DUTY STATEMENT

Employee Name: **Vacant**	Position Number: **580-XXX-0765-XXX**
Classification: Senior Environmental Scientist (Specialist)	Tenure/Time Base: Permanent / Full-Time
Working Title: Regulatory Inspection Specialist	Work Location: Various locations available. Location to be determined upon hire.
Collective Bargaining Unit: R10	Position Eligible for Telework (Yes/No): Yes
Center/Office/Division: Center for Environmental Health / Division of Food and Drug Safety	Branch/Section/Unit: Food and Drug Branch / Drug and Medical Device Compliance and Enforcement Section / Investigations and Technical Support Unit

All employees shall possess the general qualifications, as described in California Code of Regulations Title 2, Section 172, which include, but are not limited to integrity, honesty, dependability, thoroughness, accuracy, good judgment, initiative, resourcefulness, and the ability to work cooperatively with others.

This position requires the incumbent to maintain consistent and regular attendance; communicate effectively (orally and in writing) in dealing with the public and/or other employees; develop and maintain knowledge and skill related to specific tasks, methodologies, materials, tools, and equipment; complete assignments in a timely and efficient manner; and, adhere to departmental policies and procedures.

All California Department of Public Health (CDPH) employees perform work that is of the utmost importance, where each employee is important in supporting and promoting an environment of equity, diversity, and inclusivity, essential to the delivery of the department's mission. All employees are valued and should understand that their contributions and the contributions of their team members derive from different cultures, backgrounds, and life experiences, supporting innovations in public health services and programs for California.

Competencies

The competencies required for this position are found on the classification specification for the classification noted above. Classification specifications are located on the California Department of Human Resource's Job Descriptions webpage.

Job Summary

This position supports the California Department of Public Health's (CDPH) mission and strategic plan by promoting health and wellness and improving state health outcomes by advancing protective measures and reducing risks.

The Senior Environmental Scientist (ES) (Specialist) is a Drug and Medical Device Compliance and Enforcement Section (DMDCES) regulatory inspection technical expert. The incumbent serves in a lead capacity, reviewing and evaluating drug, medical device, home medical device retailer (HMDR),

and cosmetic inspection reports generated by field staff for completeness, uniformity, thoroughness, and accuracy. The Regulatory Inspection Specialist assesses the timeliness of the inspections and ensures firms operate in compliance with applicable drug and medical device safety laws and regulations. The incumbent collaborates with other DMDCES staff and provides input as needed to revise inspection reports or conduct follow-up activities with firms. The incumbent also reviews and makes recommendations regarding licensed entities complaints; develops and delivers classroom and field training to inspectors pertaining to inspection processes; and manages the program's continuous improvement projects.

The incumbent serves as a back-up with the medical device contract between the CDPH Food and Drug Branch (FDB) and the U.S. Food and Drug Administration (FDA). The incumbent plans, organizes, monitors, evaluates, and conducts the most complex medical device safety inspections under the FDA Medical Device Safety Contract; prepares and reviews contract inspection reports; and may participate in other aspects of contract management.

The incumbent works under the general direction of the Chief, Food and Drug Unit of the DMDCES, Investigations and Technical Support Unit.

Special Requirements

- ☒ Conflict of Interest (COI)
- ☒ Background Check and/or Fingerprinting Clearance
- ☒ Medical Clearance
- ☒ Travel: Up to approximately 45% in-state travel is required, which may include overnight stays.
- ☐ Bilingual: Pass a State written and/or verbal proficiency exam in
- ☐ License/Certification:
- ☒ Other: The incumbent must obtain and maintain a commission from the FDA.

Essential Functions (including percentage of time)

30% Serves in a lead capacity, reviewing and evaluating drug, medical device, cosmetic, and HMDR inspection reports for completeness, uniformity, thoroughness, and accuracy. Assesses the appropriateness of corrective actions implemented by responsible firms and enforcement actions performed by FDB personnel. Coordinates with FDB supervisors as needed to revise inspection reports or conduct inspection follow-up activities. Conducts appropriate follow-up at unlicensed drug, medical device, and HMDR firms.

30% Conducts or leads the most complex drug, medical device, and HMDR inspections. Provides technical and scientific expertise to inspectors regarding the violations associated with inspections. Reviews and makes recommendations regarding licensed entities complaints. Develops and delivers classroom and field training to inspectors pertaining to the inspection process. Assists supervisors with workplan development duties, such as inventory review and management. Leads and develops continuous improvement projects, including but not limited to improving use of technology, updating process flows, and revising application forms. Updates the section's documented training program with new components such as an audit process and additional training topics, in addition to maintaining ongoing staff training and retraining.

15% Serves as a back-up with the FDA Medical Device Safety Contract. Plans, organizes, monitors, facilitates, and conducts the most complex inspections and other activities under the FDA contract to ensure compliance with the terms of the contract. Prepares medical device contract inspection reports.

15% Drafts responses to media and legislative inquiries regarding the inspection program. As assigned, analyzes legislation and assists in the development of regulations related to the program. Represents FDB on workgroups, task forces, conferences and meetings related to the inspection program.

5% Attends training as assigned. Keeps abreast of new technologies and legal or regulatory changes in the area of drug and medical device safety.

Marginal Functions (including percentage of time)

5% Performs other job-related duties as required.

☐ I certify this duty statement represents an accurate description of the essential functions of this position. I have discussed the duties and have provided a copy of this duty statement to the employee named above.

☐ I have read and understand the duties and requirements listed above and am able to perform these duties with or without reasonable accommodation. (If you believe reasonable accommodation may be necessary, or if unsure of a need for reasonable accommodation, inform the hiring supervisor.)

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

HRD Use Only:
Approved By: Nathalia Klyn
Date: 06/03/2026