

## JOB DESCRIPTION

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<b>Post:</b>	<b>Associate Director of Pharmacy - Production</b>
<b>Band:</b>	<b>8c</b>
<b>Division:</b>	<b>Diagnostics and Therapies</b>
<b>Department:</b>	<b>Pharmacy</b>
<b>Responsible to:</b>	<b>Director of Pharmacy</b>
<b>Responsible for:</b>	<b>Pharmacy Production Service</b>

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### Job purpose

The Pharmacy Production Department manufactures aseptic and non-sterile medicines and investigational medicinal products for supply both within UHBristol and externally.

UHBristol Pharmacy Production Department holds the following Medicines and Healthcare Products Regulatory Agency (MHRA) Licenses;

- Manufacturers License 'Specials'
- Manufacturers Licence 'Investigational Medicinal Products'

Pharmaceutical Manufacturing is a high risk activity and highly regulated, requiring strict adherence to complex and demanding Good Manufacturing Practice (GMP) standards. These standards are continually monitored by regulatory agencies.

To be responsible for the operational and strategic management of the Pharmacy Production Department ensuring that patients receive safe and effective medication through managing and developing the Pharmacy Production department including:-

- Named production manager on the Specials and Investigational medicinal products (MIA(IMP) Manufacturing Licenses (issued by the Medicines and Healthcare products Regulatory Agency (MHRA) held by UHBristol pharmacy.
- Named Accountable Pharmacist for Section 10 Aseptic dispensing activity.
- Providing expert technical and professional support on current Good Manufacturing Practice.
- Responsible for the strategic development of pharmaceutical production services.
- Responsible for managing capacity and expansion and development of current services.
- Responsible for ensuring UHBristol maintains its Specials and IMP licenses to enable pharmaceutical manufacturing and income generation.
- Responsible for ensuring that the pharmaceutical production department meets or exceeds current Medicines and Healthcare products Regulatory Authority (MHRA) and GMP standards.
- Ensuring the pharmacy production department is inspection ready through development and maintenance of effective quality systems.

- Lead the strategic development of pharmacy production services to support the Trust activity including membership of the pharmacy management group
- Be responsible for the development of strategic plans for the production service and management to ensure that services provided are responsive, effective and efficient;
- Be responsible for the delivery of a cost effective service, and delivery of cost improvement plans where appropriate
- Provide professional advice to other healthcare professionals
- Provide specialist expertise in pharmaceutical manufacturing and GMP across the Trust
- Act as a recognised expert on GMP internally and externally including at a regional or national level
- Initiate, co-ordinate/manage and implement research and development activities including, where relevant, sourcing of external funding;
- Provide education and training in GMP at a local, regional, national level as requested.
- Lead service transformation initiatives to ensure correct levels of skillmix, working patterns and staff structure to meet the current and future needs of the department.
- Responsible for maintaining and increasing current levels of income generation and drug savings to support the Pharmacy department and Trust underlying position.
- Act as Trust Pharmacy lead in Intestinal Failure (IF) and Homecare Parenteral Nutrition (HPN) both technically and clinically.
- To develop and support Pharmacy 7 day working, with participation where appropriate to role.

### **Main duties and responsibilities**

To be responsible for the delivery of an appropriate pharmacy production service in pharmacy to ensure that patients receive safe and effective medicines supplied by UHBristol.

To be a member of the pharmacy management team.

**Key Relationships:** Director of Pharmacy  
 Pharmacy managers  
 Divisional management  
 Trust Senior Finance  
 Technical services managers within the South West region  
 Medicines Healthcare products Regulatory Agency personnel  
 UHBristol estates management  
 UHBristol clinicians

### **Overview of Responsibilities:**

1. To manage and develop the pharmacy production department such that an appropriate service is provided by pharmacy to the trust and external customers.
2. To communicate effectively within the division and at trust level to ensure that a QA approach is applied to the preparation, manufacture, distribution and use of medicinal products.

3. To be the named production manager on the Specials and MIA(IMP) Manufacturing Licences held by UHBristol pharmacy.
4. To generate and increase levels of income generation and drug savings to support the Trust
5. To manage staff within the department to ensure that a culture of respecting others, embracing change and meeting and exceeding current GMP standards is achieved.
6. To be a member of the pharmacy management group.
7. To develop own skills and knowledge and contribute to the development of others within the department and trust.

### **Statutory Professional Accountabilities**

- Ensure that the pharmacy production units comply with the Human Medicines Regulations 2012 and Medicines Act 1968.
- Ensure that the requirements of the Medicines and Healthcare Products Regulatory Agency (MHRA) in respect of the EC Clinical Trials Directives are complied with in relation to the manufacture of investigational medicinal products and clinical trials.
- Ensure that the requirements of the Medicines and Healthcare Products Regulatory Agency (MHRA) in respect of EC Good Manufacturing and Distribution Practice are complied with such that the Trust retains all the accreditation it requires for its pharmacy production manufacturing facility
- Ensure that the pharmacy production unit section 10 aseptic dispensing complies with the requirements of the Quality Assurance of Aseptic Preparation Services standards
- Ensure (in collaboration with relevant personnel) that the pharmacy services comply with new directives and other statutory requirements as they arise.
- Eligible and accepted to be named as Head of Production on the manufacturing licenses by the MHRA.

### **Strategic Management**

- Interpret broad professional policies and NHS guidance in collaboration with the other pharmacy technical services managers to lead the vision for pharmacy production for the Trust
- Interpret legislation and associated guidance on pharmacy manufacturing and aseptic dispensing services for the Trust and resolve any conflicting regulatory issues to ensure good clinical practice and patient care
- Support the Divisional Management in submitting service development proposals for pharmacy production and to be responsible for the development, policy implementation and future planning of pharmacy production services
- Lead the planning and development of future pharmacy production services, facilities and services as required
- In accordance with overall professional guidance and NHS policy ensure compliance with clinical governance standards in pharmacy production service provision
- Provide professional advice and support on strategic development of pharmacy production services within and outside the Trust.

### **Business planning and contracting**

- Manage, develop and implement service level agreements, policies and contracts that relate to the pharmacy production service including those that impact beyond the organisation
- Formulate long term strategic plans relating to Trust pharmacy production services and policies
- Contribute to the development of the business plan for pharmacy technical services in consultation with the Divisional Managers and Directors

### **Financial Management**

- Be responsible for all expenditure for the pharmacy production service to ensure that it remains within current resources
- Maintain and exceed current levels of income generation activity through external sales.
- Maintain and exceed current levels of drugs savings activities provided by the pharmacy production department, contributing to new and existing cost improvement programme (CIP) schemes and supporting the department underlying financial position.
- Be responsible for procurement of all equipment and materials for the service in accordance with good management practice, financial probity and the Trust's Standing Financial Instructions
- Identify possible cost reduction initiatives for pharmacy production in liaison with Divisional Managers and Directors
- Identify to the Divisional Manager cost pressures within pharmacy production and identify corrective actions

### **Operational Management and Patient Services: Clinical and scientific**

- Act as the Trust's expert advisor on pharmacy production and GMP and provide professional and scientific leadership to appropriate committees, working parties and project teams
- Actively manage the pharmacy production department to ensure the provision of a comprehensive service
- Work with key stakeholders to market the pharmacy production service and raise a positive internal and external profile
- Ensure delivery of a pharmacy production service to comply with Trust policies and national standards and licensing with the Medicines and Healthcare products Regulatory Agency requirements
- Ensure that clear appropriate procedures are in place for the pharmacy production service
- Manage and supervise the pharmaceutical production of medicinal products made under the specials and IMP licenses for clinical use in patients
- Manage and supervise the pharmaceutical production of medicinal products dispensed under S10 exemption as the Accountable Pharmacist for individual clinical use in patients

- Lead on the procurement and validation of equipment and consumables used in the pharmacy production unit.
- Contribute actively to regional and national committees and ensure dissemination of relevant information
- Collaborate with other national pharmacy technical services staff to discuss, promote and exchange information around GMP and production processes used to ensure the safe, effective and reliable manufacture, supply and use of specials and aseptically prepared medicinal products.

### **Research & Development and Teaching**

- Be responsible for the safe and effective manufacture and aseptic dispensing of IMPs within the pharmacy production department to support research and development.
- To provide advice on IMPs and investigational products to investigators, pharmacy and trials teams to ensure compliance with legislation for both MIA (IMP) activity and studies conducted within UHB under section 10 (preparation)
- Provide education and training in pharmacy production, both within the Trust and externally, to all grades of medical and other healthcare and science professionals at all levels up to advances specialist postgraduate as required
- Foster a culture of life-long learning to include provision for postgraduate and post-registration training , continuing professional education/development and vocational training of staff

### **Human Resource Management**

- Have managerial responsibility for professional, technical and other staff within pharmacy production service.
- Instigate and be responsible for performance and conduct management of these staff members
- Develop a culture that embraces change in line with core Trust values.
- Lead service transformation initiatives to ensure correct levels of skill mix, working patterns and staff structure to meet the current and future needs of the department.
- Report any deficits to the Divisional management with proposals for corrective action
- Ensure that pharmacy production staff have adequate supervision/mentorship and manage any poor performance actively within the Trust's policies and procedures framework and maintain a training log that complies with MHRA requirements
- Ensure that Trust policies and procedures are adhered to and appropriate actions taken as required
- Recruit develop and motivate pharmacy production staff to ensure that they can do and perform well in their job, contribute towards improvements to the service and achievement of the pharmacy business plan/Trust corporate objectives
- Ensure new improved ways of working in pharmacy production and that these support service objectives
- Ensure that all pharmacy staff production attend mandatory training, have an annual performance review and ensure that training needs/continual professional development are progressed through a personal development plan

### **Quality**

- Be responsible for pharmacy production service provision and management, including associated controls assurance standards and healthcare standards with clinical governance of this service and advise pharmacy Board as appropriate
- Develop pharmacy production services to pro-actively influence safe and cost effective pharmacy technical services
- Implement and monitor national initiatives and directives
- Contribute actively to the development of local, regional and National pharmacy technical services standards and policies
- Attend relevant local, regional, national meetings and represent local, national bodies as requested
- Ensure that practice is evidence based, shared and, service and standards focussed.
- Ensure that user views are accounted for in the planning and implementation of service delivery
- Ensure that complaints are managed within Trust guidelines
- Collaborate with local technical services units and Regional Quality Control staff to ensure that operating standards and facilities are maintained in accordance with the Manufacturer's 'Specials' Licence and Wholesale Dealers License as required by the MHRA and regional QA.
- Ensure that the relevant manager is made aware of any circumstances that would, or may, mitigate against safe standards of practice and advise on corrective action
- Working with the director of pharmacy and the other pharmacy managers to develop, approve and maintain a proactive state of GMP control required for all medicinal products manufactured, prepared, aseptically dispensed or supplied by UHBristol pharmacy production unit.
- Ensure that all legal, and professional requirements are met within Pharmacy Production.
- Ensure an effective internal audit programme is maintained to provide appropriate assurance.

### **Clinical Governance including health and safety and Clinical Risk**

- Undertake professional audit both for and on behalf of the Trust and for national bodies as time permits
- Be responsible for ensuring that the provisions of the Health and Safety at Work Act and Control of Substances Hazardous to Health are carried out within the pharmacy production and ensure that staff are appropriately trained/instructed in their responsibilities and provided with the necessary protective equipment to carry out their function
- Be responsible for the local implementation, development and maintenance of the national Error and Near Miss reporting Scheme ensuring appropriate interpretation, monitoring and reporting to national authorities and advising on patient safety as appropriate
- Be responsible for the investigation and reporting of defective medicinal products to the manufacturer and MHRA.
- Be responsible for decisions on the procurement of materials to ensure compliance with the Medicines Act (1968)



### **Personal Development**

- The post-holder is expected to keep professionally and scientifically updates at all times and to be aware of Trust-wide issues and trends
- The post-holder will have a personal professional development plan and identify training needs as required
- To have responsibility for ensuring a personal commitment to maintaining a high level of service to patients by continual development of practice in the light of research evidence and by audit against professionally relevant standards
- Individual staff have a major role in suggesting and implementing improvement to services and in exercising professional responsibility for both themselves and their peers with an open 'no-blame' culture

### **General Information:**

#### **The Trust's Values**

University Hospitals Bristol NHS Foundation Trust is committed to provide patient care, education and research of the highest quality. In delivering this ambition, we will be guided by the following values:

- Respecting Everyone
- Embracing Change
- Recognising Success
- Working Together

The Trust expects all staff to work in ways which reflect these values and behaviours at all times as follows:

#### *Respecting Everyone*

- We treat everyone with respect and as an individual
- We put patients first and will deliver the best care possible
- We are always helpful and polite
- We have a can do attitude in everything we do

#### *Embracing Change*

- We will encourage all change that helps us make the best use of our resources
- We learn from our experiences and research new ideas
- We look to constantly improve everything we do

#### *Recognising Success*

- We say thank you and recognise everyone's contribution
- We take pride in delivering the best quality in everything we do
- We share and learn from each other
- We encourage new ideas that help us to be the best we can

### Working Together

- We work together to achieve what is best for our patients
- We support each other across the whole Trust
- We listen to everyone
- We work in partnership

In line with the NHS Constitution, all healthcare providers, registered medical practitioners, nurses and other registered health professionals have a duty of openness, honesty and transparency (candour).

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### Transforming Care

Transforming Care challenges everyone at University Hospitals Bristol to play their part in supporting quality changes and improvements in their work place, building efficient care systems critical for our patients and their families, both today and in the future.

The Trust's mission is to deliver clinical services, teaching and research of the highest quality. Our vision is to provide first class technical care, with humanity, compassion and sensitivity to the needs of each patient.

*Delivering best care, Improving patient flow, Delivering best value,  
Renewing our hospitals, Building capability, Leading in partnership.*

These are the core elements essential to Transforming Care. Delivering sustainable healthcare services to our patients, which are effective, efficient and driven by excellence, is at the heart of our organisation.

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### Equal Opportunities

The Trust is committed to eliminating unlawful discrimination and promoting equality of opportunity. All staff have a personal responsibility to contribute towards an inclusive and supportive environment for patients, carers, visitors and other colleagues from all the equality strands (race, gender, age, sexual orientation, religion, disability).

Staff have a personal responsibility to:

- Ensure their behaviour is not discriminatory
  - Does not cause offence
  - To challenge the inappropriate behaviours of others
  - Adhere to the Trust's values, including 'Respecting Everyone', as well as the Staff Conduct Policy and the Equal Opportunities policy
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### Health and Safety

Under the provisions contained in the Health and Safety at Work Act 1974, it is the duty of every employee to:

- Take reasonable care of themselves and for others at work
- To co-operate with the Trust as far as is necessary to enable them to carry out their legal duty



- Not to intentionally or recklessly interfere with anything provided including personal protective equipment for Health and Safety or welfare at work.

*Senior Management* is responsible for the implementation throughout the Trust of suitable arrangements to ensure the health, safety and welfare of all employees at work and the health and safety of other persons who may be affected by their activities. Where health and safety matters cannot be resolved at Senior Management level the appropriate Executive Director must be notified.

*Line Managers* are responsible for the health and safety management of all activities, areas and staff under their control. This includes responsibility for ensuring risk assessments are completed and implementation of suitable and sufficient control measures put in place. Health and safety issues are dealt with at the lowest level of management practicable. Where health and safety matters cannot be resolved at a particular management level the appropriate Senior Manager must be notified.

Everyone has a responsibility for contributing to the reduction of infections.

**University Hospitals NHS Foundation Trust is 'Smoke Free'. Smoking or tobacco is not permitted on any of our hospitals sites.**

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### **Safeguarding Children and Vulnerable Adults**

University Hospitals Bristol is committed to safeguarding and promoting the welfare of all children, young people and vulnerable adults, and as such expects all staff and volunteers to share this commitment.

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### **Quality and Clinical Governance**

Quality in the NHS has three core dimensions: Patient Safety, Patient Experience and Clinical Effectiveness.

Clinical Governance is about the systems, processes and behaviours to ensure that high quality services are provided to patients. Every member of staff has a role to play in striving for excellence: it is important that everyone is aware of and follows policies and procedures that govern their work; and if something goes wrong, everyone has an obligation to report it so lessons can be learned from mistakes, incidents and complaints.

If any member of staff has concerns on any clinical governance matters, they should raise them with their line manager, professional adviser, or a more senior member of management. Reference should be made to the Trust's guidance on Raising Concerns about provision of patient care.

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### **Information Governance**

It is the responsibility of all staff to respect the confidentiality of patients and staff, as specified in the Caldicott Principles, Data Protection Act and the Human Rights Act. It is the duty of every employee to:

- Only access person identifiable information as required in the execution of their duties.
- Disclose information appropriately, in line with the Data Protection Act 1998.

- To ensure good quality data by recording, promptly and accurately, clinical and non-clinical information within agreed timescales to PAS, the health record or the appropriate clinical or non-clinical information system
- Always trace patient notes on the Patient Administration System
- Maintain the confidentiality of their password / username and if in possession of a 'Smartcard' abiding by the terms and conditions of its use.

## Workplace Health and Wellbeing

The Trust Workplace Health and Wellbeing Framework applies to all employees, students and volunteers who are encouraged to take responsibility for their individual health and wellbeing and to promote the wellbeing of colleagues. Line managers must recognise the importance of health and wellbeing and take it into account when planning tasks and designing jobs.

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**Job Description completed by: Ross Walker (Pharmacy Manager, Production)**

**Managers name: Jon Standing (Director of Pharmacy)**

**Date: June 2018**

All job descriptions are subject to review. Post holders are expected to be flexible and be prepared to carry out any similar or related duties which do not fall within the work outlined. The Line Manager, in consultation with the post holder will undertake any review.

The NHS Knowledge and Skills Framework (the NHS KSF) defines and describes the knowledge and skills which NHS staff need to apply in their work in order to deliver quality services. It provides a consistent, comprehensive and explicit framework on which to base review and development for all staff. Closely aligned with this job description is a KSF profile supporting the effective learning and development of the post holder in a variety of ways.

## PERSON SPECIFICATION

### Pharmacy Manager, Quality Assurance

Education and Qualifications		Essential	Desirable	To be evidenced by*
Q1	Registered Pharmacist	✓		A&I
Q2	Eligible to be named as Head of Production as defined by the Medicines and Healthcare products Regulatory Agency	✓		A&I
Q3	Qualified Person		✓	A&I
Q4	Postgraduate qualification in QA/GMP	✓		A&I
Q5	Postgraduate management qualification		✓	A&I
Q6	Six Sigma qualification		✓	A&I
Knowledge and Experience		Essential	Desirable	To be evidenced by*
E1	Expert knowledge and application of Good Manufacturing Practice	✓		A&I&P
E2	Expert knowledge and application of current legislation in relation to the manufacture and supply of medicinal products (incl clinical trial material)	✓		A&I
E3	Experience in manufacturing pharmaceuticals made under a 'Specials' and IMP Manufacturing license	✓		A&I&P
E4	Experience in managing a hospital pharmacy technical services department	✓		A&I&P
E5	Experience in leading regulatory (MHRA) inspections		✓	A&I
E6	Extensive experience in all aspects of pharmacy technical services including aseptically prepared products such as TPN, CIVAS or cytotoxics, as well as non-sterile items such as creams, ointments, liquids and over-labelling.	✓		A&I
E7	Experience managing, training, and motivating staff.	✓		A&I

<b>E8</b>	Experience in successfully dealing with difficult situations.	✓		A&I
<b>E9</b>	Experience in clinical nutrition and managing intestinal failure patients		✓	A&I
<b>E10</b>	Knowledge and application of root cause analysis tools	✓		A&I
<b>E11</b>	Knowledge and application of COSHH and health and safety		✓	A&I
<b>E12</b>	Proven track record in developing income generation to support service growth and development.		✓	A&I&P
<b>E13</b>	Clinical and technical expertise in Intestinal Failure and HPN		✓	A&I
<b>E14</b>	Experience in medicines procurement within specialist area and participation in regional and national purchasing contracts		✓	A&I
<b>E15</b>	Nationally recognised experience in technical services		✓	A&I
<b>E17</b>	Experience in implementing and qualifying automation and robotics into a technical services unit		✓	A&I
<b>E18</b>	Current GCP training evidenced	✓		A&I
<b>E19</b>	Experience of managing NHS Trust Capital projects		✓	A&I
<b>E20</b>	Experience in overseeing the design, build and qualification of a new Production facility		✓	A&I

Skills and Abilities	Essential	Desirable	To be evidenced by*
<b>S1</b> Excellent communication and interpersonal skills	✓		A&I&P
<b>S2</b> Ability to plan personal and departmental workload	✓		A&I
<b>S3</b> Ability to develop a service	✓		A&I
<b>S4</b> Ability to be flexible and maintain objectivity when under pressure	✓		A&I
<b>S5</b> Ability to use word, excel and Datix	✓		A&I
<b>S6</b> Able to use initiative	✓		A&I
<b>S7</b> Self and team motivator	✓		A&I
<b>S8</b> Able to complete projects and to deadlines	✓		A&I
Behaviours and Values	Essential	Desirable	To be Evidenced by*
<b>B1</b> – Respecting Everyone	✓		I
<b>B2</b> – Embracing Change	✓		I
<b>B3</b> – Recognising Success	✓		I
<b>B4</b> – Working Together	✓		I
Public Sector Language Competency			
Be able to speak fluent English to an appropriate standard.	✓		I&P

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**A = Application Form**  
**I = Interview**  
**P = Presentation**  
**T = Test**