMP aspects of building layout
- Environmental quality standards
- Process control systems
- Bioprocess modelling



Within the team there is design, commissioning, validation and operating experience covering mammalian cell culture, microbial fermentation, vaccines, transgenics and natural-derived products such as blood plasma.

Complementing these is the same level of expertise in the downstream recovery and purification operations of:

- Centrifugation
- Cell lysis & disruption
- Microfiltration
- Chromatography
- Ultra and nano filtration

Additionally, the supporting systems of biological inactivation, CIP, SIP and clean utilities complete an all round 'one-stop shop' consultancy service.

# Dosage Form Secondary Pharmaceuticals

Our secondary pharmaceutical team, consisting of specialist industrial pharmacists, chartered engineers, architects and technicians, has a wealth of experience and excellent track record in providing consultancy, design and engineering services to support our clients in meeting investment challenges.



We have supported our clients in meeting typical key challenges such as providing appropriate capacity and flexibility to ensure current and future production requirements, reducing the 'cost of goods', technology transfer, reducing lead time and time to market, project execution whilst maintaining production, and meeting increasingly demanding regulatory requirements.

## **Foster Wheeler has expertise in the following sectors and technology areas:**

- Parenterals, steriles
- Oral solid dosages
- Liquids, ointments, creams
- Packaging
- SIP/CIP technology
- Material handling
- High containment technology
- Freeze drying
- Clean utilities
- Automation and process control (S88, GAMP 4, 21CFR11, MES)

Recent work has ranged from preparing standard equipment designs; conceptualising department and facility upgrades for cGMP and higher containment; refurbishment projects of dispensing, production and packaging areas; to complete design and construction management of oral solid dosage and aseptic production facilities.

Foster Wheeler strives to keep at the forefront of emerging technologies, regulatory developments and industry trends in order to help our clients meet their business and project objectives.

One of the ways we achieve this is by performing technical investigations and benchmarking studies. Typical examples are cost and benefits analysis of the use of conventional cleanroom technology compared with isolation technology, and conventional refrigeration systems used in freeze drying compared with liquid nitrogen systems.

Consequently, we are well equipped to undertake commissions for studies and investigations into all aspects of secondary pharmaceutical production and project work.



# Clean & Service Utilities

The correct design, specification and implementation of clean utility systems is essential to biotech, secondary and API facilities. Our experience of clients' installations world-wide allows us to offer the best consultancy on systems and the ability to provide baseline assessment and investment.

## Clean utilities expertise

Water for injection, highly purified water, purified water, non compendial water and clean steam.

Foster Wheeler's technical consultancy and design capability for high purity water and steam systems encompasses all of the current issues clients may face when upgrading existing systems or considering new builds, including:

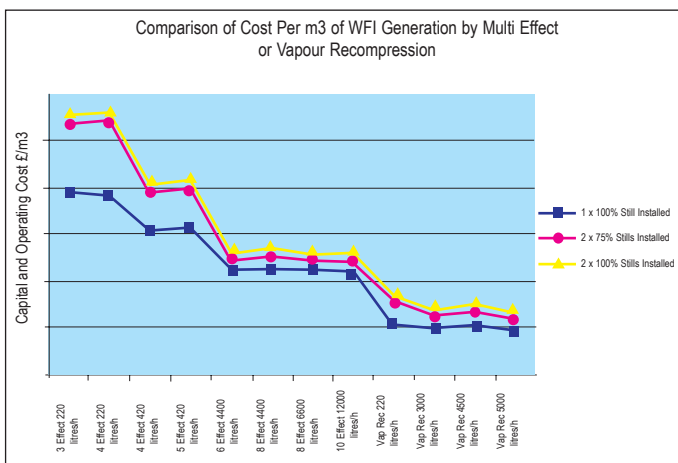
- GMP auditing and system performance troubleshooting
- Compliance with clients' requirements and regulatory standards
- Expert knowledge of regulatory inspection requirements
- Appraisal of best emerging and industry proven technology
- Water systems integration and capital/operating cost analysis
- Detailed hydraulic/thermal capacity analysis
- Utility optimisation using capacity and demand simulation

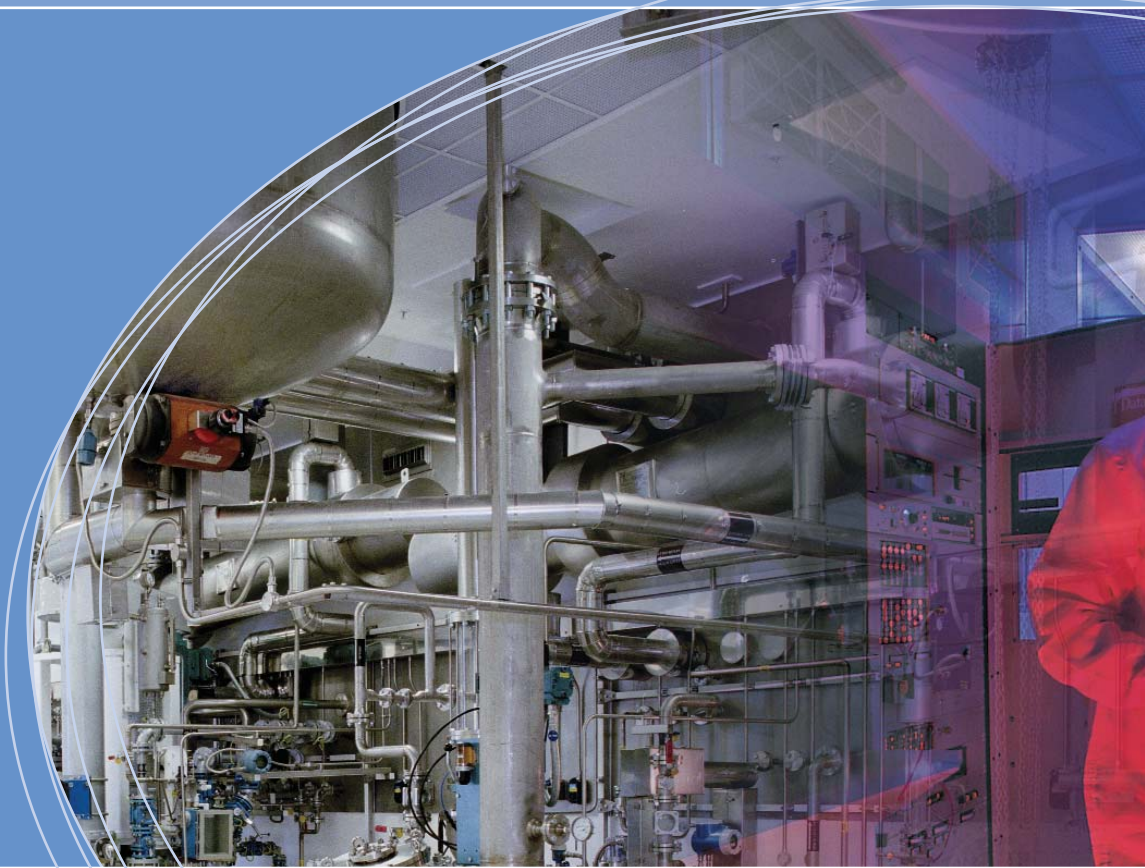


## Service utilities expertise

As a result of our experience in the planning, design and construction of major greenfield facilities, and site master planning studies, we have expertise in the evaluation of site infrastructure and upgrade requirements for all services to support pharmaceutical production, including:

- System capacity analysis, and evaluations on new builds and upgrades for existing infrastructure
- Refrigeration and single fluid heat transfer systems, for batch heating and cooling
- Waste minimisation, containment and environmental management including contaminated water, volatile organic carbon emissions, and waste incineration
- Integrated systems for water supply, heating and cooling to support all infrastructure needs





## Creating solutions

### UK Locations

Reading • Teesside • Glasgow

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