QUALITY & REGULATORY APPRENTICESHIP PROGRAM

Authorized Apprenticeship Sponsor

Learning Partners

Registered Apprentice

Host Company

SOUTHERN CALIFORNIA BIOTECHNOLOGY CENTER
### Training Topics/Outcomes

| 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 guidelines | 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 |
DOES YOUR COMPANY HAVE ANY OF THE FOLLOWING CHALLENGES?

» Difficulty finding workers with the right quality & regulatory skills?

» High turnovers in quality & regulatory positions?

» Challenges helping employees keep pace with continuing industry advances/regulations?

» Limited support in upskilling employees with on-the-job training?

» Difficulty providing professional growth experiences to retain quality & regulatory employees?

» Establishing quality practices compliant with newly enforced FSMA (Food Safety Modernization Act)?

If the answer is “yes” to any of these questions, then hosting apprentices could be the right strategy for your company to employ a highly skilled diverse workforce with higher productivity, elevated morale, and lower turnover costs. Apprentices help protect your brand, help avoid costly recalls, and support compliance in a highly regulated work environment.

WHAT IS A REGISTERED APPRENTICESHIP?

A registered apprenticeship is NOT an internship. It is structured, full-time employment combined with part-time related instruction. Key differences between apprenticeships & internships include:

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<th>APPRENTICESHIPS</th>
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<td>On-the-job training</td>
<td>Career-oriented</td>
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<td>Training designer</td>
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<td>Benefit to employer</td>
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<td>Career exploration</td>
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<td>Educational institution</td>
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<td>Coincidental</td>
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<td>Continue education / part time employment</td>
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WHAT APPRENTICESHIPS ARE CURRENTLY AVAILABLE IN THE LIFE SCIENCES INDUSTRY IN CALIFORNIA?

Nine (9) apprenticeships are registered with the California Department of Apprenticeship Standards (CA DAS) – see the table. The schedule of work task objectives have been designed by industry and approved by the CA DAS. Depending on the apprenticeship selected, apprentices will complete identified 3rd Party Certifications.

WHAT IS THE DIFFERENCE BETWEEN THE APPRENTICESHIP SPONSOR AND A HOST COMPANY?

Rx Research Services (RxRS) is the State & Federal-authorized apprenticeship program sponsor. As the program sponsor, RxRS is the employer of record for each apprentice for each of the nine (9) registered life science apprenticeships. Responsibilities include:

» Apprentice recruitment, identification, screening, and processing
» Secures OJT training site with host companies
» Covers benefits and insurance for each apprentice for the duration of the apprenticeship
» Provides a mentor for each apprentice that will facilitate training and ensure attainment of identified competencies
» Measures attainment of job competencies
» RxRS pays for all Related Supplemental Instruction, all training supplies and materials required for certification prep and for certification exam fees.
» Administers the apprentice program; liaisons with host companies, community colleges, grant and funding agencies, and the CA DAS
» Maintains all official records and paperwork for each apprentice
» Oversees registered apprenticeship program viability, compliance with all regulations including State of CA Labor Law, and ensures sustainability
» Collaborates with community colleges and host companies to continuously improve the apprenticeship program
WHAT DOES AN APPRENTICESHIP HOST COMPANY DO?

The host company is at the foundation of an apprenticeship program and the skills needed by their workforce are at the core. Host companies play an active role in the program by:

» Choosing which apprenticeships to host
» Interviewing up to three (3) potential apprentices that have been pre-screened by RxRS
» Contracting with RxRS to pay wages (beginning at a fraction of an experienced employee’s rate)
» Hosting apprentice(s) for the duration of the apprenticeship
» Providing on-the-job training
» Paying progressively higher wages as skills increase
» Verifying hours of attendance/participation and providing periodic apprentice evaluation
» Collaborating with RxRS to continuously improve the apprenticeship program

HOW LONG DOES IT TAKE FOR AN APPRENTICE TO COMPLETE A REGISTERED LIFE SCIENCES APPRENTICESHIP?

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 between 1½ and 2 years to complete their apprenticeship.

WHAT WAGES DO HOST COMPANIES PROVIDE TO LIFE SCIENCES APPRENTICES?

Each apprentice will begin earning a fraction of an experienced employee’s wage, which will increase incrementally as the apprentice becomes more experienced.
IS THE HOST COMPANY OBLIGATED TO HIRE THE APPRENTICE BEYOND THE APPRENTICESHIP TRAINING PERIOD?

No, but many companies do choose to retain these valuable employees.

WHAT STEPS DO I TAKE IF I AM INTERESTED IN HOSTING AN APPRENTICE?

Contact Paul Dionne, Apprentice Program Host Company Developer, Rx Research Services at

818 552 2625

pdionne@meirxrs.com

or complete an online request at meirxrs.com/apprenticeship-program/

WHAT ARE OTHER EMPLOYERS SAYING ABOUT HOSTING A LIFE SCIENCE APPRENTICE?

“We are pleased with [our apprentice] who has been valuable to effectively upgrade our quality control programs, bring a youthful vision and spirit to our workforce, and help us develop a competent team for the future.”

– Kevin Kimura, Red Shell Foods, Inc., Santa Fe Springs, CA

“We are always feeling pressure from the FDA, but [our apprentice] is applying his quality assurance background on our behalf. His experience in the Navy is very different, but he is a quick learner and you still have to find a way to track things and do inventory. By the end, [our apprentice] will be an expert in seafood inventory and quality control.”

– David Rudie, Catalina Offshore Products, Inc., San Diego, CA