

KARLA G LARA

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EDUCATION

**Bachelor of Science (B.S.): Agricultural
Business and Food Industry Management**
California State Polytechnic University,
Pomona
Pomona, CA
June 2015

Associate of Arts (A.A.): University Studies
Imperial Valley College
Imperial, CA
May 2012

QUALIFICATIONS

- Active member of a Product Recall Team. Supported coordinating investigation, product isolation, retrievals, customer notifications, corrective actions and reconditioning of product.
- Facilitated FDA Inspection in 2017
- Experience in ISO 9001:2015, FSSC 22000, ISO 22000, ISO/TS 22002-1, FDA Current Good Manufacturing Practices CFR 21 Parts 110, 111, 117 and 507, Kosher Certification, Halal Certification and Non-GMO Project Verification
- Spanish: native speaking, reading, and writing, with technical understanding
- Experience in Windows computers; proficient in Outlook, Word, Excel, Publisher, and Power Point.

CERTIFICATIONS

- FSPCA Preventive Controls Qualified Individual for Human Food
- FSPCA Preventive Controls Qualified Individual for Animal Food
- Hazard Analysis Critical Control Points (HACCP)
- ISO 9001:2015 Internal Auditor
- Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements (CFR 21 Part 111)
- Environmental Monitoring Program and Risk Management
- Good Manufacturing Practices for the Food Industry (CFR 21 Part 117)
- Allergen Control for Food Processors
- Food Recalls: Essentials for Action

SKILLS

- Cross-functional Team Leadership
- Recalls
- Record-Keeping
- GFSI
- Food Safety
- Quality Systems
- Auditing
- HACCP Plan

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- FDA Food Safety Plan
- Food Defense Program

EXPERIENCE

Earthrise Nutritionals

Quality Management Systems Specialist

January 2017 – Present

- Design and implemented FDA Food Safety Plan for two different processes
- Conduct yearly Mock Recall and act as the Mock Recall Coordinator
- Establish, document and maintain company Quality Management System (QMS) Program
- Conduct yearly HACCP Review
- Act as the Food Safety Team Coordinator
- Trained all employees on current Good Manufacturing Practices (GMP), Preventive Control for Human Food, HACCP, ISO 9001:2015, ISO 22000 and Allergen Awareness.
- Facilitate 3rd party audits for FDA, Certifications (GMP, FSSC 22000, ISO 9001, Kosher and Halal), and Customers.
- Ensure compliance with the GMP requirements for Disease Control, Cleanliness, Education and Training of personnel.
- Independently verify the implementation of quality issue solutions.
- Control of nonconforming products until quality issue is resolved.
- Identify adequate resources to implement Quality Management System program.
- Participate in and coordinate Management System Council meetings.
- Review Quality Management System suitability and effectiveness.
- Review documents and data for compliance.
- Identification of obsolete documents needed to be retained for historical purposes.
- Review and approval of all Standard Operating Procedures, documents and data change.
- Evaluation and selection of subcontractors.
- Independently plan and conduct internal and external audits / assessments and report results to management.
- Independently perform follow up audits to verify corrective action effectiveness.
- Process, coordinates and maintained licenses and permits.
- Managed planned and maintained the Quality Management System department budget.

Earthrise Nutritionals

Quality Management Systems Assistant

December 2015 – January 2017

- Establish, document and maintain the company's Quality Management Systems.
- Ensure compliance with GMP requirements for Disease Control, Cleanliness, Education and Training of personnel.
- Maintained and administratively control all "Controlled Copy" documents.
- Conduct Internal Audits to verify compliance with regulatory, statutory and Company requirements.
- Processing, identification, collection, indexing, accessing, filling maintenance and disposition of quality records.

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- Administration, tracking and status control of CAPA (Corrective Actions, Preventive Actions) as well as maintained appropriate logs to track initiation, evaluation, review, approval, independent verification and close out.
- Review document and data for adequacy.
- Document and data change review and approval.
- Process, coordinated and maintained licenses and permits.
- Schedule and assist during 3rd party audits.