## **DUTY STATEMENT**

Employee Name:	Position Number:
	580-733-7705-001
Classification:	Tenure/Time Base:
Public Health Medical Officer III	Permanent
Working Title:	Work Location:
Infant Botulism Consultant	850 Marina Bay Pkwy, Richmond, CA
	94804
Collective Bargaining Unit:	Position Eligible for Telework (Yes/No):
U16	Yes
Center/Office/Division:	Branch/Section/Unit:
Center for Laboratory Sciences	Infant Botulism Treatment and Prevention
	Program

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 <u>California Department of Human Resource's Job Descriptions webpage</u>.

## **Job Summary**

This position supports the California Department of Public Health's (CDPH) mission and strategic plan by contributing to the fulfillment of the statutory mandates of the Infant Botulism Treatment and Prevention Program (IBTPP) stipulated in Health & Safety Code §§123700-709.

The Public Health Medical Officer (PHMO) III Specialist, acting as the Infant Botulism Consultant, is responsible for IBTPP special projects, reports, and drills requested or required by the Center for Laboratory Sciences (CLS), federal, state, or other agencies. Oversee the clinical consultations and the distribution of BabyBIG® and is responsible for reviewing the programs processes and procedures for updates or changes and initiating the implementation of them.

The incumbent works under the general direction of the Assistant Deputy Director, Public Health Medical Administrator I.

Special Requirements		
☐ Conflict of Interest (COI)		
☐ Background Check and/or Fingerprinting Clearance		
☐ Travel: Up to 10%		
☐ Bilingual: Pass a State written and/or verbal proficiency exam in		
☐ License/Certification: Must possess a valid license to practice medicine in California		
Other:		
Essential Functions (including percentage of time)		

## Essential Functions (including percentage of time)

- 35% Responsible for coordinating and managing IBTPP special projects, reports, and preparedness drills as requested or required by the CLS, federal, state, or other agencies. Duties include planning, organizing, and executing assigned projects; developing and submitting timely and accurate technical reports; ensuring compliance with applicable regulatory requirements; and participating in statewide and national emergency preparedness drills. Provide subject matter expertise to multidisciplinary teams, represent IBTPP in interagency workgroups, and track project outcomes to support continuous program improvement and readiness.
- 25% Oversee and manage the clinical consultation process for referrals to the IBTPP for suspected cases of infant botulism, ensuring timely expert guidance and adherence to clinical protocols. Direct and coordinate the distribution of BabyBIG® (Botulism Immune Globulin Intravenous [Human]) nationwide and internationally for both suspected and confirmed cases, including logistics, chain of custody, and regulatory compliance. Provide clinical oversight, maintain collaboration with treating physicians, public health authorities, and international partners, and ensure accurate documentation, reporting, and quality assurance. Continuously evaluate processes to improve timeliness, safety, and accessibility of life-saving treatment.
- 20% Manage BabyBIG® regulatory Standard Operating Procedures (SOP). Conduct biennial review/updates to SOPs. Oversee the development, implementation, and maintenance of regulatory SOPs governing the manufacture, distribution, and use of BabyBIG®. Ensure SOPs reflect current federal (FDA), state (CDPH), and international regulatory requirements. Coordinate with clinical, legal, and regulatory teams to incorporate best practices and lessons learned into procedures. Provide staff training and guidance to ensure consistent compliance with approved protocols. Lead the systematic review of all BabyBIG® SOPs every two years, ensuring accuracy, clarity, and alignment with evolving scientific, clinical, and regulatory standards. Document review findings, track changes, and obtain necessary approvals from leadership and oversight bodies. Implement revisions, distribute updated versions to all relevant stakeholders, and confirm acknowledgment of updates through training or certification. Maintain version control and archival records for regulatory inspections or audits

BabyBIG® pharmacovigilance – manage safety reporting per SOP CDPH-004. Manage the pharmacovigilance program to monitor, detect, assess, and prevent adverse events associated with BabyBIG®. Ensure compliance with SOP CDPH-004 and related regulatory guidance for adverse event collection, assessment, and reporting. Coordinate with treating physicians, hospitals, and public health partners to ensure timely and accurate submission of safety data. Conduct safety signal detection and trend analysis and escalate findings to leadership and regulatory authorities as appropriate. Prepare pharmacovigilance reports for FDA and other agencies, ensuring deadlines and reporting standards are met.

Marginal Functions (including percentage of time)					
5% Other job-related duties.					
☐ 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: CP Date: 11/18/25