

Course: “Business Process Management Introduction: An aid to understanding the Process Approach in ISO 9001:2015 and ISO 13485:2016 Medical Devices” (2.5 CEUs and ASQ RUs)

As organizations transition to ISO 9001:2015 or ISO 13485:2016 Medical Devices, adoption of a process approach (which incorporates the Plan-Do-Check-Act cycle and risk-based thinking¹) will be essential. The revised standard calls for organizations to maintain the current focus on effective process management to produce desired outcomes; and to reflect changes in the increasingly complex, demanding, and dynamic environments in which they operate.

In today's global economy, adoption of a process approach will be essential for organizational success. For many organizations, process activities are interconnected across functional boundaries. Understanding how processes are interconnected will foster communication between process owners and cross-functional teams to resolve quality issues across linking functions. Thus, an organization structured with a process orientation and a culture of process oriented thinking would be in a good position to manage its processes effectively to meet customer requirements.

This course is designed to provide foundational concepts that enable participants to gain a better understanding of the process approach to quality management for meeting customer requirements. You will learn key concepts including:

- Function versus Process View
- Value Chain (comprises of cross-functional processes that directly deliver value to the customer.)
- The Shewhart Plan-Do-Check-Act (PDCA) Cycle (for planning and managing processes.)
- Risk-Based Thinking
- Process Hierarchy (decomposes a major process into sub-processes, activities, and tasks.)
- Activity Components (comprise of **Inputs**; **Controls** such as statutory and regulatory requirements, risks and controls; **Mechanisms** such as personnel, tools, machinery and equipment, computers and software; and **Outputs**.)

Textbook: ABPMP BPM CBOK® (Association of Business Process Management Professionals, A Guide to the Business Process Management Common Body of Knowledge); © Version 3 September 2013.

Note 1: Sources: ISO 9001:2015(E) and ISO 13485:2016 Medical Devices.



Instructor: Nancy S. Q. Chang

Nancy is a Management Consultant with Education added to her practice.

Nancy has over five (5) years of Business Process Management work experiences. As Process Analyst, she has served as a mentor to Process Owners and Process Managers in the design and implementation of business processes. She has also conducted workshops to facilitate the design of business processes. Nancy has performed process modeling at the Enterprise, Business, and Workflow Levels using the IDEF0 (Integrated Computer - Aided Manufacturing Definition for Function Modeling) Format.

Nancy has over fifteen (15) years of management consulting experiences in the Banking Industry involving Operations, and in the Healthcare Industry involving Medical Record Systems. She has worked with corporate executives, operations managers, as well as line managers in the execution of operation reviews, feasibility studies, process modeling, and software evaluations.

Nancy is an advocate of the Six Sigma methodologies which enable businesses to achieve breakthrough improvements. She has worked on two Six Sigma Black Belt Projects sponsored by an Executive for Reliability at the U.S. Army Armament Research, Development & Engineering Center, Picatinny, New Jersey.

Nancy has co-authored the article: "Know More, Do More", published in the January 2011 edition of Quality Progress. She has also been a speaker on topics relating to Business Process Management (BPM) and Quality at the ASQ North Jersey General Section Meetings in January 2012 and in February 2017. Nancy has developed this course in 2014, designed to help students better understand the process approach requirements in the ISO 9001:2015 Standard. She has added ISO 13485:2016 Medical Devices Standard to the course in 2017.

Nancy is a member of the ASQ North Jersey Education Committee and has participated in the teaching of Six Sigma certification exam preparation classes. She has earned an MBA in Operations Research and a BBA in Statistics from Bernard M. Baruch College in New York City. Nancy has the following certifications: ASQ-CSSBB (Certified Six Sigma Black Belt), and ABPMP-CBPP (Certified Business Process Professional).



Who Should Attend

Participants to include: Directors, Managers, Analysts, Quality Assurance staff, other Quality Professionals, and Knowledge workers.

Class Schedule: 25 Contact Hours; 5 Saturdays: 8:30 AM – 2:00 PM.

Course Offering: Saturdays October 21, 2017 - November 18, 2017

Public Class Target Location is either:

Parsippany United Methodist Church
903 South Beverwyck Road
Parsippany, NJ 07054

St. Paul's Episcopal Church
Hillview Avenue & Mountain Way
Morris Plains, NJ 07950

Course Fee: \$495

CEUs and ASQ RUs: 2.5

Registration is always open for onsite courses which we will be happy to run at your own facility.

ASQ North Jersey On-Site Training brings our instructor directly to your organization. This training as well as scheduling is customized to meet your company's needs, and is advantageous for groups of four or more.

For registration, as well as onsite courses, contact:

Carl Perini, Education Committee Chairperson 973-616-4371

ASQ North Jersey Section 304

cperini@asqnorthjersey.org

For e-mail registration, visit website: www.asqnorthjersey.org

- Select Education Menu
- Select Registration Contact

