

Salt Lake Community College

Biomanufacturing Program

Certificate of Competency *presented to:*

for mastery of the core skills in
Quality Systems & Regulations

"This product was funded by a grant awarded under the President's Community-Based Job Training Grant as implemented by the U.S. Department of Labor's Employment & Training Administration. The information contained in this product was created by a grantee organization and does not necessarily reflect the official position of the U.S. Department of Labor. All references to non-governmental companies or organizations, their services, products, or resources are offered for informational purposes and should not be construed as an endorsement by the Department of Labor. This product is copyrighted by the institution that created it and is intended for individual organizational, non-commercial use only."



STEP AHEAD.

Vivian Ngan-Winward, Director
Biomanufacturing Program

Date

Quality Systems & Regulations

Core Skills List

Understanding Quality: Basics & History

Quality and Regulatory System Types

Understanding Regulations: Introduction, History & Governing Bodies

ISO 9001 Quality Management System

- Structure & Function
- Documents
- Suppliers
- Inspections
- Nonconformances
- Audits
- Corrective & Preventative Actions

Continuous Improvements Tools: emphasis on

- Controlling Variation
- Radar Diagram
- Brainstorming
- Check Sheets
- Root Cause Analysis: Fishbone Diagram & 5-Whys
- Weighted Voting Technique

Working in Teams

- Initiating Teams
- Selecting Members
- Team Stages
- Team Barriers
- Decision Making