University Hospitals Bristol and Weston NHS Foundation Trust

Freedom of Information Request **Ref: 23-342**

1 June 2023

By Email

Dear Sir/Madam

Thank you for your request for information under the Freedom of Information Act 2000. The Trust's response is as follows:

- We can confirm that we do hold the information you are requesting

Name of Hospital/Trust:
University Hospitals Bristol and Weston NHS Foundation Trust

Department:
Pharmacy Technical Services

Job title: Associate Director of Pharmacy

Pharmacy contact information:
Pharmacy Department
Level 4, King Edward Building
Bristol Royal Infirmary
Marlborough Street
Bristol
BS2 8HW

A) Is compounding outsourced to an external provider in your region/city?
Yes – go to question A1) Yes
No – go to question B)

A1) What is the name of the external provider doing compounding preparation?
Bath ASU
Braun
Baxter

A2) What is the location of the external provider doing chemotherapy compounding?
Corsham, Wiltshire

B) What manufacturing/compounding work is currently being performed by pharmacists at your Hospital/Trust?
Release of various products manufactured under MS License and section 10 exemption

C) What level/grade of cleanroom do you run and how many of them do you have?
Grade B cleanroom x 6
Grade C cleanroom x 8
Grade D cleanroom x 3
Excluding change rooms

C1) What size of unit do you currently run (square footage)?
122.22sqm; 287.19 sqm; 323.09 sqm

C2) What is the number of staff in this unit?
80

C3) Do you currently run at your full capacity?
Yes Yes
No

C4) If no, what % of capacity you're currently running?
Not applicable

D) Do you provide services to any other hospital pharmacies?
Yes Yes
No

D1). If yes, please specify which other hospitals you service:
It varies, service is available to hospitals across the UK

E). How many days per week do you do compounding work? Please circle the relevant.
No of days/week 1 2 3 4 5 6 7
Five

F) Approximately, how many compounding's do you do each day in your facility?
Number of compounding's per day:
It varies

G) Approximately, how many pairs of gloves do you use per day for pharmacy compounding work in your facility? (including both under- and over-gloves)
Number of under-gloves per day (pairs):123
Number of over-gloves per day (pairs): 75

G1) What proportion (%) of these are sterile gloves?
Approximately 70%

G2) Who is your current gloves provider(s)?
NHS Supplies – Helapet – Micronclean
Sterile exam gloves (Connect 2 Cleanrooms and VWR)
Non-sterile exam gloves (Micronclean and Connect 2 Cleanrooms)
Sterile PPE (Personal Protective Equipment) gloves (Handsafe, Maxter, Mercator and IKMI)
Sterile Surgical gloves (medical device) Not applicable

G3) What types of gloves do you use during compounding? Please put % for all relevant options.

Sterile exam gloves 3%
Non-sterile exam gloves 70%
Sterile PPE (Personal Protective Equipment) gloves 27%
Sterile Surgical gloves (medical device) Not applicable

G4) What material are the majority of the sterile PPE/surgical gloves made of when used in pharmacy? Please put % for all relevant options.
Nitrile It varies between 5% to 70%
Polychloroprene 2%
Polyisoprene Not applicable
Natural rubber latex It varies between 15% to 95%
Other, please state: CoPolymer 10%

G5) What material is the packaging of your sterile gloves?
Plastic Yes
Paper Yes

H) How do you currently purchase your hospital pharmacy gloves?
NHS SC Nitrile gloves Yes
Directly from supplier Sterile and non-sterile gloves Yes
3rd Party provider / distributor (eg. Bunzl) Yes

Other

I) How frequently do you place orders and is this your preferred frequency?
NHS Supplies - Weekly
Helapet – Monthly
Micronclean – Bi-Monthly
Yes; frequency depends on usage

J) What local/national guidelines/accreditation/regulations/governing bodies do you

adhere to?
MHRA/GMP
CQC
Assurance of aseptic preparation of medicines

K) When validating a new sterile PPE/surgical glove, do you have a specific protocol/evaluation to follow?
Yes Yes
No

L) Who is involved in the validation process and what criteria do you follow (please indicate position/role, process and time frames)?
Suitably trained staff (QA, technician, Production manager, senior tech)
Process: Follow GMP i.e. log on QMS, formally assess change, validate the process/supplier, check specification/supplier and sterility
Time frames: It depends on the type of validation work/PPE, the supplier, complexity of the process, can take as little as few hours to a month or more.

M) Which of these requirements apply for a sterile PPE/surgical glove in your facility? (please tick all relevant options):
Maximum liquid particle count level
Specific outer packaging requirements
Plastic inner-wrap
Be able to stay on isolator glove port for certain amount of time
Withstand certain amount of alcohol disinfections
Chemicals / chemotherapy agents breakthrough time results
Certified for use for a certain clean room grade
We have other requirements (add them….)
Powder free ✓
Appropriate toughness/flexibility ✓
Integral ✓
No requirements are specified

N) Which of these features of a sterile PPE/surgical glove would add value in your current practice? Please tick all relevant options.
Good fit, feel and comfort ✓
Durability ✓
Easy to open sterile barrier ✓
Double gloving ✓
Puncture detection ✓
Anti-slip cuff (stays on gown) ✓
Low endotoxin level ✓
Other features add value

O) How often are gloves changed by operators working with compounding? Please state in relevant minutes.
Over-gloves Depends on session length up to 4 hours or if breach or spill
Under-gloves Depends on session length up to 4 hourss or if breach or spill

P) What safety guidelines/recommendations does the Hospital / Trust currently follow?
Regulations set out in “Quality Assurance of Aseptic Preparation Services” Royal Pharmaceutical Society, A.M. Beaney (2016); Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2022
GMP
Health and Safety at Work Act
GMO (Contained Use) Regulations

This concludes our response. We trust that you find this helpful, but please do not hesitate to contact us directly if we can be of any further assistance.

If, after that, you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of receipt of the response to your original letter and should be addressed to:

Data Protection Officer
University Hospitals Bristol and Weston NHS Foundation Trust
Trust Headquarters
Marlborough Street
Bristol
BS1 3NU

Please remember to quote the reference number above in any future communications.

If you are not content with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision. The Information Commissioner can be contacted at: Information Commissioner’s Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF

Publication

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To view the Freedom of Information Act in full please click here.

Yours sincerely

Freedom of Information Team
University Hospitals Bristol and Weston NHS Foundation Trust