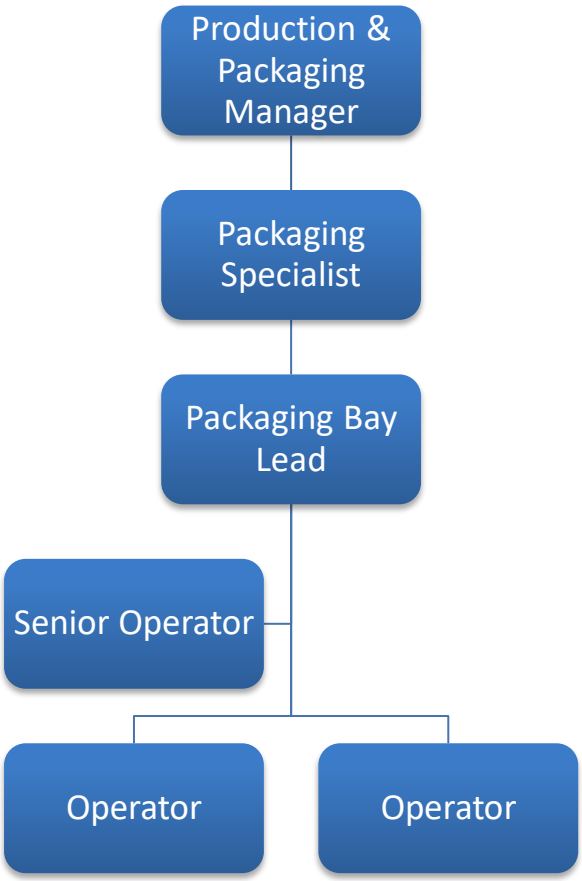
JOB DESCRIPTION

Job Title:	Packaging Bay Lead
Band/Pay:	Band 4
Department:	Production & Packaging

Torbay Pharmaceuticals



Job overview

To supervise Packaging team members in the use of equipment and carry out pharmaceutical inspection, labelling, packing and serialising processes under strict cGMP guidelines and regulations required to produce pharmaceutical products.

To ensure that all packaging tasks are completed within the working day, whilst working to tight deadlines in order to meet the requirements of the schedule.

Main duties of the job

The primary purpose of the Packaging Bay lead is to lead teams in the processing, inspecting, labelling, packing, serialising and storing pharmaceutical products 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 packaging area.

About Torbay Pharmaceuticals

Torbay Pharmaceuticals (TP) opened a new manufacturing site in 2017 supported by a £26m investment. We aim to double the size of the business in the next 4-5 years. Torbay Pharmaceuticals (TP) is a semi-autonomous business unit of Torbay and South Devon NHS Trust with its own Management Board.

Torbay Pharmaceuticals (TP) 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.

The business employs circa 200 people and has sales in excess of £20M per year.

TP is a holder of the following MHRA (Medicines and Healthcare Products Regulatory Agency) licenses:

- ✓ Manufacturers License
- ✓ Manufacturers License 'Specials'
- ✓ Wholesale Dealers Licence
- ✓ Manufacturers Licence 'Investigational Medicinal Products

TP is a holder of the following Quality Management Accreditations:

- ✓ ISO13485 – Medical Devices

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 Packaging Operator does not pose a danger to themselves or work colleagues and that all cGMP instructions are complied with)
- To supervise Packaging team members and ensure they read, understand and act on written instructions via batch records and SOP's, to perform

calculations and to record KPI data, 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 & Packaging Manager, Packaging Specialist 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 packaging activities commence
- Actively participate in internal and external audits, to act as relevant ‘expert’ during external audits
- To take an active lead in ensuring all H&S requirements are enforced, enter accidents onto the trust system, complete reports and statement where necessary
- Communicate effectively with packaging team members, senior staff, other departments and regulatory auditors
- To supervise small specialist teams, creating strong team spirit environments, valuing the contribution of others and forming co-operative working relationships with colleagues
- To develop effective interpersonal skills for the delivery of training, recognising barriers to communication and the most appropriate means of delivery depending on the individuals and activities involved
- To lead and participate in 5S and sustain the packaging areas to this standard, to lead and participate in KPI meetings
- Attend all relevant internal and Packaging team meetings as requested. Attend and lead daily production meetings when necessary
- The post holder reports to their team Packaging Specialist
- The post holder is in regular contact with all Torbay Pharmaceuticals operational and management personnel
- The post holder will interface with regulatory and customer auditors when necessary

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 inspection, labelling, packing and serialising of products in compliance with all manufacturing SOP’s, Batch Documentation, H&S requirements and cGMP

Responsibility and Accountability

- Responsible for supervising small specialist teams of operators
- Responsible for the continual effective performance of Torbay Pharmaceuticals Packaging operations in order to meet the requirements of the manufacturing schedule
- Responsible for room and line clearance between batches of product within packaging bays, ensuring that the area has been cleaned and all equipment and surrounding work areas are inspected for potential rogue products.
- Ensure compliance with cGMP within the Torbay Pharmaceuticals Packaging area

- Ensure Health and safety regulations are maintained

Policy and Service Responsibility

- Responsible for ensuring that the Packaging facility and pharmaceutical processing equipment are maintained to the standard of cleanliness and sterility required of Torbay Pharmaceuticals and regulatory guidelines and standards (Pharmaceutical cGMP)
- 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 and to supervise Packaging team members in the adherence to activities and processes
- 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 Packaging Specialist or Production & Packaging Manager. Expectation is that basic fault finding will be investigated to root cause and solution and all associated documentation managed
- To actively contribute and lead areas of continuous improvement, to take a lead role in adding value to the process adding efficiency to the organisation of work, ensuring the effective use of resources
- 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 cleaning chemicals requiring the use of personal protective equipment and clothing

Responsibility for Supervision, Leadership and Management

- Supervise the inspection, labelling, packing and serialising of products 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
- Responsible for supervising small specialist teams of operators
- Ensuring that all Packaging team members 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
- All staff must be regularly assessed on their knowledge, skills and behaviour in line with the Trust's Achievement Review (AR). The post holder will make themselves familiar with and abide by Trust policies and procedures
- To perform Packaging team member appraisals as per Trust Policy, to contribute to the setting of team objectives, training requirements and actively manage conflict where necessary

Information Technology and Administrative Duties

- To supervise Packaging team members and to ensure they enter accurately any 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 Packaging Bay lead 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. The Packaging Bay lead is also responsible for the second checking of these processes
- To input into the investigation of corrective action and deviation documents. To accurately enter production details in Q-Pulse (Electronic Quality Management System) and complete directed actions as required
- To participate in validation studies, collect technical data, read/understand and assess technical manuals

PERSON SPECIFICATION

Attributes	Essential	Desirable
Qualifications and training	• Minimum 1-year experience in the Pharmaceutical field or pharmaceutical manufacturing environment • Good general education to 5 GCSE's including English and Maths, Science or equivalent • Evidence of continued professional development • High level of H&S understanding in relation to manufacturing hazards • Basic IT Training • Evidence of formal pharmaceutical GMP courses	• Supervisory Qualification NVQ3 level or equivalent • Six Sigma Green Belt
Knowledge and experience	• Moving and Manual Handling knowledge • Able to show self-motivation and use initiative, recognise when to refer upwards • High level of experience of working within a pharmaceutical or medical device manufacturing facility • Completion of pharmaceutical competencies at NVQ 3 level or equivalent • Experience and a detailed understanding of the regulatory standards related to	• Knowledge of Human Resource polices and guidelines • Experience and knowledge of specialised IT systems such as WinMan, LIMS or Qpulse • Trained to carry out team achievement reviews • Previous Pharmaceutical Manufacturing experience or specialist pharmaceutical packaging knowledge, specialist equipment knowledge, specialist pharmaceutical process knowledge

	manufacturing (Good Manufacturing Practice,) and associated procedures • Experience with computer based (HMI) Pharmaceutical equipment and able to provide training to users • Well-developed IT skills • Experience of writing and working with Standard Operating Procedures • Knowledge of pharmaceutical root cause analysis and investigation techniques • Experience and understanding of the Pharmaceutical Quality Management System, (PQS) • Good time management & organisation skills required to assist the Packaging Supervisor in the department prioritisation of workstreams	• Experience of working within an ISO accredited organisation or regulated environment
Specific Skills	• Able to adapt to and lead change within a team • Able to read, understand and follow written and verbal instructions and perform complex reconciliation calculations • High level of experience of working with Standard Operating Procedures and ability to troubleshoot and resolve issues with specialised pharmaceutical manufacturing equipment • Previous experience of operating and setting up PLC controlled manufacturing equipment • Good communication and interpersonal skills	

	• Effective teamwork and ability to supervise and lead a small team • Involvement in pharmaceutical investigations and the resulting CAPA • Highly developed skills where high levels of accuracy and dexterity is important. Utilising complex pharmaceutical tools and equipment • Knowledge of Home Office Controlled drug requirements	
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 a controlled environment in manufacturing areas • Exposure to disinfectants and cleaning agents within the manufacturing areas • Able to work within a noisy environment	

Physical skills	• Good manual dexterity to perform accurate manipulations and measurements
Physical effort	• 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 • Highly developed skills and concentration where accuracy is important • Good visual acuity for inspection or products • Able to calibrate and maintain complex equipment

Emotional effort	• Ability to work on own and in teams • Able to deal and resolve complaints from staff and other production personnel in relation to service provision
Mental effort	• Able to concentrate on detailed and repetitive work • Able to respond to changes in workload and interruptions for urgent work • Able to remain calm and level headed under pressure • Able to prioritise workload and manage upwards where necessary