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# POSITION SUMMARY

The Technical/Regulatory Affairs Officer reports directly to the Essence Head of Quality and is responsible for all Regulatory functionality of Essence Group and related companies. The objective of this role is to ensure that all formulations/products meet regulatory requirements and are accurately documented. The Technical/Regulatory Affairs Officer will also manage the Essence Group Standards Names List and Vendor Assurance Programme.

# POSITION DETAILS

* 1. Reports to : Head of Quality
	2. Department : Technical/Quality
	3. Location : Greenwich, NSW
	4. Date prepared : April 2021
	5. Date to be reviewed : April 2023
	6. Document Number : PD:003.01
	7. Version : 01
1. **KEY OBJECTIVES**
	1. Manage the regulatory compliance of new and existing products to meet the company’s requirements.
	2. Review of formulations to ensure they meet the marketing countries’ regulatory requirements.
	3. Maintain company regulatory certifications and licenses.
	4. Review printed artwork against regulatory requirements to ensure claims/allergens are substantiated and compliant. e.g., FSANZ, TGO92.
	5. Create and/or check new product specifications and batch documents following the document control and change control procedures.
	6. Maintain the filing system of approved master documents.
	7. Manage the Essence Standard Names List for new and existing Items.
	8. Manage the Essence Vendor Assurance Program following standard operating procedures.
	9. Maintain Item BOM’s and Vendor approval in SAP.
	10. Pharmacovigilance subject matter expert for Essence Group and Related companies listed products.
	11. Attend the Nowra manufacturing site as required for cross functional meetings.
	12. Supervise direct reports, where applicable.
	13. Other duties as assigned by management.

# DECISION MAKING SCOPE

## Financial

## Nil

## Staffing

* + 1. Reporting structure for this position - as per below Organisation Chart

Head of Quality

**NPD Team Leader**

QA Manager

* Nowra

NPD/Technical Officer

NPD/Technical Officer

Technical/Regulatory Affairs Officer

* 1. **Policy and Procedure**
		1. As per Essence HR Policy Manual and Company SOP’s

# ESSENTIAL REQUIREMENTS

## Education

The employee must possess the following:

* + 1. Tertiary qualification(s) in science related discipline. Bachelor level preferable.

## Experience

The employee must have the following level of experience in, or knowledge of:

* + 1. At least 3 years technical/regulatory experience in a food/complementary medicine/pharmaceutical role.
	1. **Knowledge, Skills and Attributes**

The employee must have the following knowledge, skills, and attributes:

* + 1. Knowledge of and ability to interpret current cGMP Principles.
		2. Good knowledge of FSANZ/TGA/HALAL/ACO regulatory requirements.
		3. Experience in master document control and change control processes.
		4. Ability to multitask and prioritise projects to meet company requirements.
		5. Excellent interpersonal skills, ensuring effective working relationships with all relevant stakeholders.
		6. Positive attitude towards change.
		7. Understand the importance of continuous improvement.
		8. Demonstrate commitment to work tasks.
		9. Accept responsibility for own work.
		10. Attention to detail, and good work ethic.
		11. A high level of initiative, energy, and enthusiasm.
		12. Excellent communication and writing skills.
		13. Good Microsoft word and Excel skills.
	1. **Safety and Health**

The employee must:

* + 1. Participate in and take responsibility for workplace health and safety, as required for the position.
		2. Report all breaches of WH&S to Reporting Manager/Supervisor.
	1. **Quality**

The employee must always:

* + 1. Ensure complete compliance with the Australian Code of GMP/FSANZ/ACCC or other regulatory requirements for the importing country.
		2. Bring GMP behaviour/issues to the attention of colleagues.
		3. Ensure complete compliance with all company Standard Operating Procedures (SOP).

**4.5.4** Make recommendations for improvement to SOPs.

**4.6 Company Values**

The employee must possess the following attributes and observe the Company Values:

**4.6.1** To remain quality focused.

**4.6.2** To demonstrate open and transparent communication.

**4.6.3** Be participative and Teamwork based.

**4.6.4** Apply continuous improvement and benchmarking.

**4.6.5** Participate in a culture of sustained excellence.

**4.7 Special Requirements (if applicable)**

**4.7.1** Understand the importance of specifications to ensure safe, high quality product is manufactured by Essence.

**4.7.2** Understand the importance of master document control to ensure only current documentation is accessible.

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| --- | --- | --- | --- | --- |
|  | **Name** | **Position** | **Signature** | **Date** |
| Manager | Wayne Rides | Head of Quality |  |  |
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