

Date: June 12, 2019

Time: 8:30am-4:30pm

Ohlone College  
Newark Center Campus  
Room TBA

# APPLIED STATISTICS (WITH EMPHASIS ON RISK MANAGEMENT) IN MANUFACTURING, R&D AND QA/QC — INTERMEDIATE

## Life Sciences/Biotechnology Workshops

### THE WORKSHOP

This one-day workshop provides an introduction to (or a review of) the most commonly used statistical methods and tests used in the biotech industry. The major topics covered include: relevant regulatory requirements, confidence intervals, null-hypothesis, significance, p-values, t-tests, statistical "power", confidence/reliability calculations, tolerance limits, attribute vs. variables data calculations, normal vs. non-normal data calculations, K-tables, and normality-tests / normality-transformations, & how to choose sample size for validation lots (including justification for use of only 3 validation lots). After finishing this workshop, the attendee will be better able to comply with company SOP's on statistics, and better able to perform data analysis required by product/process validation protocols. This workshop provides 0.7 recertification units for those seeking or renewing ASQ CQE or RQE or similar certifications. Previous completion of the "Basic Statistics" workshop in this series (or equivalent training/experience) is required.



### THE INSTRUCTOR

John Zorich (MS, ASQ CQE) has worked in the biotech industry (in QA/QC, Mfg. and R&D) since 1979, and has been an independent statistical consultant and trainer to that industry since 1999. His consulting clients have included several large multi-national biotech companies as well as many Silicon Valley (SV) startups. He designs, validates, and sells statistical application software programs that have been purchased by more than 110 companies, world-wide. He's been the in-house statistical consultant and trainer since 2006 for DEKRA (one of the EU MDD "Notified Bodies"). He's taught seminars in Applied Statistics for many of his clients as well as for SV ASQ Biomedical, UC Santa Cruz Extension, San Jose State Univ. (Graduate Biomedical Dept.), and SV Polytechnic Institute. He's given more than 140 statistical seminars/webinars through commercial training companies since 2014. And he's taught this Ohlone workshop annually since 2005.

**Registration:** Enrollment fee is \$100.

<https://bit.ly/2HbGgYv>

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Ohlone College  
Newark Center Campus  
39399 Cherry Street  
Newark CA 94560

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Questions?  
Contact  
Phone: 510-742-3159  
E-mail: [workshops@ohlone.edu](mailto:workshops@ohlone.edu)

Sponsored by the Northern California Bay Area Biotechnology Center at Ohlone College in partnership with the Life Sciences/Biotechnology initiative of the California Community Colleges Chancellors Office of Workforce and Economic Development.

