

Sterling Pharma Solutions

North East Maintenance Forum – Feb 2018

Introductions

- ⬡ Simon Howick – Plant Engineer
- ⬡ John Ferguson – Assistant Plant Engineer
- ⬡ Trevor Jewitt – Central Engineering Services Manager

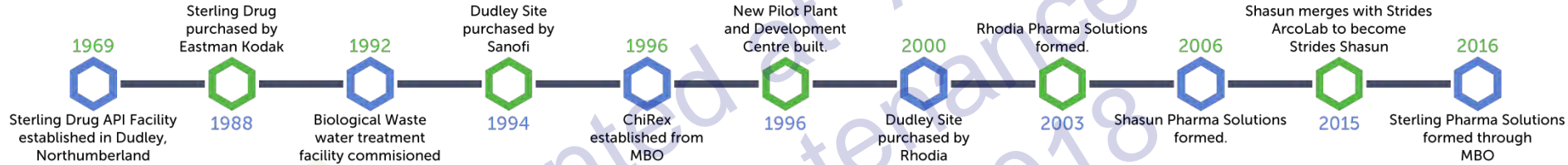
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What Do We Manufacture?

- ⬡ API – Active Pharmaceutical Ingredients.
- ⬡ Intermediate Pharmaceuticals.
- ⬡ Human and Animal Medicines

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Dudley History



**Strong Pharma and Technology heritage
coupled with 45 years experience of
Contract Research, Development &
Manufacturing**

Dudley Overview

- 42 Acre site
- Process Research & Development Laboratories
- Scale Up Laboratory Facilities
- Highly flexible Pilot Plant
- 3 Major Production Facilities – D1, D1.5 & D2
- 450 m³ cGMP reactor capacity
- Commercial Biological Waste Water Treatment Facility



Dudley Manufacturing Overview

- Broad range of intermediate (22) and API trains(6)
- 300 - 3000 gallon scale
- Range of pressure filters, centrifuges and blender driers
- USP Purified water system and Cleanroom facilities for API offload
- Cryogenic capability (-90°C)
- High temperature capability (+260°C)
- High vacuum WFE / SPE unit; fractionating unit –30 theoretical plates
- Range of milling facilities in cleanroom environment
- Extensive range of capabilities including Fluorination, Hydroxylamine handling, Organometallic, Friedel Craft and Carbonylation capability
- Bulk Br₂, Cl₂, H₂, Ethylene Oxide, Propylene Oxide



All operations to cGMP

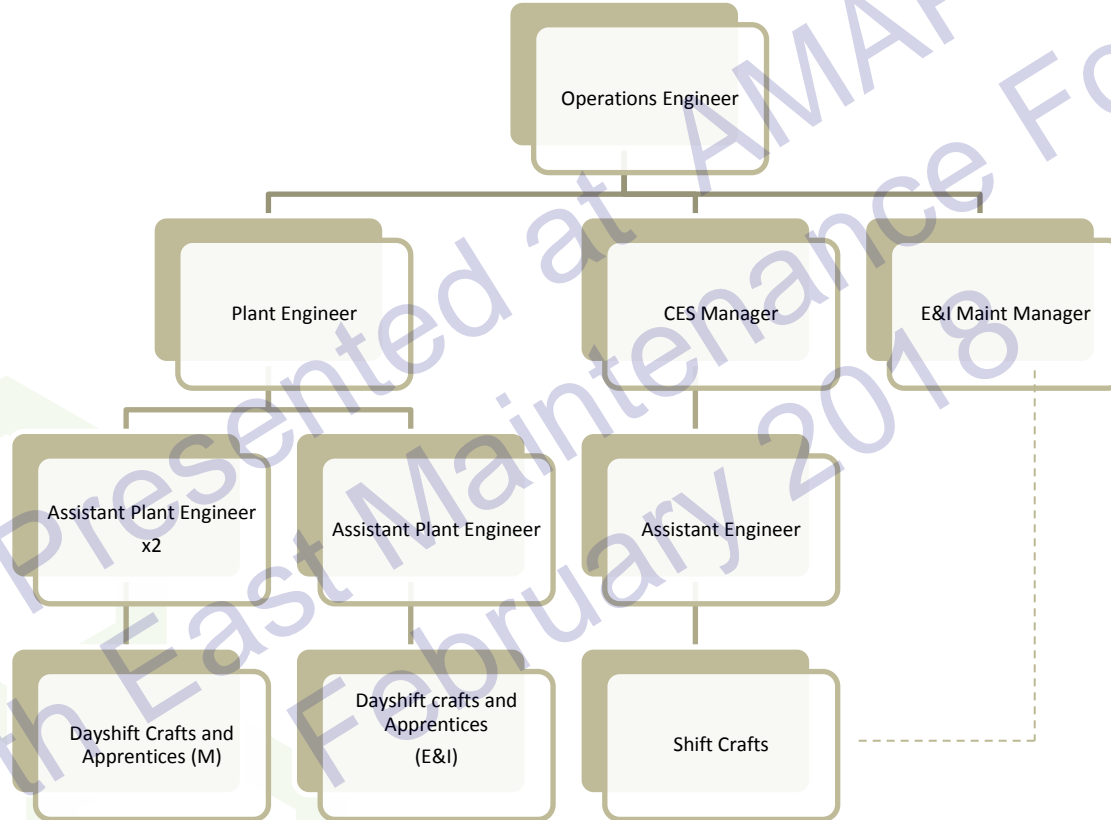
Batch Production

- ⬡ Varied Production Campaigns
- ⬡ Equipment Streams
- ⬡ Rapid and Varied Plant Change over
- ⬡ Production Schedule Adherence

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Maintenance Challenges





What Type of Equipment Do we Maintain?

- Glass lined reactors
- Steel/Hastelloy Reactor vessels
- Filter Dryers
- Centrifuges
- Pumps
- Vac pumps
- Mills
- Ovens
- Clean rooms
- Ventilation
- Reverse osmosis
- Boilers and steam systems
- Biological Treatment plant
- Lab equipment
- Fire and safety systems
- N2 plant and system
- Bulk Solvents



What Governs our Maintenance ?

- ⬡ Safety
- ⬡ COMAH – Top Tier Site
- ⬡ Quality – cGMP
- ⬡ Compliance (PSSR, SIL/SIS, cGMP, Legionella)
- ⬡ Production/ production schedule adherence

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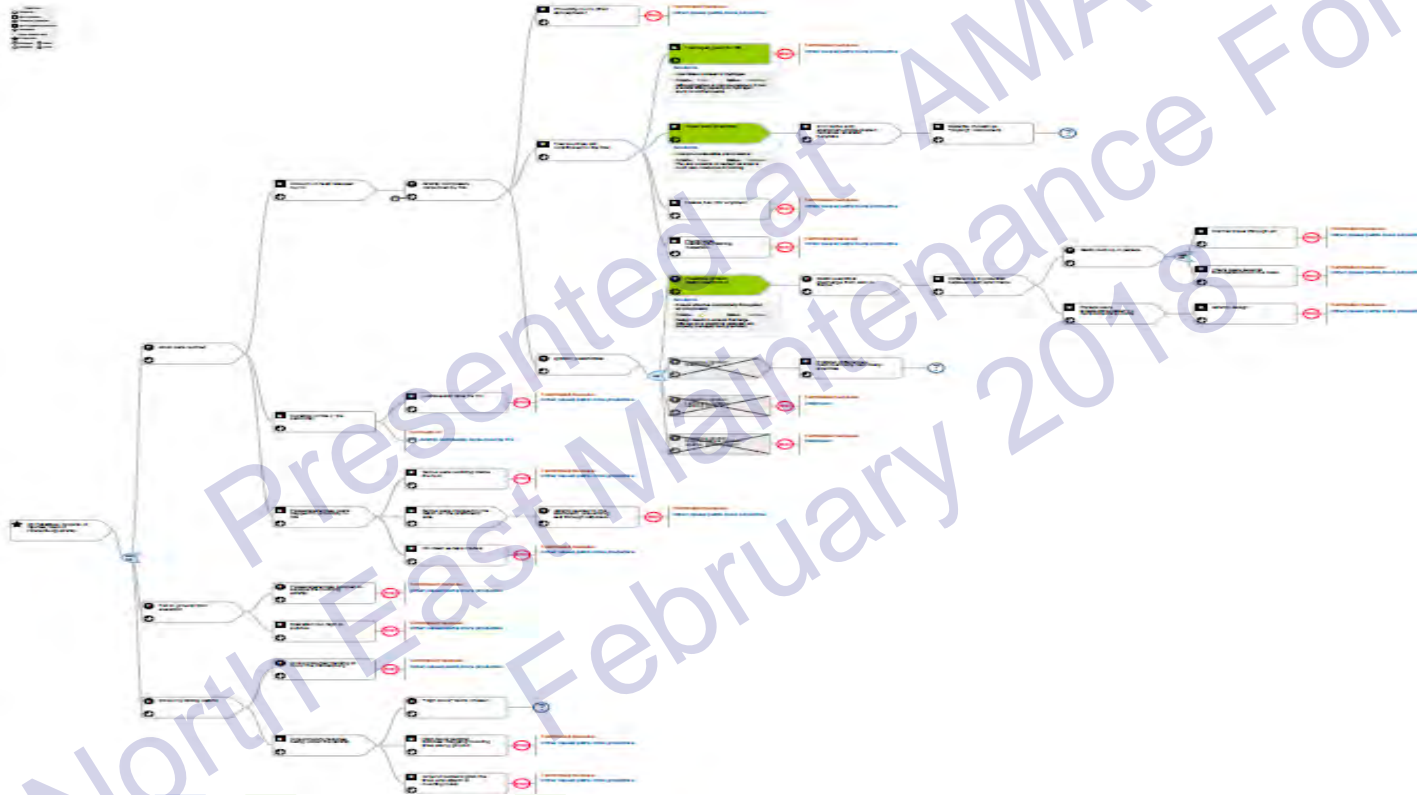
Challenges

- ⬡ Loss of experience (Retirement)
- ⬡ New Management team
- ⬡ Ageing plant
- ⬡ Ageing workforce.
- ⬡ Inexperienced Work Force
- ⬡ New products
- ⬡ Major Projects
- ⬡ Expansion

Reactive to Proactive

- ⬡ Planned Preventative Maintenance
- ⬡ Condition Monitoring – VA, Inspection, Thermography
- ⬡ Root Cause Analysis – Treat the cause not the symptom

Example RCA Cause and effect chart



Changing Attitude and Behaviour

- ⬡ “But we have always done it this way !!”
- ⬡ “I just want to fix stuff !!”
- ⬡ Don't run before you can walk.



- ⬡ Here to learn and share
- ⬡ What are other industries doing?

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Thank you for listening

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