 <p>Prolacta BIOSCIENCE Advancing the Science of Human Milk</p>	<h2>Job Description</h2>	<p>Owner: VP, Quality and Regulatory Affairs</p> <p>Revision No: N/A</p> <p>Effective Date: 06/23/2017</p> <p>Supersedes: N/A</p> <p>Page No: 1 of 4</p>
<h1>Director, Quality Control</h1>		

Department(s):	Quality Control – Indirect
Reports To:	VP, Quality and Regulatory Affairs
Date Posted:	January 4, 2018

Company

Prolacta is the pioneer in human milk-based nutritional products for premature infants in the neonatal intensive care unit (NICU). Prolacta believes that there is no adequate replacement for human breast milk and, as such, we believe infant nutritional products should be human milk-based. As a privately held, scientifically driven company, committed to improving premature infant nutrition, we are using human milk to change the standard of care in the NICU. Prolacta operates and/or owns milk banks that provide the starting material for the products Prolacta sells.

Job Summary


Join our busy and growing company - dynamic job with opportunity for growth. We are seeking an individual with strong laboratory management skills to train and build our laboratory team. This outgoing individual will provide leadership to and coordinate the company testing, assay validation and R&D support functions. This position reports to and works closely with the Vice President of Quality and Regulatory Affairs.

Primary Duties and Responsibilities

1. Maintain a safe, efficient, functional and compliant laboratory operational environment developed to the required standards in accordance with corporate guidelines
2. Provide microbiological and chemical expertise and support for training, product investigations, deviations, CAPA, quality and operational improvements, etc. to ensure continued compliance with regulations
3. Oversee daily operations of QC laboratory including incoming raw materials testing, screening and release of milk donations, in-process product testing, final container testing, and utilities/environmental monitoring.
4. Coordinate activities with Planning, Manufacturing and Quality Assurance to ensure production schedules are met.
5. Oversee investigations related to the laboratory including OOS and nonconformance investigations
6. Streamline and standardize various laboratory processes to improve efficiency, accuracy and responsiveness.

Prolacta Bioscience Inc. • 757 Baldwin Park Blvd. • City of Industry, 91746

Phone: 1-888-776-5228 • Fax: 1-626-599-9269 • Website: www.prolacta.com • Email: info@prolacta.com

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7. Oversee development, validation and implementation of new assays and transfer of assays from R&D.
8. Assist in identification and qualification of outside testing laboratories and raw material vendors
9. Develop short and long term plans to support Prolacta's Strategic Imperatives, including staffing, infrastructure and equipment plans

Job Requirements and Qualifications

1. Master's Degree or Ph.D. – chemistry, biochemistry or biological science
2. Minimum 12 years' experience, 7 years in a leadership or supervisory role (preferably in pharmaceuticals or biologics)

Other Knowledge, Skills and Abilities

1. Detailed knowledge of quality fundamentals, quality control, and quality management systems, including laboratory investigational tools
2. Experience with presenting information to the Regulatory Authorities
3. Experience with Operational Excellence in fast moving laboratory and/or manufacturing environment
4. Experience with project management and statistical analysis
5. Ability to manage the use including changes/upgrades to LIMS (laboratory information management systems)
6. Skills in personal computer operation with appropriate work process, database, project management and spreadsheet software (e.g. Microsoft Office)
7. Demonstrated ability and flexibility in a 7 day/multi-shift operation
8. Strategic planning experience
9. Able to create and manage budgets, including capital planning and long-term strategic planning
10. Ability to work without supervision
11. Effectively interview and select candidates
12. Handle conflict management and bring resolution
13. Effective relationship building skills
14. Ability to produce and present clear, concise and professionally written communications and presentations
15. Performance Management, effective coaching and directing of others
16. Positive attitude and motivation
17. Ability to operate in a complex matrix environment
18. Visionary and forward-thinking
19. High level of business acumen

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- 20. Strong PC skills, MS Outlook, Word, etc.
- 21. Must be able to work under pressure, meet deadlines, and be flexible when working on multiple projects simultaneously
- 22. Strong Critical thinking and decision making skills
- 23. Strong business ethics
- 24. Scorecard Management

Work Environment (Location, travel, shift, on-call, etc.)

Location

City of Industry, CA and Duarte, CA

Travel

On occasion


Physical Requirements

- a. Activities. How much on-the-job time is spent in the following physical activities? Show the amount of time by checking the appropriate boxes below.

Amount of Time				
Activity	None	Up to 1/3	1/3 to 2/3	2/3 or more
Stand		X		
Walk		X		
Sit				X
Talk or hear				X
Use hands to finger, handle or feel		X		
Climb or balance	X			
Stoop, Kneel, crouch or crawl	X			
Reach with hands and arms	X			
Taste or smell	X			

- b. Lifting. Does this job require that weight be lifted or force be exerted? If so, how much and how often? Check the appropriate boxes below.

Amount of Time				
Activity	None	Up to 1/3	1/3 to 2/3	2/3 or more

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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			

Direct Reports

Sr. QC Manager
LIMS Administrator
Method Development Principle Analyst

Disclaimer

The above statements are intended to describe the general nature and level of work being performed by people assigned to this classification. They are not to be construed as an exhaustive list of all responsibilities, duties, and skills required of personnel so classified. All personnel may be required to perform duties outside of their normal responsibilities from time to time, as needed.

“Prolacta Bioscience, Inc. is an Equal Employment Opportunity Employer.” Prolacta Bioscience, Inc. is committed to a proactive program of affirmative action and diversity development. The Company will continue to recruit, hire, train, and promote into all job levels without regard to race, religion, gender, marital status, familial status, national origin, age, mental or physical disability, sexual orientation, gender identity, source of income, or veteran status.