

Qualification Engineers Job Description



Job Title: Qualification Engineer
Report to: Senior Process Engineer
Business: FFDB UK
Location: Billingham - Teesside

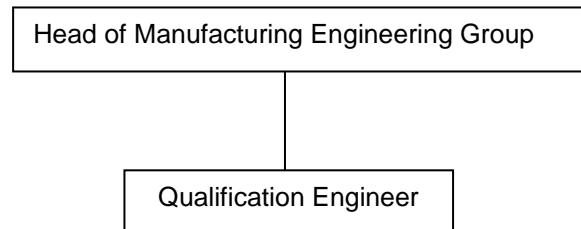
PURPOSE OF JOB

- Perform and plan activities to maintain the qualification status of manufacturing systems.
- Project manage delivery of asset support projects
- Provide System Ownership to manufacturing operations through implementation of best practice operating methods

DIMENSIONS

Number of projects	12-24 /year
Size of projects:	Up to £0.1m
Project Duration:	0.2 – 3 months
Capital value of plants:	£25m

ORGANISATION CHART



PRINCIPAL ACCOUNTABILITIES

1. Schedule, plan and maintain qualified status for GMP utilities across all manufacturing assets.
2. Ensure best practice operating methods are deployed by providing System Ownership
3. Ensure permanent inspection readiness for GMP utilities across all manufacturing assets.
4. Deliver improvements to GMP utility systems through the execution of improvement plans, utilising knowledge of process performance and risks.
5. Resolve operational problems such as deviations/ QIPs/ CAPAs by acting as System Owner
6. Act (or deputise) as VSP Owner for direct impact equipment and utilities on site.
7. Maintain System Records which effectively capture and convey corporate knowledge of site GMP utility systems. Write and issue operating philosophies which deliver the required availability of site services.

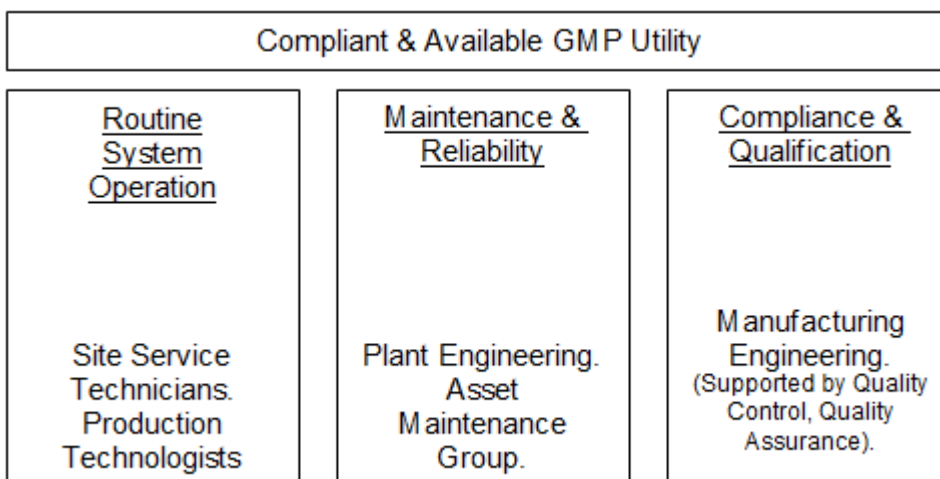
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8. Interface with internal or external technical experts and peers to maintain a broad knowledge of the technology and regulatory issues which impact on GMP utilities.
9. Promote the Manufacturing Engineering Group's purpose, competencies and activities to the FFDB community.

KEY COMPETENCIES

Results Orientation	Concern for Impact
Will discern and focus on key objectives to achieve effective outcomes.	Anticipating and responds to the needs and concerns of others including customers
Sets and routinely reviews specific and measurable objectives for self and others	Takes actions to ensure objectives can be effectively delivered through others including cross functional delivery
Clear communication of status and results	Values and preserves relationships across functions
Organises and brings together resources in support of objectives	

SPECIAL FEATURES



1. The job holder will be required to work flexible hours to manage peak work demands. They are not expected to work on demand.
2. The job holder will be required to work in a cGMP environment.
3. The job holder will consult with the line management over major technical issues and work planning but otherwise must be capable of operating with minimum supervision.
4. This role delivers qualified operational manufacturing facilities to meet the required manufacturing plans. The essence of the role is to provide and execute a well planned validation schedule in alignment with the S&OP system.
5. Given the high degree of interaction with other disciplines within the organisation the individual must have excellent interpersonal skills which will enable him/her to communicate effectively with other functions.
6. Demonstrable experience and understanding of the regulatory requirements for validation of pharmaceutical facilities and equipment is required.

Accepted by(sign)(print) Date.....

Agreed by(sign)(print) Date.....