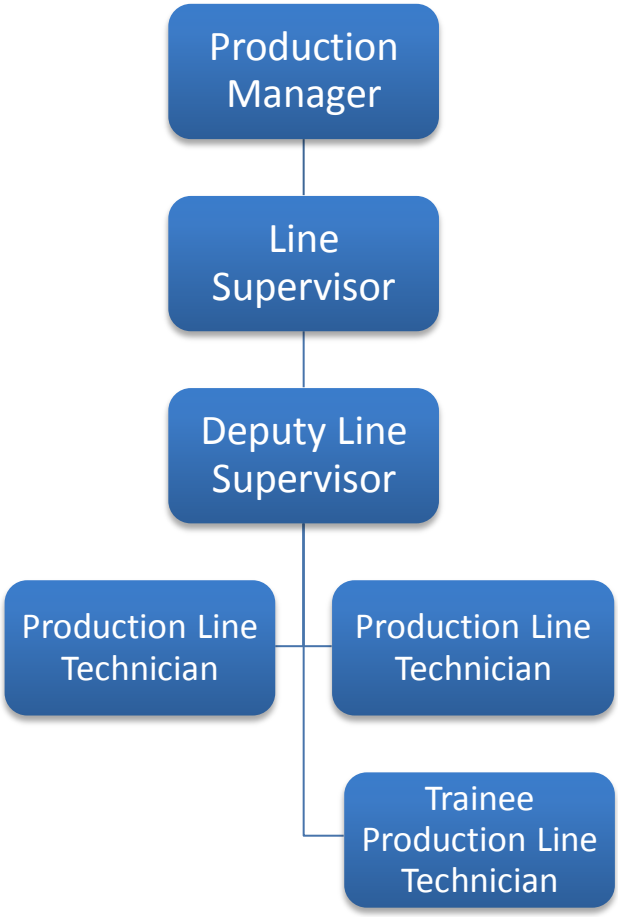
JOB DESCRIPTION

Job Title:	Trainee Production Line Technician
Band/Pay:	Band 3 (Training role starting on Band 2)
Department:	Production

Torbay Pharmaceuticals



Job overview

A development role has become available for a full-time trainee production line technician to join the existing Production team, within a cleanroom environment, here at Torbay Pharmaceuticals. The developmental role starts as a trainee production line technician, (Band 2) and then progresses to cleanroom production line technician once competency is achieved in the required lines/departments.

Main duties of the job

The job involves working as a member of a small specialist team manufacturing pharmaceutical products within a sterile controlled environment.

The applicant must have good attention to detail and be able to understand and follow written procedures. The candidate will preferably have previous cleanroom experience and will be able to work as part of a team.

The primary purpose of the cleanroom production line technician is to work as a member of a small specialist team manufacturing pharmaceutical products within a sterile controlled environment. This involves chemical preparation, formulation, automatic filling, over sealing of products together with cleaning and sterilising of equipment in compliance with all manufacturing SOP's, Batch packaging records, in line with H&S requirements and following Pharmaceutical cGMP.

To be a member of the Operations team that will create and drive a culture in order to meet and exceed the business objectives of being a Class leading Pharmaceutical business within the NHS, setting high standards of Environment, Health and Safety (EHS), Quality Management System (QMS), and Good Manufacturing Practice (cGMP)

To be an 'area' expert and carry out training for new or less experienced members of the team on complex equipment and processes within the pharmaceutical manufacturing cleanrooms.

About your new team and department

Torbay Pharmaceuticals is a flagship business within the National Health Service and manufactures and distributes terminally sterilised injectables for the secondary care market in the UK and worldwide. We believe that by thinking and acting differently we can make a positive difference to people's lives across the world.

The business employs around 200 people and is achieving year on year growth. Our specialist portfolio includes licensed and unlicensed terminally sterilised injectables, high-quality electrolyte solutions for TPN compounding, and a range of non-sterile oral solutions.

At Torbay Pharmaceuticals you'll work for a truly unique organisation and alongside the most committed people in the business. We have ambitious plans to grow our business over the next few years and we know that we can't do that without everyone playing their part. That's why we believe in the One TP way of working.

If successful you'll be part of a 30 strong production team working in specialist sub teams manufacturing life saving pharmaceutical products.

You'll become part of team who really make a difference worldwide.

Detailed job description and responsibilities

Communication and Working Relationships

- Ensuring that the requirements of the Health & Safety at Work Act 1974, and where applicable the Medicines Act 1968 are complied with (e.g. that the Production Operator does not pose a danger to themselves or work colleagues and that all cGMP instructions are complied with)
- To work both as an individual in certain tasks and also as part of a small specialist team within various sections of the Production department
- To read, understand and act on written instructions via batch records and SOP's, to perform calculations and to record KPI data, calibrate process test instruments, assemble technical equipment and understand product critical quality attributes
- To complete all documentation in a clear, precise, contemporaneous and legible manner in accordance with Data Integrity principles
- To inform the Production Manager, Line Supervisor, Deputy Line Supervisor or any member of the engineering team of anything concerning any defect or issue with a product, equipment, facilities, components, documentation and to check equipment is "fit for purpose" before any production commences
- Communicate effectively with production team members, senior staff, other departments and regulatory auditors
- Work as a member of a small specialist team, valuing the contribution of others and forming co-operative working relationships with all colleagues
- To participate in 5S and sustain the production areas to this standard, and to participate in KPI meetings
- Attend all relevant internal and Production team meetings as requested
- Attend daily production meetings when necessary
- The post holder reports to their team Line Supervisor or Deputy Line Supervisor
- The post holder is in regular contact with all Torbay Pharmaceuticals operational and management personnel

Planning and Organisation

- Demonstrate the ability to multitask when required and respond to a variable workload with unexpected interruptions with changed deadlines. To manage aggressive customer deadlines in relation to on-time/in full product delivery
- Responsible as part of a specialist team for chemical preparation, formulation, automatic/manual filling and over-sealing of products together with cleaning and sterilising of equipment in compliance with all manufacturing SOP's, Batch Documentation, H&S requirements and cGMP
- To 'set up' and operate complex equipment as set out in the appropriate SOP's
- Responsible for performing daily & monthly cleanroom cleaning activities as set out in the appropriate SOP's
- Prepares equipment by performing cleanroom cleaning as per cGMP using cleaning-in-place (CIP)and servicing-in-place (SIP) systems

Responsibility and Accountability

- To assist the Production Manager, Line Supervisor & Deputy Line

Supervisor in ensuring that the Production department and related activities comply with cGMP, the unit's ISO accreditation standards and other relevant guidelines, procedures and practices
- To perform the dispensing and preparation of raw materials including specialist and potentially hazardous chemicals as instructed and in accordance with the batch documentation and in compliance with applicable SOP's and hazard data sheets
- To understand the importance of all activities/perform quality control checks such as IPC's (in process checks) and process challenges.
- Participate fully in departmental training programmes and ensure compliance of all mandatory training courses
- To undertake any other reasonable duties consistent with the grade as indicated by the team Line Supervisor or Deputy Line Supervisor
- Responsible for the continual effective performance of Torbay Pharmaceuticals cleanroom operations in order to meet the requirements of the production schedule
- Ensure that cGMP requirements are maintained for the area
- Ensure Health and safety regulations are maintained
- To operate cleanroom production equipment and carry out pharmaceutical manufacturing processes under strict cGMP guidelines and regulations required to produce pharmaceutical products
- Carry out daily cleaning activities after completion of the production batch as set out in standard operating procedures in preparation for the next planned production run
- Be able to work within a controlled/graded cleanroom environment whilst wearing specialist cleanroom gowning to minimise contamination

Policy and Service Responsibility

- Responsible for maintaining the cleanroom facility and pharmaceutical processing equipment to the standard of cleanliness and sterility required of Torbay Pharmaceuticals and regulatory guidelines and standards (Pharmaceutical cGMP). To include the sanitisation, maintenance and monitoring of a controlled/graded clean room environment
- To read and understand all applicable SOP's, to understand the importance of all activities and processes. To understand the importance of the pharmaceutical products being manufactured
- To work both as an individual and as part of a team, to support operational efficiency and continuous improvement programmes and to ensure that at all times all activities comply with "Good Manufacturing Practice", the units ISO accreditations and other relevant guidelines; H&S guidelines, procedures and practices

Responsibility for Finance, Equipment and Other Resources

- Responsible for basic fault finding and once this process is exhausted responsible for escalating production issues to the Line Supervisor or Production Manager
- Requires the frequent movement of items weighing up to 15kg without the use of mechanical aids in accordance with H&S regulations. Requires frequent movement of loaded pallets and product trolleys
- Occasional handling of hazardous chemicals and materials requiring the

use of personal protective equipment

Responsibility for Supervision, Leadership and Management

- To support, encourage and assist in the training of new starters and less experienced staff
- Ensuring that they are suitably dressed in accordance with Company dress code and that any personal protective clothing provided is correctly worn as directed by SOP's, Hazard Data Sheet or COSHH Assessment sheets. To include the wearing of specialist clean room gowning whilst working in a controlled/graded pharmaceutical cleanroom
- All staff will be regularly assessed on their knowledge, skills and behaviour, and application of all aspects of the job description, in line with the Trust's Achievement Review (AR) process

Information Technology and Administrative Duties

- To enter accurately any appropriate data required on batch documentation, complete necessary documentation and to take signatory responsibility for key events where suitably trained and authorised to do so
- The Cleanroom Line Technician is responsible and accountable for the quality of the task or process that they are performing; they are responsible on completion of satisfactory training for the set-up, entry of data to computerised systems and operation of complex equipment
- To assist and take appropriate action in the investigation of corrective action and deviation documents. To accurately enter production details in Q-Pulse (Electronic Quality Management System) and manage directed actions as required
- To participate in validation studies, collect and assess technical data, read, understand and assess technical manuals

PERSON SPECIFICATION

Attributes	Essential	Desirable
Qualifications and training	• Good general education to 5 GCSE's including English and Maths, Science or equivalent or significant experience within a regulated manufacturing environment or clean room	• Basic IT training • NVQ3 or equivalent in science-based discipline
Knowledge and experience	• Moving and Manual Handling knowledge • Able to show self-motivation and use initiative, recognise when to refer upwards • Good experience of working within a pharmaceutical or medical device manufacturing facility • An understanding of the regulatory standards related to manufacturing (Good Manufacturing Practice, GMP) • Essential requirement to progress to Band 3 – Completion of pharmaceutical competencies at NVQ 3 level or equivalent • Essential requirement to progress to Band 3 – Experience and a detailed understanding of Good Manufacturing Practice and associated procedures • Experience of working with Standard Operating Procedures and ability to troubleshoot and resolve issues with specialised pharmaceutical	• Detailed understanding of Good Manufacturing Practice

	manufacturing equipment • Previous experience of operating and setting up PLC controlled manufacturing equipment	

Specific Skills	• Able to adapt to change • Able to read, understand and follow written and verbal instructions and perform basic calculations • Good communication and interpersonal skills • Effective teamwork • Essential requirement to progress to Band 3 – Ability to supervise within a small team • Essential requirement to progress to Band 3 – Involvement in pharmaceutical investigations and the resulting CAPA • Essential requirement to progress to Band 3 – Highly developed skills where high levels of accuracy and dexterity is important. Utilising complex pharmaceutical tools and equipment	• Previous Pharmaceutical Clean Room experience or specialist pharmaceutical formulation knowledge, specialist equipment knowledge, specialist pharmaceutical process knowledge • Experience of working within an ISO accredited organisation or regulated environment
Requirements due to work environment/conditions	• Able to deal with hazards associated with occasional exposure to fumes and chemicals • Gowning in enclosed clothing to minimise contamination • Able to work within an enclosed 'cleanroom' environment in manufacturing areas • Exposure to disinfectants and cleaning agents within the manufacturing areas • Able to work within a noisy environment	• Experience of working within restricted physical environment (Laminar Flow cabinet or restricted cleanroom environment with restricted breaks)
Physical effort	• Good manual dexterity to perform accurate manipulations and measurements • Ability to lift weights to the limit of 15kg • Frequent requirement for physical effort in the moving and handling of inanimate loads • Frequent sitting or standing in a restricted position due to continuous operation of equipment • Frequent moderate effort required for several short periods	

Emotional effort	• Able to work on own and in teams
Mental effort	• Able to concentrate on detailed and repetitive work • Able to respond to changes in workload • Able to remain calm and level headed under pressure