

GSK Barnard Castle
Aseptic Facility Project
Procurement / Delivery Model



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GSK Barnard Castle

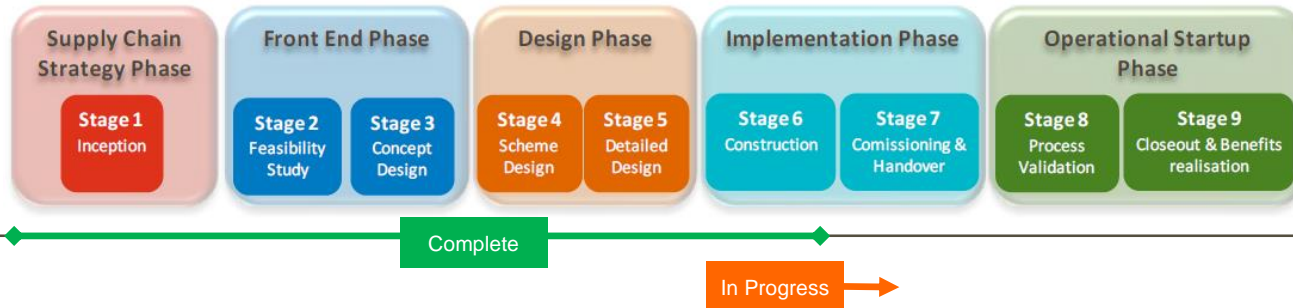


Site Overview

- ❑ GSK Barnard Castle is a secondary manufacturing site with three distinct business units:
 - Steriles* – Liquid fill sterile pharmaceuticals in Vials and Pre-Filled Syringes
 - Cephalosporins* – Antibiotics in Tablet and Suspension forms
 - Derms & Inhalations* – Creams, Ointments, inhalers and intranasal sprays
- ❑ New Product Introduction (NPI) and Global Supply Site for sterile liquids

Project Background

- ❑ £94m investment to secure aseptic liquid fill operations at GSK's flagship manufacturing site for next 20+ years
- ❑ In line with GSK capital base / asset replacement spend to ensure regulatory compliance
- ❑ Patient impact: Real medical need for specialised biological products that are difficult to manufacture
- ❑ Challenges: Major construction works within live / highly regulated site + Managing Design Complexity



Introduction



Project Background (cont'd)

- Purpose designed new build facility based around modular principles*
- Initially only 1 of the manufacturing suites will be fitted out*
- Process designed for cold chain small batch, high value Biopharm products*
- Advanced robotic filling technology under VHP isolator*
- Capability to process both vial and syringe formats*
- Manufacturing and filling using single-use technology as first intent*
- Fully Integrated IT / Automation solution with eBRS*

High Level Plan

Project Timelines



System	2018			2019												2020											
	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
HVAC										IQ		OO - pre Filling line install					OO - confirm balancing							Re qual			
Steam								IQ				OO		PQ													
Gases								IQ				OO															
WH								IQ				OO		PQ													
PCS7						Install	Com					IQ/OQ															
Digital		Design																									
Parts Washer	FAT					Install				IQ	Com		OO														
Autoclave		FAT							IQ	Com		OO		Cycle development	PQ									Re qual			
Filling line + Isolator							Manufacture		Test			FAT		Install		IQ		Filling OQ					Isolator OQ		Micro PQ + requal		
Cleaning												Facility clean														Facility Clean PQ	
Media trails + hold period																										Hold period	Media trials

Project Complete

Previous Delivery Models



EPC

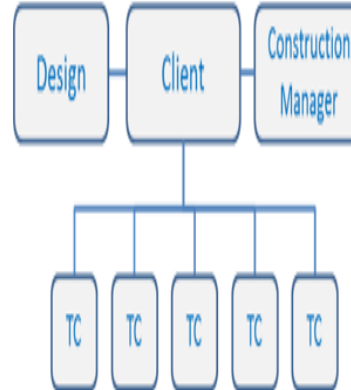
- Turnkey contract. Contractor tender based on a performance spec rather than detailed design. EPC Contractor enters into contracts with work packages (subcontracts). Similar to D&B as it is a single contract. Payment can be lump sum or reimbursable but generally Clients seek cost certainty and use lump sum.

EPCM

- Similar to EPC from a design and procurement perspective, but Client employs the work packages directly and the EPCM contractor acts as a construction manager and manages the work packages

- Management Contracting, all the work is undertaken by works contractors who are subcontracted to the management contractor.
- Construction Management, all the work is carried out by trade contractors who are individually contracted to the client.

Construction Management



Management Contracting



Capital Project Delivery



Background

Barnard Castle have self managed Capital Projects for many years and maintained small team of SME discipline Engineers. The team continuously look to provide greater value in project delivery to GSK and maintain a continuous improvement culture.

The Q Block project was the largest capital investment on site for 30 years and presented a great opportunity to maximise value to GSK by self delivery it was essential :

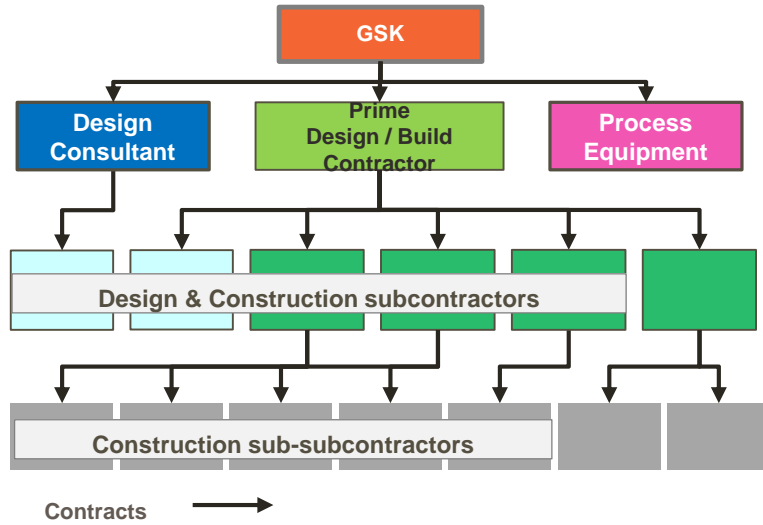
- ❑ GSK Team include the skills to manage and deliver the project
 - ❑ Perform role / legal duty of principal contractor
 - ❑ Co-locate the GSK team with our tier 2 contract partners
 - ❑ Establish safety and 5S culture
 - ❑ Establish leadership governance structure
-

Why Did We Choose Integrated Project Delivery (IPD)?

IPD was a way of **driving project value** by planning our project delivery strategy with the 5 main principles were:

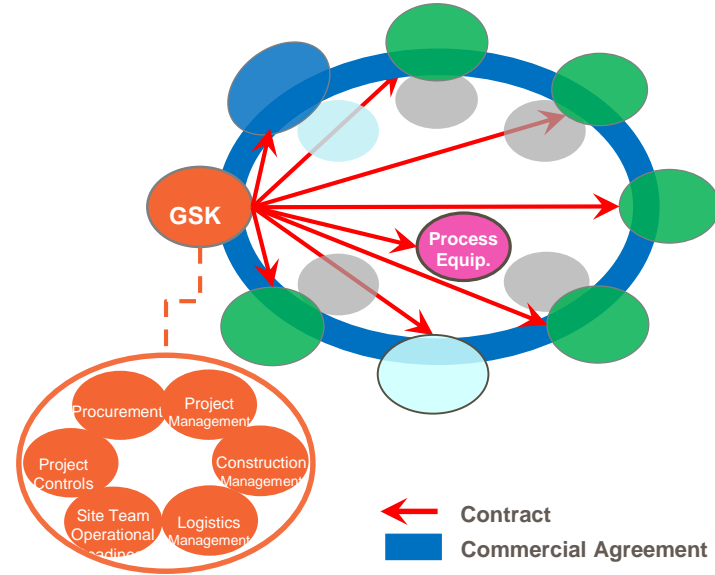
1. Creating an **unified team** collaborating on an aligned common purpose, with coordination by GSK
2. Maximising **early contractor involvement**
3. Maximising **installer design** avoiding design duplication
4. Getting the **best supplier in each position**, instead of a mixed bag via a EPC, EPCM or Main Contractor
5. Utilising internal **subject matter expertise** in Aseptic Process and Manufacturing

IPD being Different from the Traditional Models?



Traditional

Risk Transfer through Hierarchy



Collaborative

Risk Management through Integrated Sharing

Integrated Project Delivery

Aseptic Manufacturing Facility - IPD Relationship Model



Hybrid IPD Organisation

Key Suppliers

Relationships

- Contract (Red double-headed arrow)
- IPD Controls Protocol (Blue line)

Team Members

- GSK Project Team (Orange circle)
- Equipment Suppliers (Blue circle)
- GSK Personnel and Support Service Providers (Light Orange circle)
- Core IPD Team Member (WP) (Green circle)
- IPD Team back to back subcontractor (Grey circle)

Organisation Chart – Commissioning Stage



Governance & Sponsorship

External and internal regulation to ensure that legal, financial, regulatory and stage gate reviews take place. Alignment of the project with business needs

STEERING TEAM

Project Sponsor

Assurance

A management function that systematically provides confidence that an organisation, product or service meets the project requirements

Head of Project Controls

Regional Project Director

Site Capital Director

PC Assurer

Project Manager

Delivery

Integrated Project Delivery Team

Project Leadership Group

Procurement

Project Controls

Construction Management

GSK Team Design & Engineering

Delivery Suppliers

Key Equipment Suppliers

Business Readiness

BC Procurement Support

Commissioning Planning

Commercial Management

NEC Contract Support

Construction Manager
EHS Manager
Permit Manager

Management of Construction

Commissioning Manager
Equipment x4
Process x4
Mechanical Services x2
Electrical Engineer
Automation x4
Building Services
Utilities x1
Civil and Structural x1
BIM Manager x1
Validation x2

Design & Build Suppliers by WP:
Shell and Core
MEP
Clean Utilities
Clean Room
Cold Store
Furniture

List of equipment:
Filling Line
Parts Washer
Autoclaves
Carousel
Downflow Booth
Dispensing Isolator
Pallet Equipment

Digital Lead x1
Operational Lead x1
Engineering Lead x1
Building Services Team x5
PCS7 Lead x1
Production Team x5
Quality x2
Micro x1
Document Controller x1

Collaborative Project Team

Integrated Project Delivery

Key Benefits



- Ensure highest quality Standards delivered Civils / MEP / Process
- Deliver Value to GSK (Facility delivery cost fully qualified).
- Co-located GSK / Contract organisation team to deliver all phases of the project with comprehensive on-boarding process
- Shared communication platforms - viewpoint, MS team-site.
- Transparency of information and rapid problem sharing aided by BIM Model
- Continual visible and interactive planning (one master schedule).
- Single Project Charter for the Team .
- Teambuilding – planning, development and communicating.
- Promotes open and honest communication and swift decisions
- Carefully chosen people / partners committed to collaboration principles.
- Sponsor and Steering groups clearly aligned.

Integrated Project Delivery

Benefits in Leadership and Collaboration



- Allows full control of the project design and delivery phases.
- Visible and committed leadership
- Empowering Team
- Identifying our collaborative partners with common aim
- Build on success not fear of failure culture
- Respect for people / all team members treat equal
- Shared risk management and increased certainty of outcomes through de-risking
- Commercial opportunities encouraging efficiency
- Change in basic concepts and practices from traditional 'contractual combat' to collaborative environments.

Integrated Project Delivery

Commercial Benefits



- Reform procurement practices – early contractor engagement moving from traditional delivery
- Reduce risk profile by active risk management and share of risk exposure
- Incentivise efficiency and innovation, both individually and collectively including team building and individual awards.
- Creation of a culture of best for project, not best for self
- Ensured our relationships was an approach to doing business, not a contract change
- Open transparent environment building trust not at the expense of the project

Integrated Project Delivery

Lessons Learnt



1. Maximise understanding of process / equipment to fully understand impact on the facility where possible prior to civil utility detailed design.
2. Review procurement route choice for facility delivery – Deliver the shell and core package by design / install avoid encouraging non collaborative approach with traditional contract.
3. Earlier engagement with clean utility supplier to allow specialist scheme design following concept sign off – Information was late to the table (Quality Utilities need priority routing!).
4. Appreciation of how automation / manufacturing execution systems had an impact to key equipment
 - Clear defined digitalisation scope (our paperless / digital scope was defined later and influenced change).
5. Choice of contracts – did we select the right contract and clauses to allow true collaboration?
 - NEC3 applied v NEC4
 - Failed to share risk with delivery partners
 - Price v best value – procurement are changing!
6. Part integration of facility vendors into the project governance team the key personnel and decision makers where direct staff (Change!)

IPD Model can work well to deliver significant benefits for advanced sites but essential to establish capable skilled team

The project remains on time and within budget



Thank You !