

Roles & Responsibilities

Role	Quality Engineer	Issued	25 June 2019
Grade	QE2	Reporting to	QA & Systems Manager
Department	QHSE	Location	AEU

Main Purpose of Job

To ensure and verify acceptable standards of product quality and service are maintained in accordance with national & international standards, customer and internal requirements

Fulfilling an essential role taking Advanex to be **No.1 in the World at what we do!**

Main Duties and Responsibilities

To be carried out in accordance with Quality Management System, Work Instructions, Good Manufacturing Practices (GMP), departmental and company procedures including but not limited to:

- Perform required product inspection in accordance with company procedures
- To perform product release activities and produce the required associated documentation. (C of C, APQP PPAPS, FAIRS, ISIR etc)
- Perform product audit as required by company procedures
- To take appropriate action to prevent the release non-conforming product.
- Authorise the final disposition of product
- To ensure that any non-conforming product is controlled so as to prevent accidental use.
- Perform calibration and verification activities on measuring equipment and methods
- Organising external calibration of measurement equipment as required
- To obtain inspection results, required to evaluate process performance.
- To analyse data and performance using statistical methods
- To manage, investigate and provide reports on customer concerns as required
- Approve suppliers and sub-contractors
- Assist in the monitoring of suppliers and sub-contractors
- To manage, investigate and provide reports relating to supplier concerns as required
- Assisting with the development of products and processes.
- Organising and performing systems audits
- Maintaining required records
- Producing reports as required
- KPI reporting and performance evaluation
- To assist in the generation of control plans, FMEA's, RBIA's etc
- To review, report and react to departmental KPI's and feedback.
- Assist in the planning of processes and equipment validation
- Approve validation documents
- Generate Drug Master Files
- Raise necessary purchases requisitions to maintain department supplies.
- To provide training and development of all personnel in quality standards and methods
- Ensure all work stations and areas are kept in a clean and safe condition
- Deputise for other department members as required
- Provide timely and sufficient information and instruction to deputies to ensure production and quality can be maintained during absence.
- Record and report accurate information as required
- Attend and present at meetings as necessary to perform duties and aid business development.
- Attend training to develop relevant knowledge, techniques and skills.
- Promote the company in a positive light at all times especially during contact with outside agencies
- Perform any other duties as reasonably required by your Manager or a Director.

Communication, Attributes and Relationships

- Communicate and liaise with your deputy/deputies to ensure the smooth running of your role during times of absence and provide training to ensure the nominated deputy is able to perform the basic functions of your role to provide adequate cover.
- Attend, present and provide a positive contribution at meetings as necessary
- Communicate departments with any item that could affect lead times and other commercial factors.
- Strive to be efficient and helpful with internal and external contacts
- Maintain and develop good working relationships with external organisations, other departments and Group companies promoting the company in a positive light at all times
- Maintain an innovative approach to your work, looking to develop and suggest improvements
- Maintain behaviour, attitude and ethics in line with the Advanex Group Core Values and Advanex Ethics and Compliance Policy
- Maintain behaviour in line within the company policy of anti-discriminatory practice of equality and diversity throughout the company.
- Always promoting behaviour in ourselves and others that will take us towards being **No.1 in the World at what we do!**

Internal Liaison

All departments

External Liaison

Suppliers

Contractors

Customers

Systems Auditors

✓be honest and trustworthy ✓be respectful ✓possess cultural awareness and sensitivity
✓be flexible ✓demonstrate sound work ethics ✓use our Group Core Values
✓BE BRILLIANT!

Health & Safety - General

- In accordance with the management of Health and Safety at Work Regulations 1992 and other relevant Health and Safety legislation, as an individual you have a duty to take responsible care to yourself and to others who may be affected by your work activities.
 - To assist Production Managers, Heads of Department and Leaders in promoting a positive and proactive Health and Safety culture.
 - Shall use correctly all work items provided in accordance with training and instructions received.
 - Shall co-operate with others to enable compliance with statutory duties for Health and Safety.
 - Assist in maintaining a safe working environment for self, colleagues and others by ensuring all areas are free from hazardous obstructions.
 - To ensure that any work situation which may present a serious and imminent danger is reported immediately to a director/manager/health and safety representative.
 - To either correct or notify management of any unsafe working practices and of any person behaving in an unsafe manner.
 - To be aware of any responsibilities as laid down in company Health and Safety Policy and relevant risk assessments.
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Quality - General

- All duties will be carried out in line with the Company Procedures for Planning, Production and Manufacturing.
 - Strive to maintain quality in line with the Company Management systems and procedures.
 - Alert your line manager, manager and/or directors to any issues of quality and risk.
 - Contribute to the effectiveness of the team by reflecting on own and team activities and making suggestions on ways to improve performance.
 - Effectively manage own time, workload and resources.
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Environment - General

- Ensure that production and manufacturing schedules are made in line with Company Energy targets.
- Be aware of your responsibilities in line with Company Environmental Management Systems and procedures.
- Always try to save resources, energy and power consumption.
- Minimise waste by promoting the 3R principles REDUCE REUSE RECYCLE.
- Alert your line manager or other senior manager to any actions by yourself or others that may have a negative effect on the environment.

Job descriptions are not designed to be all-inclusive, but to provide a clear description of the role as far as practicable.

The nature of our company demands a flexible approach in order to provide the best possible service for customers and ensure continuous improvement to meet business demands and the future success of our company.

Roles and responsibilities can be changed in line with the changing demands of the business.

Be Unique

We don't mimic others. Uniqueness is the value of our existence

Embrace & Create Change

Think it through, build up your courage and make your case to initiate change.

If there is no precedent, make it.

KISS Keep is Simple and Speedy

Let's simplify and speed up. Avoid bureaucracy. Be Lean.

Act with your own initiative

Create your own energy to keep moving forward

Focus on your own responsibility

Define your own work & perform it as you should and beyond. Provide Satisfaction Plus. Focus on you, do not get lost in what others are not doing.

Put your heart into it

Passion should mark everything we do.

Enjoy your work!

Let's eliminate bureaucracy that disrupts our enjoyable work environment. Happy workplace.



I _____ Confirm that I have read and understood my roles and responsibilities as outlined

Employee Signature: _____

Date: _____

