QUALITY & REGULATORY
APPRENTICESHIP PROGRAM

Authorized Apprenticeship Sponsor

Learning Partners

Registered Apprentice

Host Company

SOUTHERN
CALIFORNIA
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CENTER

TRAINING TOPICS/OUTCOMES
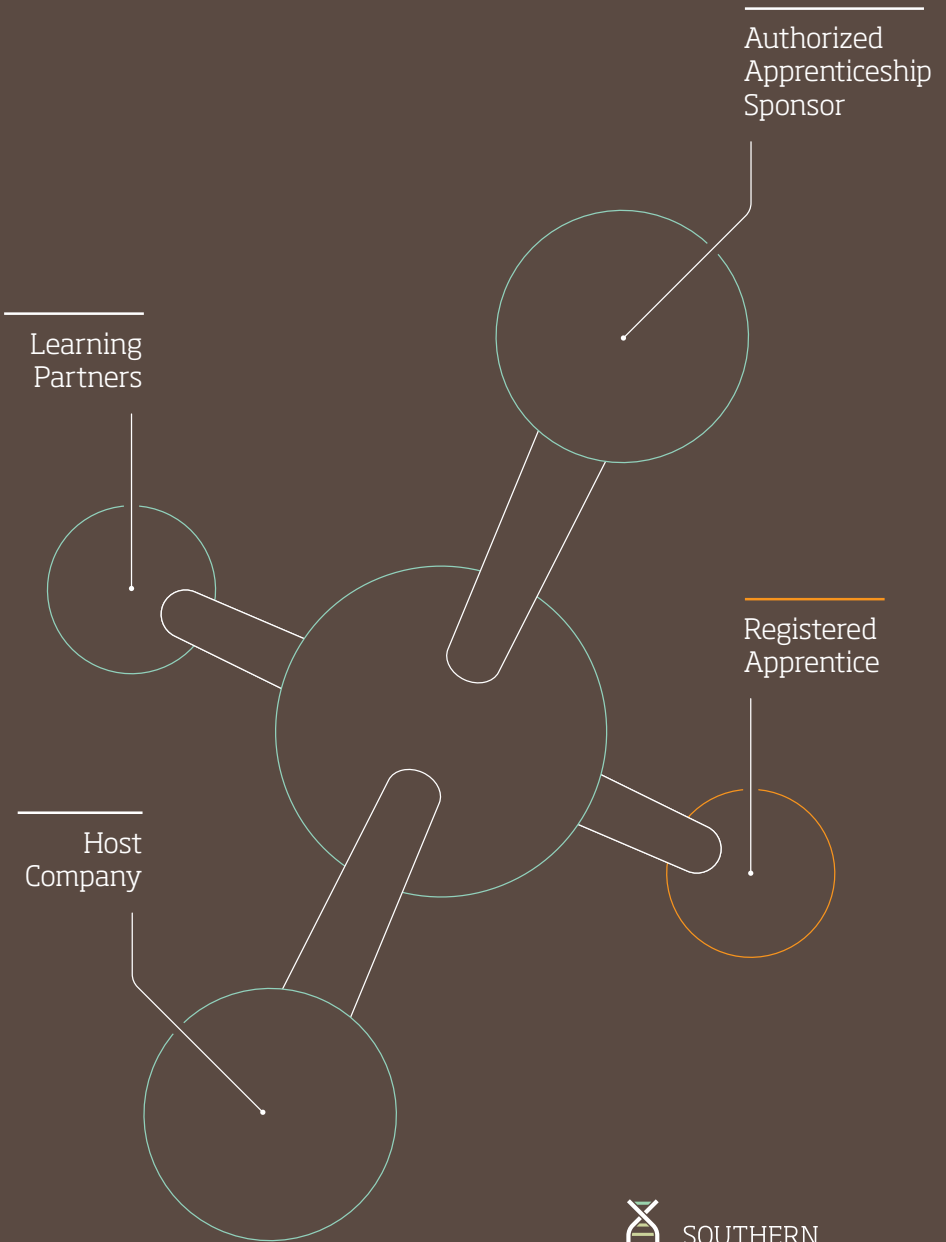
Training Topics/Outcomes	Microbiology Quality Control Technician	Chemistry Quality Control Technician	Clinical Data Coordinator	Clinical Research Coordinator	Clinical Trial Associate	Quality Assurance Associate	Drug Safety Associate	Regulatory Affairs Associate GXP Auditor	Regulatory Affairs Specialist	Regulatory Compliance Associate
Microbiological testing finished products	•									
Analyze microbiological test data	•									
Calibrate/maintain testing equipment	•									
Aseptic techniques	•									
Inventory control	•									
Quality assurance concepts/techniques	•									
Laboratory test methods	•									
Quality improvement tools	•	•						•		
Apply good documentation practices	•	•	•	•	•	•	•	•	•	•
Industry regulatory guidances	•	•	•	•	•	•	•	•	•	•
Product testing & inspection		•								
Environmental monitoring		•								
Validate data with written reports		•								
Apply good manufacturing practices		•						•		
Continuous improvement techniques		•						•		
Clinical trial team support			•	•	•					
Collect essential clinical trial data			•							
Data entry, queries/resolutions, verification			•							
Data maintenance			•							
Clinical trial operational/logistical assistance			•	•	•					
Apply good clinical practices			•							
Electronic data capture			•							
Clinical trial data oversight & support			•							
Laboratory & medical terminology			•	•	•					
Collect, maintain, & file clinical trial documentation				•	•					
Iclinical trial oversight & support				•	•					
Trial master file oversight & support				•	•					
Drug safety management support							•			
Medical monitoring support							•			
Sop & regulatory compliance							•			
Triage incoming reports (complete, legible, valid)							•			
Safety & adverse event reporting							•			
Investigator, sponsor, monitor roles/responsibilities							•			
Inspect vendor products (stds/specs compliance)								•		
Inspect vendor facilities (stds/specs compliance)								•		
Submit audit reports (compliance, correctives)								•		
Coordinate & document internal regulatory processes									•	
Assist in compile/prepare submission docs									•	
Regulatory pathways/operations									•	•
Regulatory submissions/review process									•	
Manage/integrate quality management program										•
Manage/integrate quality improvement program										•
Guidance/tech support for quality programs										•
Strategic planning for recalls										•
Industry-recognized 3rd party certification*										
CQIA	•	•	•	•	•	•	•	•	•	•
RAC	•									
GLP										
OSHA 30	•	•						•	•	•
OSHA HAZW OPER	•	•						•	•	•
CRCC				•	•					
GCP							•			
SCDM			•							

WHAT IS A REGISTERED APPRENTICESHIP?

A registered apprenticeship is NOT an internship. It is structured, full time employment combined with part-time related instruction.

WHAT APPRENTICESHIPS ARE CURRENTLY AVAILABLE IN THE LIFE SCIENCES INDUSTRY IN CALIFORNIA?

Nine (9) apprenticeships are registered with the California Department of Apprenticeship Standards – see table.

WHAT ARE THE BENEFITS OF ENROLLING IN A LIFE SCIENCES APPRENTICESHIP?

With a registered apprenticeship you receive:

» **A PAYCHECK:** From day one, you will earn a paycheck guaranteed to increase over time as you learn new skills alongside a mentor/expert in the field.

» **HANDS-ON TRAINING:** As an apprentice, you will receive practical on-the-job training in a wide selection of life sciences industries, such as: food manufacturers and processors, pharmaceuticals, biotechnology companies, medical device manufacturers, nutraceuticals and cosmeceuticals.

» **AN EDUCATION:** You'll receive hands-on training and have the potential to earn college credit and an industry-recognized 3rd party certificate.

» **A CAREER:** Once you complete your apprenticeship, you will be on your way to a successful long-term career with a competitive salary, and little or no educational debt.

» **NATIONAL INDUSTRY CERTIFICATIONS:** When you graduate from an apprenticeship program, you will be certified in a number of industry recognized areas such as safety, data management, clinical practices, and others. In addition, you will receive an Apprenticeship Completion Certificate that is recognized nationwide.

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HOW LONG DOES IT TAKE TO COMPLETE A LIFE SCIENCES APPRENTICESHIP PROGRAM?

Each apprentice will complete approximately 4000 hours of paid on-the-job training and approximately 300 hours of related supplemental instruction (online and classroom-based). Most individuals will take 1 ½ and 2 years to complete their apprenticeship.

WHAT ARE THE COSTS ASSOCIATED WITH APPRENTICESHIP THAT I WILL BE RESPONSIBLE FOR?

There is currently no charge to apply or enroll in a life sciences apprenticeship program in California. Training and mentorship are currently covered by grant funds. The company that hosts the apprentice contributes to base pay so that an apprentice earns the entire time they are learning.

WHAT WAGES CAN I EXPECT DURING MY LIFE SCIENCES APPRENTICESHIP?

Each apprentice will begin earning approx. 50% of an experienced worker's wage, which will increase incrementally as the apprentice becomes more experienced. Apprentices are paid (as W2 employees) and are eligible for benefits that include health insurance, paid sick leave, 401K and dental during the entire program.

WHAT WAGES CAN I EXPECT ONCE I HAVE COMPLETED A LIFE SCIENCES APPRENTICESHIP?

Once experienced worker status is achieved pay scales range between $30 and $40 per hour.

WHAT TYPES OF COMPANIES HOST REGISTERED LIFE SCIENCES APPRENTICES?

Companies that manufacture & process food or medical devices and those that create pharmaceutical, biotechnology, nutraceuticals, or cosmeceuticals would like to host apprentices.

HOW DO I KNOW IF I AM ELIGIBLE FOR A LIFE SCIENCES APPRENTICESHIP?

Apprentices must either be a military veteran or have a minimum of an Associate's degree from a Science, Technology, Engineering or Math (STEM) program. Bachelor's, Master's, or PhD degrees will reduce the apprentice's required time to complete the program. Those individuals who are currently not eligible, should inquire, and will be counseled as to pre-apprenticeship opportunities available to better prepare for entry into a life sciences apprenticeship.

WHAT STEPS DO I TAKE IF I AM INTERESTED IN ONE OF THE LIFE SCIENCE APPRENTICESHIPS?

To apply for a life sciences apprenticeship in California contact Lewie Casey, CQIA, Apprentice Program Logistics Coordinator, Rx Research Services at 818 552 4173 or lcasey@meirxrs.com http://meirxs.com/apprentices/
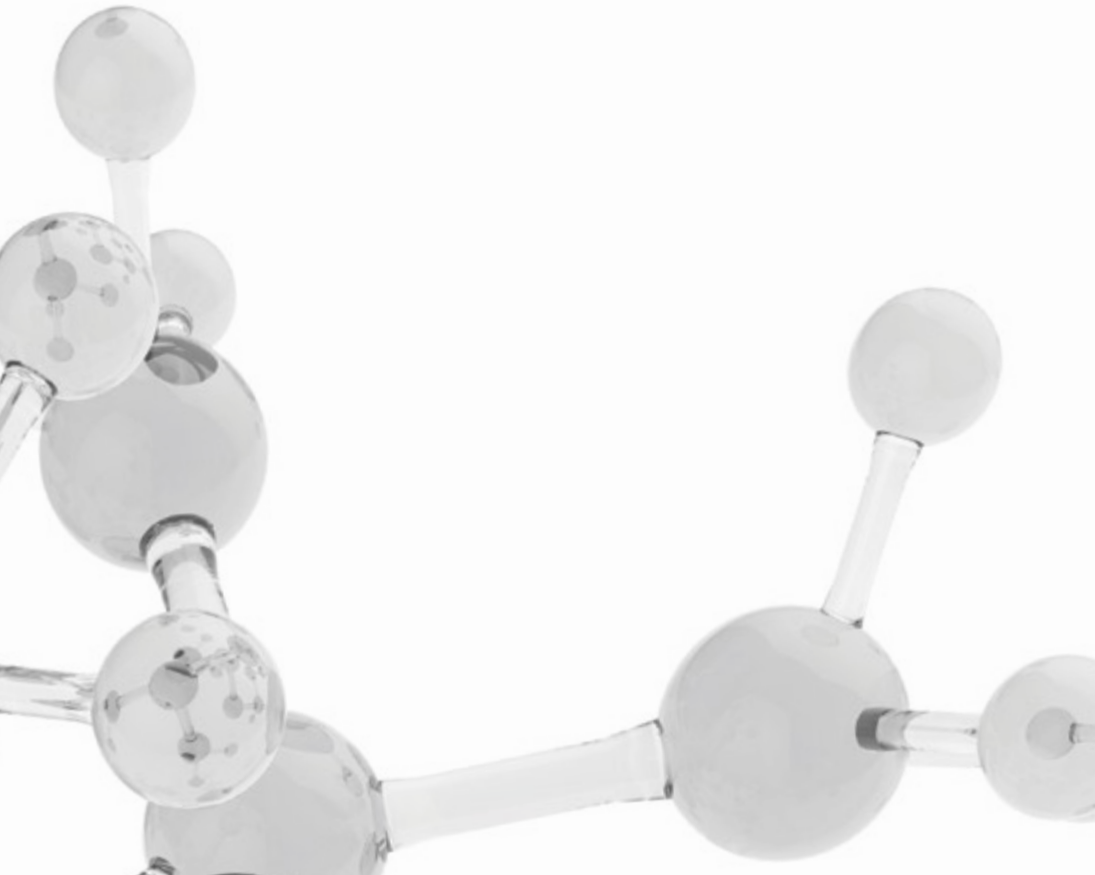
WHAT DO APPRENTICES WHO ARE CURRENTLY IN THE PROGRAM OR HAVE COMPLETED THE PROGRAM HAVE TO SAY?

Eddie Needham is a Quality Control Technician Apprentice at Catalina Offshore Products, Inc. (April 13, 2016) and shared his story…

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Food companies can expect approximately ten inspections per year from federal, state and local regulating entities. In order to stay compliant, and more importantly protect their brand and avoid a costly recall, food companies are turning to apprentices in quality control and regulatory affairs. U.S. Navy Veteran Eddie Needham is a Quality Control Technician Apprentice for Catalina Offshore Products and the Innovative Apprenticeships for Life Sciences Industry program's first apprentice in San Diego. While the military and food industry are very different, Eddie has been able to use his previous experience in the Navy to thrive at Catalina Offshore Products doing quality and inventory control. "I feel the apprenticeship program has given me a great opportunity to transfer my Navy aviation quality control experience into the food industry so I can start a completely new career." Eddie is pleased with his experience at Catalina Offshore Products and feels that he is learning a lot. Likewise, owner Dave Rudie and manager Nathan Phillips are just as pleased. They are always feeling pressure from regulating agencies like the FDA and welcome Eddie's quality assurance background. They feel he will soon be an expert in seafood inventory control and quality control, and will have ample opportunity to grow in this field.

Karina Rodriguez has a Master's degree in Food Science from Chapman University; however her previous food industry experience was very limited.

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The apprenticeship program while working with a mentor to guider her in her learning process has provided many opportunities for her to gain important skills and knowledge in order to advance in her career as a quality assurance technician, auditor, and overall food professional. In the past year she has worked for six companies as a quality assurance technician; and as a food consultant and bilingual trainer for another. As a food consultant she has also worked to help companies get ready for third party audits that are sometimes required by customers or as suppliers. Her work mainly involves in facilitating all food companies to get ready for FSMA. Working for so many food companies has also provided her with a wide knowledge of food production and the necessary leadership skills to communicate effectively with others on the importance of food safety. "I'm very grateful to the apprenticeship program and the mentor for guiding me this past year. They truly value us and make all possible efforts to provide the tools necessary to make us succeed and grow as individuals and professionals.