FAREVA
RICHMOND

POSITION DESCRIPTION

POSITION TITLE:	Senior Validation Engineer
POSITION GRADE	
JOB CODE	Exempt
REPORTS TO POSITION TITLE:	Sr. Quality Manager
DATE LAST UPDATED	August 2023
PEOPLE MANAGER (YES) (NO)	No

POSITION SUMMARY

Summarize the primary purpose & key accountabilities of the position, including scope of responsibility in 5-7 concise sentences. It may be helpful to complete this section after you have finished the other sections of the document.

This position is responsible for managing the Cleaning and sanatitization Program for the site. Position requires knowledge of Cleaning and SanitizationValidation for OTC and cosmatics. The position requires to be the Subject Matter Expert in the field of Cleaning and sanitization program and validation. Be able to support the facility and attest to cleaning during internal and external audits. Position requires ability to problem solve, work on cross functional teams, mentor staff, work with cross functional teams from batch processing, packaging and micro laboratory and work independently.

POSITION RESPONSIBILITIES

In order of importance, list the primary job areas of responsibility critical to the performance of the position. Identify supporting activities demonstrative of expected behavior and activities. Indicate expected percentage of time for each area of responsibility to a total maximum of 100%.

Responsibility	Supporting Activities	% of Time
Lead the Cleaning, sanitization & Validation Program	• Plans, implents a robust cleaning and sanitization program by authoring and leading the sanaitization Validation Program for all products and product contact equipment. • Leads the excuation of the cleaning and sanitization validations by authoring protocls, hands on excuation of the protocols and authoring the final report • Ensures that deliverables are carried out in a timely and compliant manner. • Author or update SOP's to support the cleaning the sanitization program. • Lead the training for the processing and packaging personal on the execuation of the cleaning and sanatizion SOP's • Supports the Sr. Quality Manager during external and regulatory audits. • Leads the activities related to investigations for Micro OOS's, initiates and follows-up on the implementation of corrective actions • Subject Matter Expert in the field of Cleaning and santatization program & Validations • Leads the personal Hygine program to ensure proper PPE's for the site are appropriate for each area of the facility and ensuring cGMP's are followed and adhered to.	60%

General Activities	• Support the Cleaning & Sanatization processing and packaging personal • Reviews performances of Cleaning and Sanitization program in regard to the achievement of goals, objectives and key result areas.	20%
Support	• Designs, develops and evaluates plans for projects/studies/investigations/reviews. • Completely responsible for planning and execution of all tasks needed to the execuation of the cleaning validations. • Seeks advice on planning from management when there are priority conflicts.	10%
SOPs and Administration	• Able to make independent contributions to the development of new technologies, developing and revising methods and procedures to assure compliance with applicable regulations; carries out technical and administrative duties as assigned.	5%
Trains and Mentors	• Trains on new and existing procedures, techniques and governmental regulations as directed by management.	5%

ORGANIZATIONAL RELATIONSHIPS

Provide the primary groups or key positions that this position will have interaction with as a regular part of the position responsibilities. Include any external interactions as appropriate.

Quality Operations/Primary Processing Unit/Engineering & Maintenance management – general and specific discussions of Cleaning Validation related issues; recommends corrective action to potential or observed cGMP violations.
Quality Operations/Primary Processing Unit/Engineering colleagues – workload priorities; consult on analytical interpretations of methods and SOPs. Builds credibility within the group by performing high quality work.
Lead training, mentoring, reviewing records, acting as subject matter expert for cleaning and sanatization.

FINANCIAL/ASSET ACCOUNTABILITY

Indicate the Average Budget or Revenue accountability, as applicable.

NA

SUPERVISION

Indicate the typical number of Colleagues managed. Include direct & indirect reports, matrix responsibility and or additional resources (i.e. contingent workers), as applicable.

None.

EDUCATION AND EXPERIENCE

Indicate the formal education, certification or license required and/or preferred. Include the minimum number of years of relevant experience required for the position (where legally permissible).

BS degree in Biology, Chemistry, Microbiology, Biochemistry or relevant science discipline – 8 years of relevant Quality experience preferably in the pharmaceutical industry.

MS degree in Biology, Chemistry, Microbiology, Biochemistry or relevant science discipline – 6 years of relevant Quality experience preferably in the /pharmaceutical industry.

Strong background in Cleaning and sanitization progam and validations

Mentor/trains in routine procedures demonstrating expertise.

TECHNICAL SKILLS REQUIREMENTS

Indicate the technical skills required and/or preferred, as applicable.

- Extensive practical and solid theoretical knowledge of applicable compliance guidelines of the FDA or other regulatory bodies; and relevant Fareva SOPs.
- In addition to high technical competence, understands and can articulate the scientific/regulatory principles that underlie practices and guide future projects/studies/reviews development. Continues to expand breadth of technical expertise.
- Ability to interpret and document results according to standard operating procedures using all Quality Systems guidelines.
- Demonstrated ability to independently develop, document and troubleshoot methods of moderate complexity.
- Ability to lead teams from work cross functional areas
- Ability to provide equipment and procedure training and to share technical expertise with less experienced colleagues to solve problems.
- Can independently design and carry out a series of studies/reviews to solve a problem or evaluate a process/procedure. Solutions may involve the development of new techniques and procedures. Uses literature and colleagues as resources in order to solve problems.

PHYSICAL POSITION REQUIREMENTS

Note the physical conditions in which work will be performed, if applicable to the position. Examples: Lifting, sitting, standing, walking, ability to travel, drive, unusual attendance requirements, weekend work or travel requirements, etc.

Must be able to be to walk carrying equipment (cart and sampling instruments) through Operations, climb stairs, and lift at least 25 lbs.

SIGNATURE

All employees should have on file a copy of their signed position description.

Employee's Name & Signature:		Date:	
Supervisor's Name & Signature		Date:	