FUJIFILM

Diosynth biotechnologies

Job Description

Job Title:	CSV Senior Engineer
Job Holder:	
Reports To:	IT CSV and e-Data Management Manager
Location:	Billingham
Date	
Grade	34 (proposed)

Job Purpose

To ensure all computerised systems used to support GMP manufacture, are appropriately validated and controlled. Where validation and control includes appropriate specification and verification of e-data security and e-data management practice.

Dimensions

No of staff reporting to individual	0
No of Systems	10-15 key Computerised (Automated) systems
Types of Systems	Manufacturing / PCS, Lab Equipment, IS applications & S/S.[#]
No of Projects	3-4 / annum
Forward Work Plan	12 months.
Desirable Skills & Knowledge	Knowledge and experience of CSV and GAMP.
	Self-motivated, flexible and able to work under pressure
	Good management, documentation & communication skills
	Strategic thinking, concern for standards, rational persuasion
	Concern for impact, when dealing others

e.g. EDMS, CAPA, LMS, LIMS, CDS, ERP, DMS, eMBR, HVAC, PCS, ELN etc

Principle Accountabilities

1. Ensure computerised systems are appropriately validated

2. Provide implementation or upgrade project teams with (expert) computerised systems validation (CSV) guidance

3. Help project teams define appropriate computerised systems validation strategies including, stage gate deliverables.

4. Prepare or review all levels of validation documents (internal or external SDLC) including :

    a. Validation (Strategy) Plans, User Requirement Specifications,

    b. Definition Documents, including Functional Specifications S/W Design Specifications or Configuration Documents and SOPs

    c. Qualification Documents and Test Specifications (DQ, IQ, OQ, PQ/ FATS / SATS)

    d. Traceability Matrices, Risk Analysis

    e. Validation Reports, Change Controls/ Events / Deviations etc

5. Provide CSV technical sign-off for all of the above.

6. Provide training on Computerised System Policies, SOPS, industry regulations trends and "hot topics" to project team, members, system owners and users.

7. Audit as CSV subject matter expert, suppliers of computerised systems or external service providers.

8. Works closely with the Security and e-Data Compliance Manager to ensure requirements for electronic data security and e-data management are defined and delivered during any implementation or upgrade project.
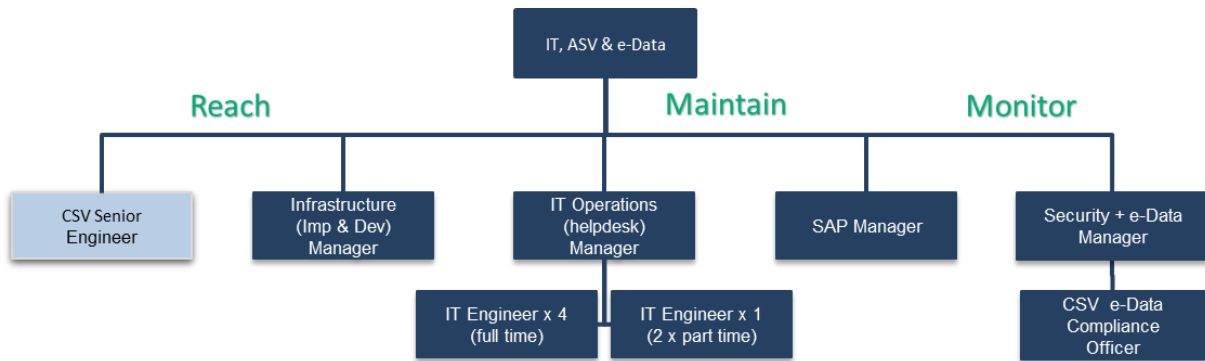
Competencies

Competency	Demonstrated Behaviours
Critical Information Seeking	• Gathers key information from relevant people or existing records to diagnose a problem. • Carefully structures questions to find out more about a problem.
Concern for standards	• Sets high personal standards as an example. • Takes action to ensure consistent application of procedures/systems. • Makes sure that work meets quality standards. • Checks on projects to make sure they are being done properly.
Thoroughness	• Makes sure all necessary tasks have been completed. • Checks work for errors and omissions. • Takes care of both small and large aspects of a task. • Keeps track of many details without forgetting items.
Rational persuasion	• Draws on reason and logic in making a case. • Presents arguments based on factual information. • Relates suggested solutions to the needs of the listener.
Concern for impact	• Considers in advance the impact of actions on others and adjusts actions in order to influence or facilitate the desired effect. • Considers the likely reactions of others and acts to address them in planning a communication. • Effectively communicates in order to influence.
Flexibility	• Modifies own behaviours in response to a situation. • Adjusts behaviour to suit new procedures and systems. • Maintains effectiveness during rapidly changing assignments or priorities.
Independence	• Takes a stand on critical issues. • Is prepared to disagree with colleagues or more senior people. • Is prepared to question established systems, organisational norms, and values.

Special Features

1. Is educated to degree level in Software or related Engineering discipline.

2. Has an extensive knowledge (minimum 10 years' experience) of GAMP, risk based approach to validation and a good understanding of electronic records and signatures.

3. Maintain awareness of data management and data integrity needs in a GMP regulated environment

4. Works closely with the Security and e-Data Compliance Manager to ensure requirements for electronic data security and e-data management are defined and delivered during any implementation or upgrade project.

5. Work closely with the CSV and e-Data Compliance Officer where issues identified and remediation required

6. A team player with good verbal and written communication skills

Organisation Chart

Signatures

Job Holder: …………………..…………………….. Date: …………………………

Manager: ………………………………………….. Date: …………………………