Premises and Equipment

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Conflict 0f interest: Nothing to disclose

Overview

QCNW
Design and validation steps
Standards
Key design requirements
Examples of layouts

Quality Control North West (www.qcnw.nhs.uk)

Provides Pharmaceutical Quality Assurance and Quality Control Services across North West England
Population approx 7.5m
33 Acute General Hospitals
12 Aseptic Preparation Units
19 Licensed Manufacturing Units
88 Pharmaceutical Isolators
35 Laminar flow cabinets

Quality Control North West (www.qcnw.nhs.uk)

Liverpool, Stockport, and Preston
3 Divisions:
Research and Scientific Services
Good Practice (GxP)
Medicines Management

Design and Validation Steps

User Requirement Specification (URS)
Functional Design Specification (FDS)
Design Qualification (DQ)
Installation Qualification (IQ)
Operational Qualification (OQ)
Performance Qualification (PQ)

User Requirement Specification (URS)

The URS is used to inform the potential service providers of the requirements of the client and is used to generate the tender documentation.

Functional Design Specification (FDS)

Supplied by the service provider in response to the tender and contains the detail of what can be provided by the service provider. This should be the same as the URS, however, some parts of the URS may not be achievable. Negotiations between the client and the service provider should take place at this stage to ensure that the final design specification is fit for purpose.

Design Qualification (DQ)

The documented verification that the proposed design of the facilities, systems and equipment is suitable for the intended purpose.

Installation Qualification (IQ)

The documented verification that the facilities, systems and equipment, as installed or modified, comply with the approved design and the manufacturer's recommendations.

Operational Qualification (OQ)

The documented verification that the facilities, systems and equipment, as installed or modified, perform as intended throughout the anticipated operating ranges.

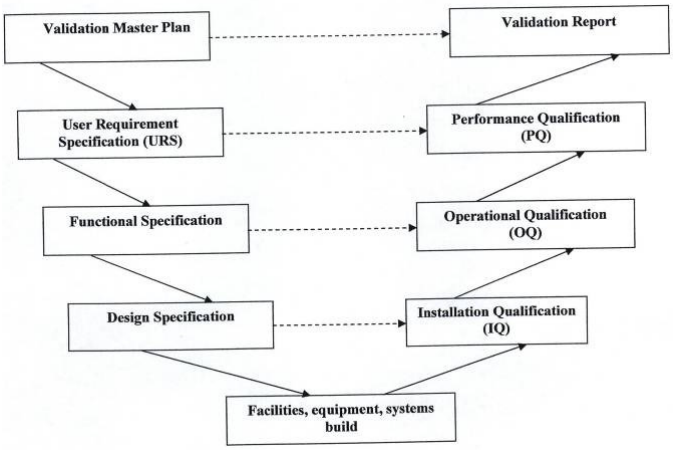
Operational qualification should follow installation qualification and should permit a formal 'release' of the facility, system or equipment.

Performance Qualification (PQ)

The documented verification that the facilities, systems and equipment, as connected together, can perform effectively and reproducibly, based on the approved process method and specification.

Performance qualification should follow successful completion of installation qualification and operational qualification. In some cases it may be appropriate to perform this stage in conjunction with operational qualification.

The V Model (fishbone diagram)



Documentation

Validation Committee / Validation Master Plan	Documents - initial	Responsibility
	User Requirement Specification (URS)	Contractor
	Functional Design Specification (FDS)	
	Drawings/elevations	
	Documents - Pre handover	
	Design Qualification (DQ)	
	Installation Qualification (IQ)	
	Operational Qualification (OQ)	
	Documents - Post handover	Hospital
	Performance Qualification (PQ)	
	Validation History File	

Standards

Handbook of Extemporaneous Preparation. Jackson and Lowey. 2010. ISBN 978-0-85369-901-9

EU Guide to Good Manufacturing Practice. 2007. ISBN 978-0-85369-719-0

Quality Assurance of Aseptic Preparation Services. 4th edition. 2006. ISBN 0-85369-615-2

Pharmaceutical Isolators. 2004. ISBN 0-85369-573-3

UK Health Building Note 14-01. 2008. ISBN 978-0-11-322795-2

EN ISO 14644 (1999)
EN ISO 12469:2000 (Safety cabinets)

Key Design Fundamentals

Compliance with GMP and environmental standards

Critical zone grade A in grade B background

No difference between licensed and unlicensed

Sufficient space (Min 50 sq m per critical zone)

Segregation of activities and products

Facilitation of checking at critical stages

Unidirectional work flow

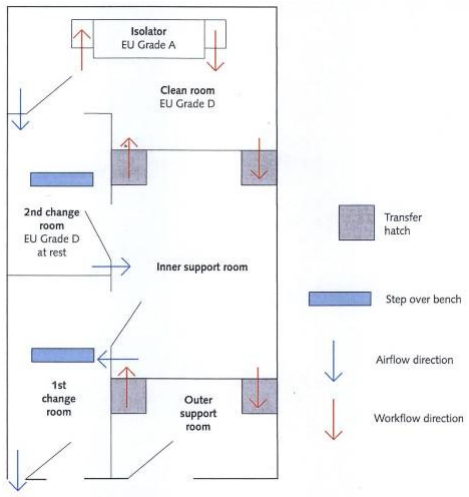
Dedicated personnel entry and exit facilities

Separate dedicated goods entry and exit facilities

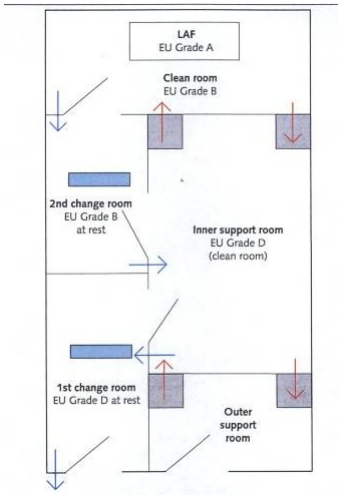
Pharmaceutical clean room fabric & construction

Examples of layouts

Isolator suite



Laminar Flow Cabinet suite



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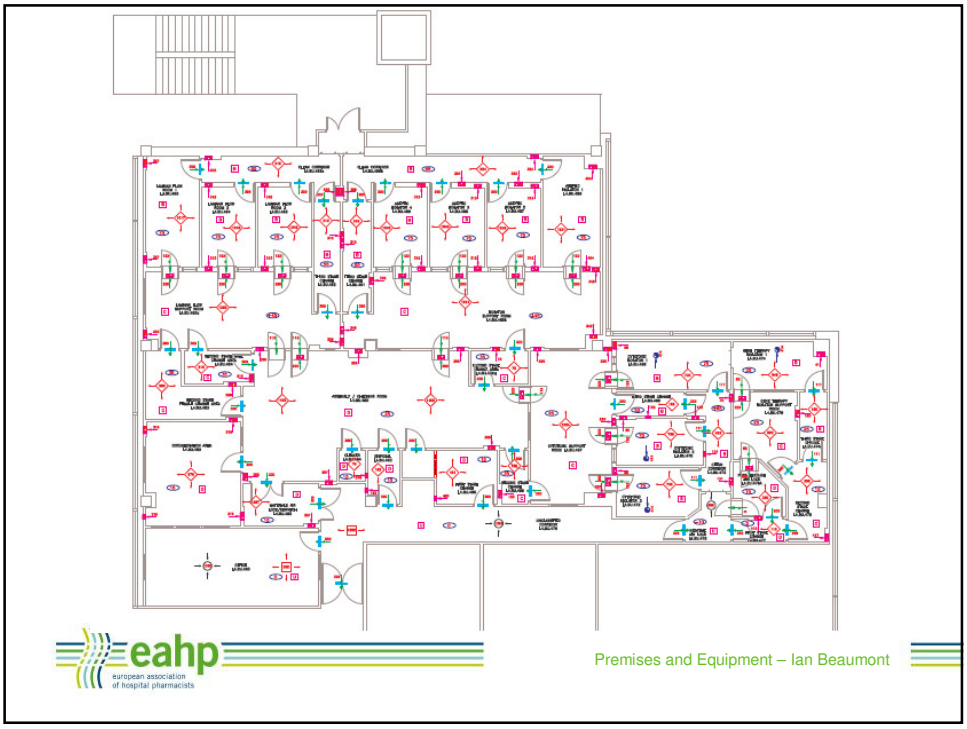

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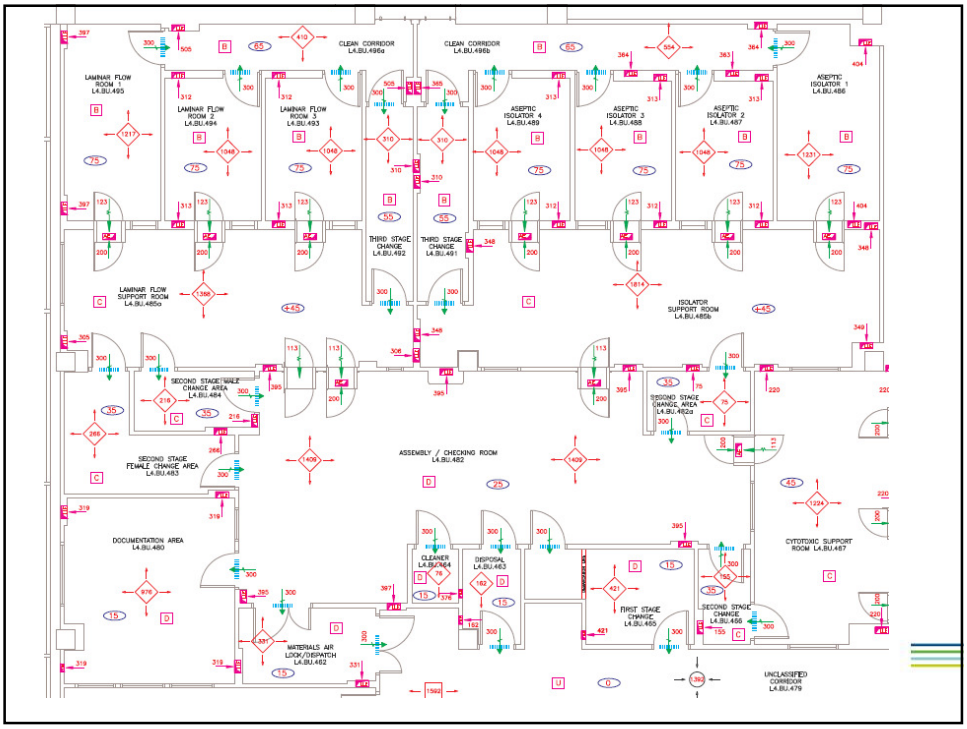

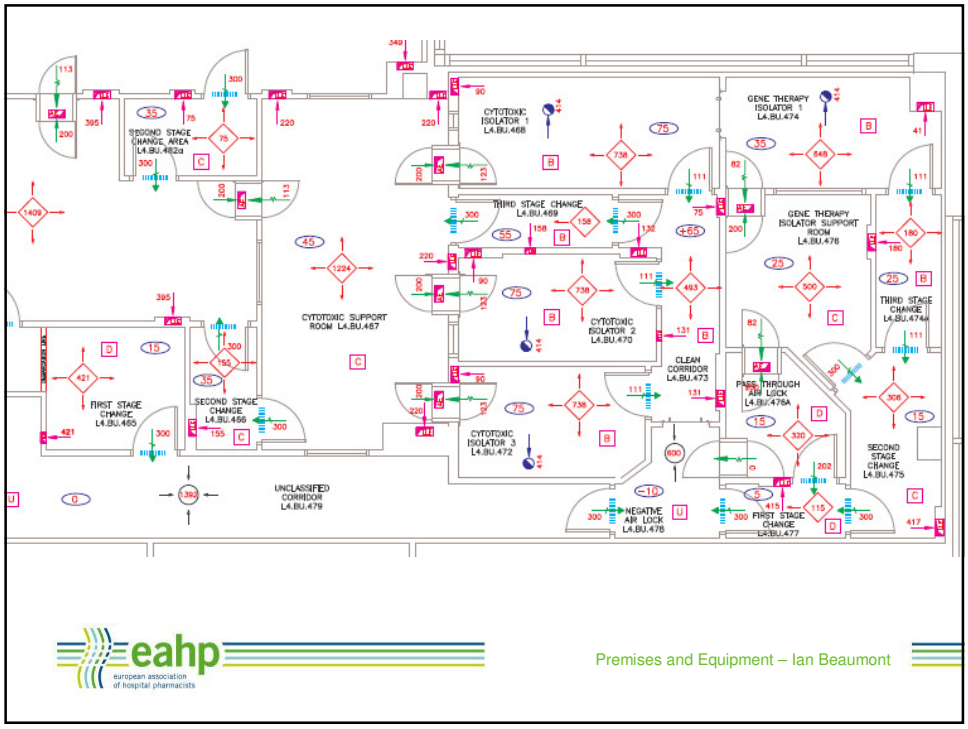

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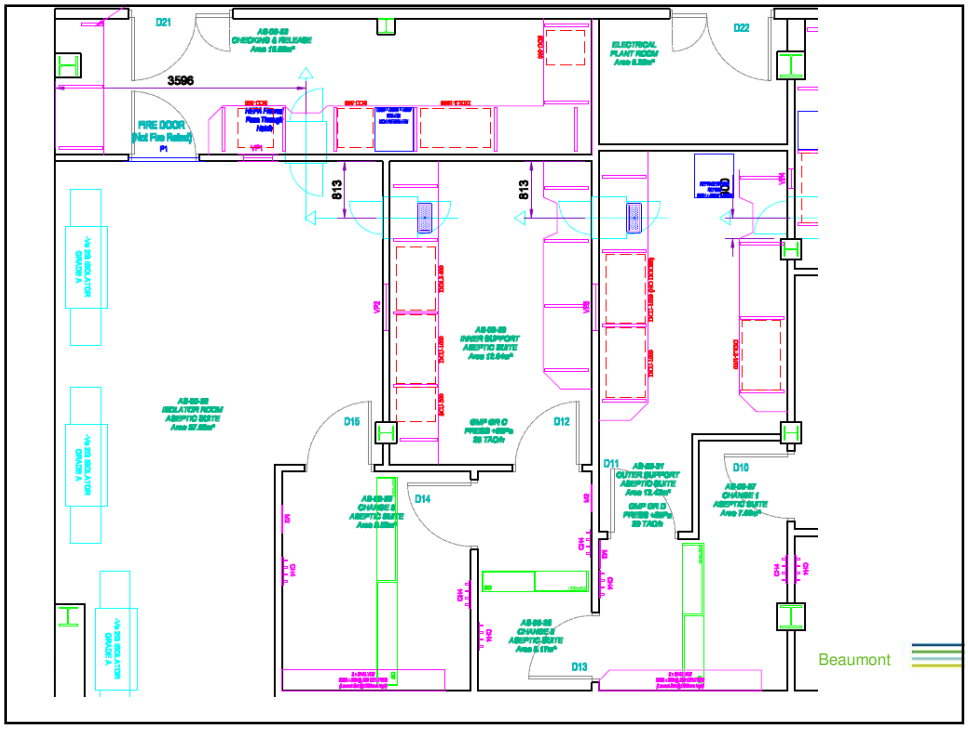

Beaumont

Good design principles - general

- Not an exhaustive list of features
- No sinks & facility situated as far away as possible from toilets (consider what is on the floor above)
- Three stages of change
- Two support areas (inner and outer)
- Separate documentation room
- Separate checking area
- Vision panels
- Continuous particle monitoring
- Vapourised Hydrogen Peroxide (VHP)
- Independent facilities for chemotherapy

Good design principles – Air Handling Unit (AHU)

- Not an exhaustive list of features
- Plant located as close as possible to the facility
- Air supplied through ceiling mounted terminal HEPA filters
- Air extracted by low level return extract ducts
- 100% fresh air for chemotherapy and gene therapy
- 80% re-circulated and 20% fresh air for aseptic services
- Ductwork fitted with ports to allow introduction of aerosol for filter integrity test and upstream measurement ports fitted to all filter housings
- Filter rating at least H14

Good design principles - finishes

Vinyl

No suspended ceilings

Doors

- Easy to clean hinges and door closers
- Single swing
- Interlocked

Hatches

- Interlocked
- Ventilated
- 316L stainless steel
- Separate “in” and “out” hatches
- Flush fitted in room of highest grade

Good design principles - fixtures

Benching

- Not in isolator/LAFC rooms
- Coved to the wall
- Supported appropriately

Intercom

- Flush fitting
- Sited appropriately

Step-over barriers

- Stainless steel and moveable

Shelving

- Fixed or with appropriate brackets (easy to clean)

Mirrors

- In change rooms (clean side)

Coat hooks

- In change rooms

Facilities for products for short term use (max 24hrs) – (Satellite Units)

Appendix 4 of QA of Aseptic Services 4th edition

Isolators – defined microbiological limits

LFCs – compliance with standards

Conclusion

Have a good design – know what you want and design for the future

Be specific and have the right level of detail in URS/FDS

Ensure that essential design criteria have not been changed at any stage

Don't assume anything!

Set up a Validation Committee

- Have the right members
- Generate a VMP as soon as possible
- Have key documents approved by the committee

Meet regularly

Follow the detail in the VMP

Visit site regularly

Ask to see samples of things as appropriate