



PROCESS &  
CLEANROOM  
TECHNOLOGY

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## Bridging the Gap between Research & Commercialization



# Introduction to WHP



- Privately-owned UK-based company with £20m + turnover
- More than 30 years experience in designing and building facilities in the UK and overseas
- Successful projects completed in:
  - Biotechnology
  - Pharmaceutical
  - Healthcare
  - Food & Beverage
  - Industrial Containment
  - Various industrial products



# Some of our Clients



Design and construction of a new multipurpose biological API cGMP production facility with associated support laboratories, complete with cGMP warehousing.



Design and construction of a Japanese Encephalitis vaccine facility, designed and constructed as a turn key project



Specials manufacturing facility designed with ISO class 7 Cleanrooms c/w Analytical, microbiology and chemistry laboratories



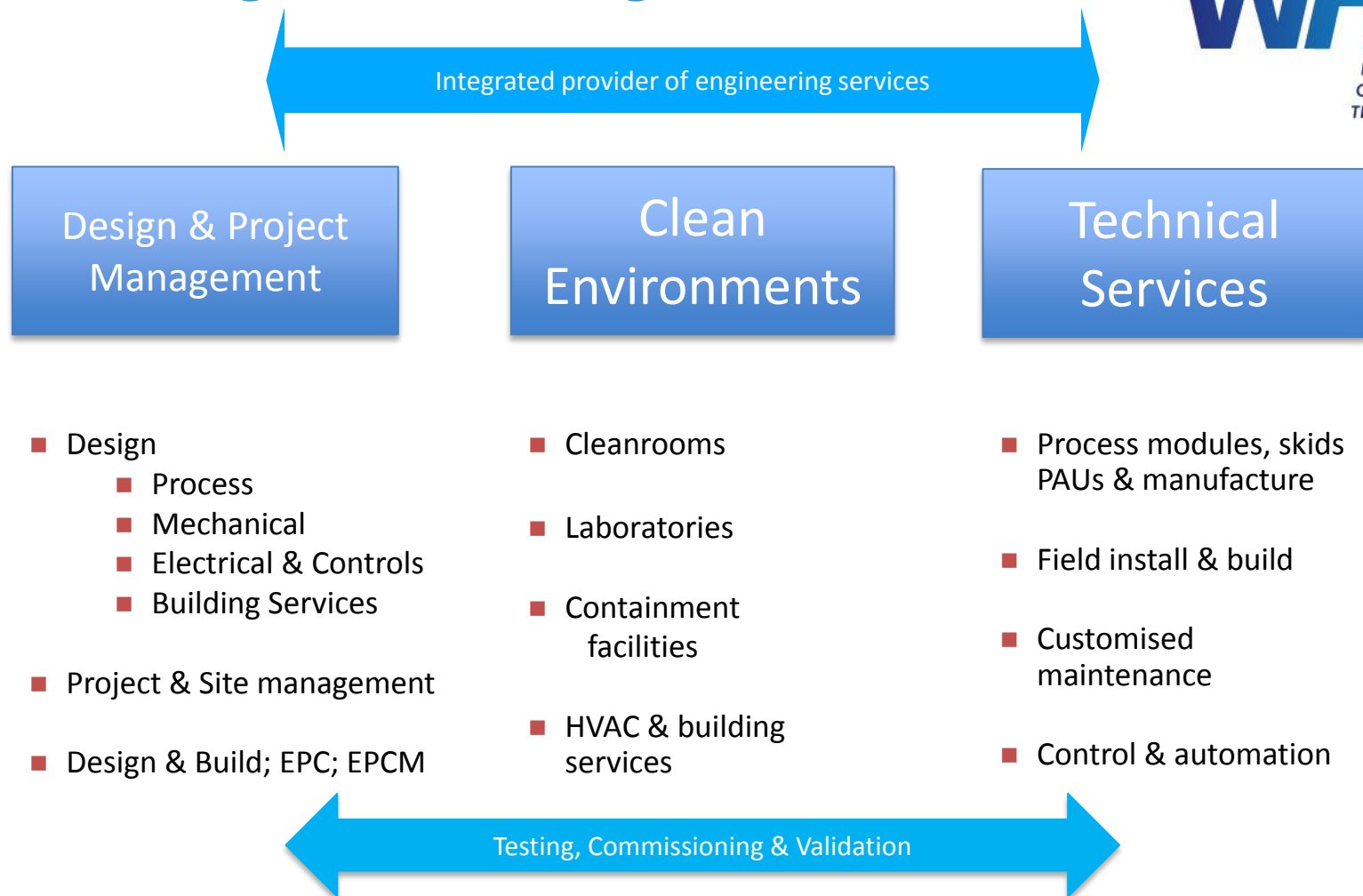


# Experience influences our operations

- In the 1980's WHP with GRC Consultants attempted to establish a fully integrated service to the clean industries
- The opportunity presented itself in 2009 to integrate the process plant capability of WHP with Bassaire North East 's clean room capability
- This enabled WHP to offer a completely integrated service which did not depend on external design or management to deliver complete plant in the sectors in which it works
- This capability is often most valued by research and development companies that neither have the resources or the experience to manage the design and build of integrated facilities



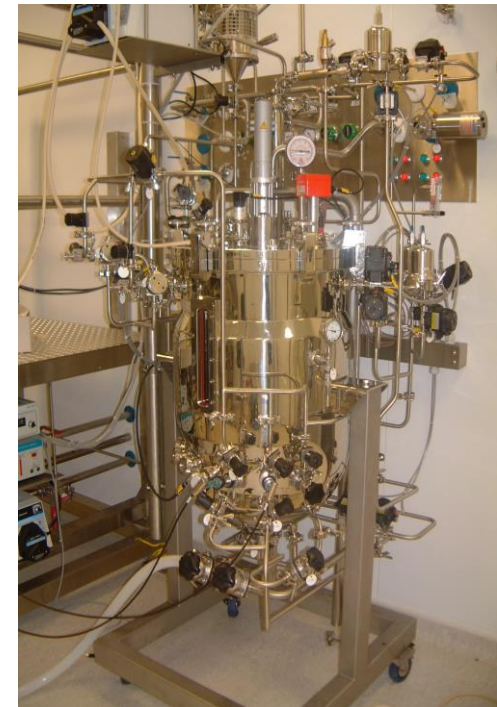
# How we organize for integration



# Our experience in the R&D Sector



- Early involvement in UK's biotechnology boom 1980s
- Collapse in investment in mid-1990's due to lack of investor confidence
- Causes mainly scientific over optimism and unrealistic times to commercialisation
- Those that succeeded had adopted mainstream pharma and chemical industry practices e.g. Genzyme, Serilogicals, Avecia etc.



# Common problems

- Poor estimating leads to cost overruns
- Poor User Requirement Briefs
- Business Plan developed without in-depth project execution plan
- Lack of detailed project scheduling leads to delays
- Lack of peer review can lead to failure in scale-up and commercialisation
- Overall loss of investor confidence and subsequent investor disinterest



# Lessons Learned

- Need for early experienced engineering input
- Recognising the end product requirements and ensuring all disciplines are in-place
- Business Plan linked to a detailed User Requirement Specification and Project Plan
- Establish a phased development – we use a proven stage gate process to establish funding requirements and technical & engineering/construction targets
- Involve the regulators once the basic processes & designs are established





# Common causes of project failure

- Current funding methods lack linkage between:
  - Finance
  - Legal
  - Engineering
  - Project Management
  - Regulatory
- Lack of ability of the parties to communicate or understand each other



WH Partnership (WHP) and NCL Innovations (NCL) have recently formed an association based on the following:

- Both parties recognised the difficulties being encountered by start-up and small developing enterprises
- Both had independently been involved with a wide range of development projects
- NCL considered that the funding market was essentially broken
- WHP had financially supported some of its developing clients
- NCL realised it needed early engineering involvement to underpin technical and financial due diligence

We aim to provide:

- An holistic approach to novel development projects
- We start from early stage process development where we work closely with the R&D teams
- We aim to bring early integrated project management and financial controls based on sound engineering and realistic estimating
- We assist with scale up, infrastructure and regulatory input
- We support the project from concept to start-up and follow through with maintenance if required



## Project profile



- Novel anti-cancer treatment
- Client approached WHP at the concept stage needing a fast programme and equally fast regulatory approval
- WHP supported TC Bio pre-contract and with some financial input
- WHP & TC Bio worked together as one team
- Project was completed in 12 weeks
- Operating licence from MHRA in 12 weeks
- We are now engaged in considering the next phase of expansion well ahead of TC Bio's programme needs





**manufacturing**  
**CHEMIST PHARMA**



“Built to comply with UK Good Manufacturing Practice (GMP) regulations, the multi-million pound facility took 12 weeks to build from start to finish.



“The facility has also been granted a licence to produce human cell therapy products by the UK's Medicines and Healthcare products Regulatory Agency (MHRA).



“The team has done an amazing job building and commissioning our facility in record time.

“Not only has WHP built an impressive GMP facility in the heart of Scotland, it also ensured that costs were managed in a supportive and proactive manner. WHP & TCB will jointly evaluate logistics of facility expansion on a geographical basis, using a combination of modular and mobile cleanroom systems.”

Angela Scott, Operations Director, TCB

# Concerns for the Future

- The process sector seems to be importing attitudes and methods from the building industry
- Procurement often seems to be based on cost alone rather than the total service required
- Payment terms are deteriorating which can often catastrophic impact on the small to medium contractors
- Lack of adequate training and experience is putting the industry at risk
- This will lead to the potential loss of a quality supply chain which could severely undermine the process industries and the hoped for Northern Power House

