

Growing the Fermentation Capacity at Porton Biopharma Limited



Ian King – Process Engineering Manager

Contents

- **An Introduction to Porton Biopharma Limited**
- **Project Objectives**
- **Project Scope**
- **Project Status and Timings**
- **Process Design Philosophy**
 - **Equivalence to existing licensed process**
 - **Automation**
 - **Redundancy**

An Introduction to Porton Biopharma Ltd

- Newly formed company in April 2015
 - Corporatised out of Public Health England to grow business of developing and manufacturing life-saving products.
 - Based at Porton Down, Wiltshire, UK
 - Now 260+ employees
- Limited company
 - Private Limited Company with UK Secretary for State for Health the sole share holder
- Licensed Products
 - Erwinase®
 - UK approval 1985, US approval 2011
 - Anthrax Vaccine
 - UK approval 1979

Capabilities

- Specialisation
 - Biological pharmaceutical manufacture and development
 - Containment GMP facilities
- Licensed facilities
 - MHRA
 - FDA
- Full process and analytical development capability with proven track record
- Production capacity for GMP clinical trial material
- Since 1982 a long history of working closely with partners to ensure project success
- Further details www.portonbiopharma.com

Project Drivers and Objectives

- Fermentation capacity limited to 750L
- One existing facility → Two process steps
- High occupancy to achieve required output
- Limited capability to stockpile material
- Debottleneck via 3x fermentation scale up
- Create a dedicated facility for fermentation only
- Create capacity to enable further capital spend
- Material for Process Development
- Modernise where possible a traditional process

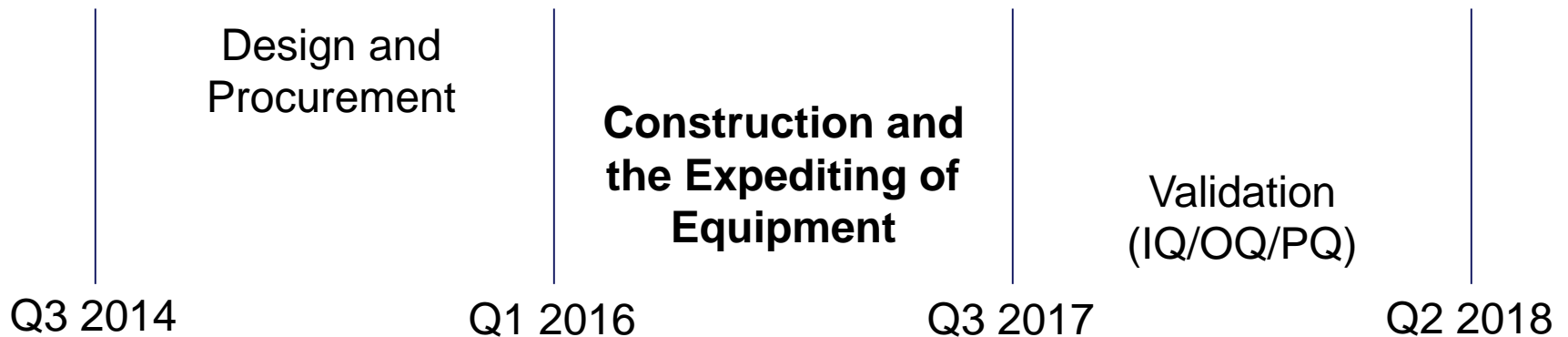


Project Scope Summary

- Scaled up fermenter chain (200 L intermediate, 3000L production)
- New centrifuge
- Self contained utilities
- Effluent treatment plant
- Raw material storage
- Product freezer capacity
- Located in a new building
- Linked to existing facility



Current Status and Project Timings



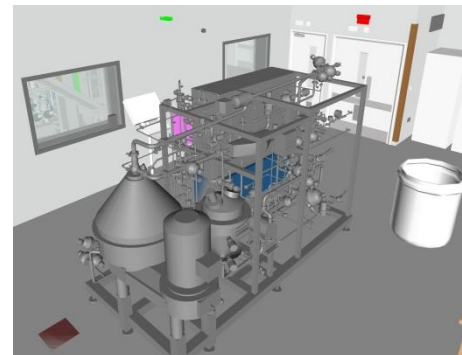
Process Design Philosophy

Key objectives in the design phase were:

- Ensure speedy demonstration of equivalence with existing licensed process to Regulators
- Ease of use for operators
- Automation where possible
- Utility design for self sufficiency/redundancy
- Use of disposables where possible

Equivalence Built Into Design

1. Define Critical Quality Attributes (CQA) from current process validation (e.g. fermenter yield)
2. Specify linked Key Process Parameters(KPP) to achieve these (e.g. required agitation speed)
3. Define design requirement in URS to ensure equipment can achieve KPP
4. Used to inform process design decisions e.g. centrifuge selection



Automation and Control Philosophy

- Existing process very reliant on manual control
- Opportunities for operator error
- Repeatability of operations
- Need for data collation for batch reports

HENCE

Increased Automation and Control is a
key feature of the completed design



Individual vs. Central Control

Individual control - equipment supplier includes standard control package

Central control – single integrator installs overall system for all equipment

	Individual Control	Central Control
Advantage	<ul style="list-style-type: none">• Control design by equipment specialist	<ul style="list-style-type: none">• One system for operators to learn• Data collection from single compliant system
Disadvantage	<ul style="list-style-type: none">• Many interfaces to manage between suppliers• Historical issues with previous projects	<ul style="list-style-type: none">• Need for integration testing e.g. at FAT

Redundancy and Self Sufficiency

Design to ensure continuity of supply:

- Twin Purified Water Generators
- Twin Clean Steam Generators
- Twin Air Compressors & Dryers
- 24 hours Effluent Tank capacity
- 24 hours Potable Water capacity in two tanks
- Extra steam boiler and backup generator capacity

