

DPT Laboratories, Ltd.

Job Description

Job Title: Validation Support Coordinator
Job Group: Professional Non-Technical
Department: Quality Engineering
Reports To: Validation Supervisor
FLSA Status: Non-Exempt

SUMMARY

To perform tasks related to review, implementation, issue of documentation, and support of validation execution studies. Maintain departmental documentation systems to support tracking of documentation and associated tasks. Assist Validation employees in studies execution and facilitate work flow between departments, ensure that documents are complete, follow DPT procedures, and complies with cGMP practices. Analyzes data in order to prepare reports and studies.

ESSENTIAL DUTIES AND RESPONSIBILITIES include the following. Other duties may be assigned.

1. Support the circulation of and obtain comments to and revise validation documentation (**include: generation and execution of validation/ qualification documentation including protocols, reports, and SOPs**).
2. Route and obtain comments for new and modified validation documents.
3. Ensure the timely review and comment for all associated documentation.
4. Obtain and implement recommendations/comments from cross-functional panel or reviewers.
5. Assist in tracking and drive time lines for deliverables.
6. Meet with interdepartmental representatives, clients and key stakeholders to ensure timely turnaround time for reviewing or issuing of documents.
7. Assist in maintaining filing/tracking system for departmental documentation materials. Archive and retrieve documentation materials.
8. Assist in the generation of validation/qualification protocols (including Process, Packaging, and Cleaning Validation and Installation, Operational, and Performance Qualification protocols) and rationales for design of the study, sample collection, and the development of acceptance criteria for a variety of products, processes, facilities/utilities, and equipment.
9. Assist in the execution of qualification/validation protocols, collect field samples, tabulate and statistically analyze results (as applicable), and summarize deviations, as well as troubleshoot failures/problems.
10. Within area of responsibility, understand and comply with all DPT safety, environmental and quality practices and procedures as outlined in organizational/departmental guidelines and SOPs as well as applicable federal, state and local regulations.
11. Performs and/or assists with the execution of qualification protocols.
12. Collects samples according to prepared worksheets. Sampling will include swabs of compounding and filling equipment after cleaning, rinse water samples, product samples, etc.
13. Perform other duties as assigned.

SUPERVISORY RESPONSIBILITIES

This job has no supervisory responsibilities.

QUALIFICATIONS To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, skill, and/or ability required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

EDUCATION and/or EXPERIENCE

1. Associate's degree or equivalent from a two-year college or technical school with an emphasis in Engineering; or six months to one year of related experience and/or training; or equivalent combination of education and experience.
2. Minimum 0-1 years of related experience is required. Related experience should include experience in the compounding and packaging of pharmaceutical or food products, a working knowledge in chemistry or environmental laboratory, and a working knowledge of GMP's.
3. Pharmaceutical or Industry related experience desired.

LANGUAGE SKILLS

Ability to read, analyze, and interpret general business periodicals, professional journals, technical procedures, or governmental regulations. Ability to write reports, business correspondence, and procedure manuals. Ability to effectively present information and respond to questions from groups of managers, clients, customers, and the general public.

MATHEMATICAL SKILLS

Ability to calculate figures and amounts such as discounts, interest, commissions, proportions, percentages, area, circumference, and volume. Ability to apply concepts of basic algebra and geometry.

REASONING ABILITY

Ability to solve practical problems and deal with a variety of concrete variables in situations where only limited standardization exists. Ability to interpret a variety of instructions furnished in written, oral, diagram, or schedule form.

CERTIFICATES, LICENSES, REGISTRATIONS

None.

PHYSICAL DEMANDS The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

How much on-the-job time is spent in the following physical activities? Check the appropriate boxes below (1= least, 5= most.)

<u>Physical Demand</u>	<u>Amount of Time</u>				
	1	2	3	4	5
Stand				X	
Walk				X	
Sit			X		
Use hands to handle or feel			X		
Reach with hands and arms		X			
Climb or balance	X				
Stoop, kneel, crouch, or crawl	X				
Talk or hear					X
Taste or smell	X				

If this job requires weight be lifted or force be exerted, how much?

Physical Demand

	Yes	No
Up to 10 pounds	X	
Up to 25 pounds	X	
Up to 50 pounds		X
Up to 100 pounds		X
More than 100 pounds		X

Special Vision requirements apply.

- Close vision (clear vision at 20 inches or less)
- Distance vision (clear vision at 20 feet or more)
- Color vision (ability to identify and distinguish colors)
- Peripheral vision (ability to observe an area that can be seen up and down or to the left and right while eyes are fixed on a given point)
- Depth perception (three-dimensional vision, ability to judge distances and spatial relationships)
- Ability to adjust focus (ability to adjust the eye to bring an object into sharp focus)

WORK ENVIRONMENT The work environment characteristics described here are representative of those an employee encounters while performing the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

How much exposure to the following environmental conditions does this job require? Show the amount of time by checking the appropriate boxes below.

Work Environment

	Yes	No
Wet or humid conditions (non-weather)		X
Work near moving mechanical parts	X	
Work in high, precarious places		X
Fumes or airborne particles		X
Toxic or caustic chemicals		X
Outdoor weather conditions		X
Extreme cold (non-weather)		X
Extreme heat (non-weather)		X
Risk of electrical shock		X
Work with explosives		X
Risk of radiation		X
Vibration		X

How much noise is typical for the work environment of this job

- Moderate noise (examples: business office with computers and printers, light traffic)

SUPPLEMENTARY INFORMATION

This description is based in management's assessment of the requirements and functions of the job as of the date this description was prepared. It is a general guideline for management and employees, but it does not purport to be an exhaustive list of all the elements of the job. Management reserves the right to modify the description at any time, or to vary the duties and responsibilities of the job on a temporary or indefinite basis to meet production, scheduling or staffing needs.