



B U S I N E S S
EXCELLENCE
C O N S U L T I N G **Inc.**

Passion for Quality

TRAINING TITLE:

ASQ Certified Quality Engineer Academia
(ACAD-002)

OVERVIEW:

The Certified Quality Engineer is a professional who understands the principles of product and service quality evaluation and control. This body of knowledge and applied technologies include, but are not limited to, development and operation of quality control systems, application and analysis of testing and inspection procedures, the ability to use metrology and statistical methods to diagnose and correct improper quality control practices, an understanding of human factors and motivation, facility with quality cost concepts and techniques, and the knowledge and ability to develop and administer management information systems and to audit quality systems for deficiency identification and correction.

TARGET GROUP FOR THE TRAINING:

This training is aimed at all persons interested in preparing for the ASQ Certified Quality Engineer exam provided twice per year by the American Society for Quality.

LEARNING OBJECTIVES:

- Identify the most widely used quality engineering tools and techniques
- Apply the appropriate tools for each situation faced on a daily basis by a quality engineer
- Prepare for the ASQ Certified Quality Engineer exam

MATERIALS:

Each participant will receive:

- *CQE Primer and Solution Text*, published by Quality Council of Indiana
- *The Certified Quality Engineer Handbook*, published by ASQ Quality Press
- Certificate of Attendance

TRAINING DURATION:

42 contact hours



BEC is authorized by IACET to offer 4.2 CEUs for this program. FULL attendance to the learning event is mandatory to receive CEUs.

NOTE: This is not an Engineering Degree, as prescribed by the laws of the Commonwealth of Puerto Rico.

COURSE INSTRUCTOR:

Hector Ortiz Beltrán is Senior Business Excellence Manager for Johnson & Johnson and has been responsible for supporting the institutionalization of Process Excellence for J&J-PR affiliates, reinforcing the leadership competencies and change management mindset needed for an effective deployment of continuous improvements techniques. He has over 20 years of experience at Johnson & Johnson, in positions of increasing responsibility on the consumer (J&J Hemisferica) and medical devices (Ethicon) sectors as well as J&J Business Services organization. He also provides internal and external consulting services to J&J Master Black Belt Leadership Groups. He received his Master's Degree (MBA) in Materials Management from Turabo University, in Gurabo PR. He is also a licensed Professional Engineer registered in Puerto Rico. Hector is a Master Black Belt for Johnson & Johnson and ASQ Certified Quality Engineer.

Gloryvee Maldonado Pérez is a training consultant within the FDA-regulated industries with more than 10 years of pharmaceutical and medical devices industry experience, in the areas of quality assurance, quality control, regulatory, validation, manufacturing, and packaging. She has a Bachelor Degree in Chemistry from the University of Puerto Rico at Rio Piedras Campus. She also has a Master of Science in Manufacturing Competitiveness, with a specialization in pharmaceutical products, from the Polytechnic University of Puerto Rico in Hato Rey, P.R. Since year 2012, she is fully devoted to consulting under Business Excellence Consulting Inc, focusing on training on related Quality sectors. She is an ASQ Certified Six Sigma Black Belt, and Certified Quality Engineer. She is also a CAPA System Expert Investigator and ISO 13485 Lead Auditor.

Manuel E. Peña-Rodríguez is a process improvement and training consultant within the textiles, electronics, and FDA-regulated industries with more than 20 years of experience in those fields. Since January 2006, he is fully devoted to consulting under Business Excellence Consulting Inc, focusing on training and implementation of Lean Six Sigma initiatives and CAPA / Root Cause Analysis workshops. He also serves as professor in the graduate program in biochemistry at the University of Puerto Rico, Medical Sciences Campus, in San Juan. Manuel received his J.D. degree from the Pontifical Catholic University of Puerto Rico and his master's of engineering in Engineering Management from Cornell University in Ithaca NY. He is also a licensed Professional Engineer registered in Puerto Rico. Manuel is an ASQ Certified Six Sigma Black Belt, Manager of Quality & Organizational Excellence, Quality Engineer, Quality Auditor, Biomedical Auditor, and HACCP Auditor. He is also a Senior member of ASQ and former Chair of the Puerto Rico ASQ Section. He is the author of the book "*Statistical Process Control for the FDA-Regulated Industry*", published by ASQ Quality Press in April 2013 and co-author (with José Rodríguez-Pérez) of the article "*Fail-Safe FMEA*" published in the January 2012 edition of the ASQ Quality Progress magazine.



Title: ASQ Certified Quality Engineer (Day 1)

Lunch from 12:00 – 13:00.

Coffee break: 15 min. each during morning and afternoon session. Time schedule are rough estimates and may vary consequently.

Agenda

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| 8:30 – 9:00 | Certification Overview |
| 9:00 – 10:15 | Management and Leadership <ul style="list-style-type: none"> • Quality Foundations • Quality Management Systems • Strategic Planning • Stakeholders |
| 10:15 – 10:30 | Break |
| 10:30 – 12:00 | Management and Leadership (cont.) <ul style="list-style-type: none"> • Benchmarking • Project Management • Quality Information Systems • ASQ Code of Ethics |
| 12:00 – 13:00 | Lunch |
| 13:00 – 15:00 | Management and Leadership (cont.) <ul style="list-style-type: none"> • Leadership Principles • Facilitation Techniques • Communication Skills |
| 15:00 – 15:15 | Break |
| 15:15 – 17:00 | Management and Leadership (cont.) <ul style="list-style-type: none"> • Customer Relations • Supplier Management • Barriers to Quality Improvement • Practice exercises |



Title: ASQ Certified Quality Engineer (Day 2)

Lunch from 12:00 – 13:00.

Coffee break: 15 min. each during morning and afternoon session. Time schedule are rough estimates and may vary consequently.

Agenda

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| 8:30 – 10:15 | <p>Quality Systems</p> <ul style="list-style-type: none"> • Quality System Elements • Quality System Documentation • Quality Standards & Guidelines • Quality Audits • Audit Types • Audit Components |
| 10:15 – 10:30 | <p>Break</p> |
| 10:30 – 12:00 | <p>Quality Systems (cont.)</p> <ul style="list-style-type: none"> • Cost of Quality • Quality Cost Categories • Quality Cost Bases • Quality Training • Training Needs Assessment • Training Effectiveness • Practice exercises |
| 12:00 – 13:00 | <p>Lunch</p> |
| 13:00 – 15:00 | <p>Product and Process Design</p> <ul style="list-style-type: none"> • Quality Characteristics • Design Review • Quality Function Deployment • Technical Drawings • GD&T Definitions |
| 15:00 – 15:15 | <p>Break</p> |
| 15:15 – 17:00 | <p>Product and Process Design (cont.)</p> <ul style="list-style-type: none"> • Design Verification • Reliability and Maintainability • Preventive Maintenance • Hazard Assessment Tools • Practice exercises |



Title: ASQ Certified Quality Engineer (Day 3)

Lunch from 12:00 – 13:00.

Coffee break: 15 min. each during morning and afternoon session. Time schedule are rough estimates and may vary consequently.

Agenda

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| 8:30 – 10:15 | Product and Process Control <ul style="list-style-type: none"> • Control Plans • Material Control • Material Identification • Material Segregation • Classification of Defects |
| 10:15 – 10:30 | Break |
| 10:30 – 12:00 | Product and Process Control (cont.) <ul style="list-style-type: none"> • Acceptance Sampling • Sampling Concepts • Sampling Standards • Sampling Integrity • Practice exercises |
| 12:00 – 13:00 | Lunch |
| 13:00 – 15:00 | Testing and Measurement <ul style="list-style-type: none"> • Measurement Tools • Definitions • Destructive Tests |
| 15:00 – 15:15 | Break |
| 15:15 – 17:00 | Testing and Measurement (cont.) <ul style="list-style-type: none"> • Nondestructive Tests • Metrology • Measurement System Analysis • Practice exercises |



Title: ASQ Certified Quality Engineer (Day 4)

Lunch from 12:00 – 13:00.

Coffee break: 15 min. each during morning and afternoon session. Time schedule are rough estimates and may vary consequently.

Agenda

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| 8:30 – 10:15 | Control and Management Tools <ul style="list-style-type: none"> • Quality Control Tools • Flow Charts • Histograms • Pareto Diagrams |
| 10:15 – 10:30 | Break |
| 10:30 – 12:00 | Control and Management Tools (cont.) <ul style="list-style-type: none"> • Management & Planning Tools • Affinity Diagrams • Matrix Diagrams • Prioritization Matrices • Activity Network Diagrams • Practice exercises |
| 12:00 – 13:00 | Lunch |
| 13:00 – 15:00 | Improvement Techniques <ul style="list-style-type: none"> • Improvement Models • PDCA • Six Sigma • Kaizen • Lean Techniques |
| 15:00 – 15:15 | Break |
| 15:15 – 17:00 | Improvement Techniques (cont.) <ul style="list-style-type: none"> • Total Quality Management • Corrective & Preventive Actions • Root Cause Analysis • Mistake Proofing • Practice exercises |



Title: ASQ Certified Quality Engineer (Day 5)

Lunch from 12:00 – 13:00.

Coffee break: 15 min. each during morning and afternoon session. Time schedule are rough estimates and may vary consequently.

Agenda

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| 8:30 – 10:15 | Basic Statistics <ul style="list-style-type: none"> • Collecting Data • Types of Data • Measurement Scales • Data Collection Methods • Descriptive Statistics • Graphical Relationships |
| 10:15 – 10:30 | Break |
| 10:30 – 12:00 | Basic Statistics (cont.) <ul style="list-style-type: none"> • Quantitative Concepts • Statistical Conclusions • Probability Terms • Probability Distributions • Continuous Distributions • Discrete Distributions • Practice exercises |
| 12:00 – 13:00 | Lunch |
| 13:00 – 15:00 | Statistical Applications <ul style="list-style-type: none"> • Statistical Process Control • Common vs. Special Causes • Rational Subgrouping • Control Charts |
| 15:00 – 15:15 | Break |
| 15:15 – 17:00 | Statistical Applications (cont.) <ul style="list-style-type: none"> • Control Chart Analysis • Pre-control Charts • Short-run SPC • Capability • Capability Studies • Practice Exercises |



Title: ASQ Certified Quality Engineer (Day 6)

Lunch from 12:00 – 13:00.

Coffee break: 15 min. each during morning and afternoon session. Time schedule are rough estimates and may vary consequently.

Agenda

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| 8:30 – 10:15 | <p>Advanced Statistics</p> <ul style="list-style-type: none"> • Statistical Decision Making • Point Estimates • Confidence Intervals • Hypothesis Testing • Paired-comparison Tests |
| 10:15 – 10:30 | Break |
| 10:30 – 12:00 | <p>Advanced Statistics (cont.)</p> <ul style="list-style-type: none"> • Goodness-of-fit Tests • Contingency Tables • Analysis of Variance • Relationships Between Variables • Linear Regression |
| 12:00 – 13:00 | Lunch |
| 13:00 – 15:00 | <p>Advanced Statistics (cont.)</p> <ul style="list-style-type: none"> • Simple Linear Correlation • Time-series Analysis • Design of Experiments • Terminology • Planning Experiments |
| 15:00 – 15:15 | Break |
| 15:15 – 17:00 | <p>Advanced Statistics (cont.)</p> <ul style="list-style-type: none"> • Block Experiments • Full-factorial Experiments • Fractional Factorials • Other Experiments • Practice Exercises |