

**PROGRAM APPROVAL APPLICATION**  
**NEW or SUBSTANTIAL CHANGE or LOCALLY APPROVED**  
**(This application may not exceed 3 pages)**

**Fill In Form**

Medical Device Quality Assurance  
 Proposed Program Title

Fall 2017  
 Projected Program Start Date

Santa Ana College  
 College

Rancho Santiago Community College District  
 District

**Contact Information**

Bart Hoffman  
 Voting Member

Dean, Career Education and Workforce Development  
 Title

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 Phone Number

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 Email

**Goal(s) of Program (Check all that apply):**

X Career Technical Education (CTE)       Transfer       Other

**Type of Program (Check all that apply):**

Certificate of Achievement 12-17 (or 17-27 quarter) units      X Certificate of Achievement 18+ semester (or 27+ quarter) units  
 Associate of Science Degree       Associate of Arts Degree

**Reason for Approval Request (Check One):**

X New Program       Substantial Change       Locally Approved

**Program Information**

0934.60      Recommended [Taxonomy of Program \(TOP\) Code](#)

Units for Major-Degree

\_\_\_\_\_ Total Units for Degree

18      Required Units-Certificate

**Written Form**

**1. Insert the description of the program as it will appear in the catalog. (See PCAH pp. 142 and 170)**

A certificate in the Medical Device Quality Assurance program prepares students for prospective careers in the manufacturing, development, and/or design of medical devices, depending on work experiences and academic skillsets. Students will gain knowledge of FDA requirements for Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP) enhanced by experienced lecture materials, in-class workshops, presentation exercises, laboratory demonstrations, and exposure to other manufacturing technology disciplines. Students will have hands-on lessons to develop skills needed in the production or laboratory setting. Students will be prepared for entry level positions in medical device repairs and medical device preparations, such as Medical Device Assembler, Medical Device Inspector and Medical Equipment Repairer.

**2. Provide a brief rationale for the program.**

There is a lack of skilled employees in this area. We have heard this repeatedly from our Advisory Committee members as well as researching the labor market. Furthermore, there is much student interest in this program both from those first entering and upskilling.

**3. Summarize the Labor Market Information (LMI) and employment outlook (including citation for the source of the data) for students exiting the program. (See PCAH pp. 85-88, 136, 147, 148, 165, 168, and 176)**

According to the Labor Market Information of Estimated Employment and Projected Growth for Medical Equipment Repairers and Precision Instrument Repairers, the average number of yearly job openings for Los Angeles and Orange Counties for Medical Equipment Repairers is estimated to be 141 and for Precision Instrument Repairers is estimated to be 68. This results in 209 job openings annually. According to the Chancellor’s Office DataMart, over the past 3 years, there were 47 completions at the community colleges in Los Angeles and Orange counties for programs with a TOP code of 0934.60 Biomedical Instrumentation. The highest year was in 2014-2015 with 18 completions. Therefore 209 minus 18 would result in a Net Annual Labor Demand of 191 jobs.

<http://www.labormarketinfo.edd.ca.gov/>

**4. List similar programs at other colleges in the Los Angeles and Orange County Region which may be adversely impacted. (There is space for 10 listings, if you need more, please contact [laocrc@rscdd.edu](mailto:laocrc@rscdd.edu))**

| College    | Program  | Who You Contacted | Outcome of Contact |
|------------|--|-------------------|--------------------|
| NOCCCD SCE | Quality Assurance Management for Medical Devices | Steve Donley      | Email--Supportive  |
| LA Valley  | Biomedical Equipment Technology                  | Alex Davis        |                    |
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5. List all courses required for program completion, including core requirements, restricted electives and prerequisites. (There is space for 20 listings, if you need more, please contact [laocrc@rscdd.edu](mailto:laocrc@rscdd.edu)).  
 (See PCAH pp. 143 and 171)

| Courses  | Course Number | Course Title                           | Units |
|----------|---------------|--|-------|
| Required | MNFG 111      | Basic Mechanical Blueprint Reading     | 2     |
| Required | MNFG 153      | Technical Mathematics                  | 3     |
| Required | MNFG 114      | Geometric Dimensioning and Tolerancing | 3     |
| Required | MNFG 116      | QC Operations with Verisurf Software   | 3     |
| Required | MNFG 117      | QC Operations with PC-DMIS CMM-1       | 3     |
| Required | MNFG 120      | Introduction to Medical Device Quality | 2     |
| Required | MNFG 121      | Quality Control for Medical Devices    | 2     |
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| Total    |               |  | 18    |

6. Include any other information you would like to share.

Santa Ana College currently has many students taking CNC courses. These students can apply these skills to the Medical Devices area.