• Basic water chemistry
• Water quality selection criteria
• EPA, EU, and WHO drinking water standards
• The governing regulatory agencies with direct impact on water systems
• Analytical water grades (1, 2, 3) and reagent water types (I, II, III, IV, with A, B & C subgroups)
• Pharmacopeia water grades (Purified, Highly Purified, Water for Injection & Clean Steam)
• Pretreatment component equipment - selection and operating principals
• Final treatment options (reverse osmosis, vapor compression, single-effect and multiple-effect stills)
• Opportunities for energy and water resource conservation
• Point of use criteria such as temperature, location, time-of-day, and demand (GPM & GPD)
• System design including materials of construction, generation, storage and distribution options
• Trend reports (analysis, problem identification, predictive value)
• Control systems, data historian, secure access, set points and alarms
• Managing performance deviations and component failure
• Direct and in-direct impact analysis
• Quality by design including risk assessment
• Instrument calibration for critical, non-critical, and informational only devices
• Maintenance impacts to system performance, reliability, and validation
• The importance of as-built documentation- user and field directed changes

ABOUT CfPIE
Learn from the Leader
In a life sciences industry that has faced nearly $15 billion in fines and compliance-related settlements over the last several years, The Center for Professional Innovation & Education (CfPIE) is a better alternative for maintaining high standards, protecting industry reputations, and enhancing personal growth. Since 2001, we have embraced a singular goal—to provide the highest quality education to life science professionals. Today, as the global leader in quality life sciences training, we offer the largest range of course options for professional development in pharmaceutical, medical device, biotech, and skin/cosmetics disciplines. We are dedicated to enriching that reputation by conveying content relevant to the needs of individuals and organizations facing intense scrutiny in those highly technical disciplines.

COURSE DESCRIPTION
The course consists of interactive lectures, discussions, and imbedded exercises. Participants will also be placed in several real life situations where they complete a compliance review of a schematic process flow diagram, analyze failures using trend reports, critique a risk assessment, and perform a change control analysis including the impact of requested or proposed modifications.

The course is designed to provide the attendee with a practical understanding of the following topics:

• Basic water chemistry
• Water quality selection criteria
• EPA, EU, and WHO drinking water standards
• The governing regulatory agencies with direct impact on water systems
• Analytical water grades (1, 2, 3) and reagent water types (I, II, III, IV, with A, B & C subgroups)
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HOW TO REGISTER

1. Go to http://www.cfpie.com
2. Go to “REGISTER HERE” and select your course.
3. Create an account and register for your course.

The Center for Professional Innovation & Education, Inc.
7 Great Valley Parkway
Suite 295
Malvern, Pennsylvania 19355

CANCELLATION POLICY
All cancellations must be in writing and are subject to a $350.00 cancellation fee. If cancellations are made more than 30 days prior to the course, a refund less the cancellation fee will be provided. If cancellations are made less than 30 days prior to the course, a voucher good for attendance at an upcoming course will be provided. The voucher, which can be used by the registrant or anyone else within his/her company, will be valued at the registration fee minus the $350.00 cancellation fee.

If a registered attendee does not cancel and fails to attend, neither a refund nor voucher will be issued. All course cancellations must be in writing and emailed sent to info@cfpie.com. Registrants are responsible for contacting the hotel and canceling their room reservations.

CfPIE reserves the right to alter the venue, if necessary.

Substitution Policy - Classroom Courses
Substitutions are accepted at no penalty with written notification from the original registrant in advance of course. All substitution requests must be in writing and emailed to info@cfpie.com.

CfPIE also offers on-site courses for 10 or more attendees. Contact us at info@cfpie.com.
INSTRUCTOR CREDENTIALS

Richard F. Newmiller has over 20 years of Pharmaceutical Industry experience. Presently he is a Management Consultant supplying Engineering and project management services with a unique background that includes corporate, contractor, designer and owner perspective.

He has provided Engineering, consulting, operations, and maintenance expertise as an employee for a variety of manufacturing and research organizations including Merck, SmithKline Beckman (now GlaxoSmithKline), Centocor (now Johnson & Johnson) and Wyeth (now Pfizer) where he was Senior Director of Project Engineering in Global Engineering Services. Richard is also consulting in the regulated medical marijuana industry providing guidance and direction in the areas of scope definition, compliance, operating environment, design and engineering management, budget and schedule development, and commissioning.

Richard has executed hundreds of Pharma projects with a value in excess of $2 billion. Responsibilities included obtaining funding, contractor selection, design, engineering, start-up, commissioning, validation and assisting with establishment and product licensing. Those projects produced products that ranged from topicals, liquids, and solid dosage to injectables supporting OTC, diagnostic, biological, and pharmaceutical operations in the US, Canada, Puerto Rico, England and Holland. Rich received his B.S. in Mechanical Engineering from Drexel University, and an MBA from Temple University; he earned his Professional Engineering (PE) license in Pennsylvania.

LEARNING OBJECTIVES

Upon completion of this course, each participant will have a comprehensive overview and understanding of water systems and how they are selected, installed, commissioned, validated, operated, and maintained in a regulated environment. The course content will enable the participant to understand system design, analyze performance data, ask more informed questions, and challenge findings when communicating in a group setting on a broad variety of water issues. In addition, the regulatory agencies with a direct impact on the design and operation of both compendial and non-compendial systems will be presented.

HOTEL INFORMATION

The Hilton LAX, Los Angeles, CA (CfPIE room rate of $167/night if booked 3 weeks in advance of the course date)

The Desmond Hotel & Conference Center, Malvern, PA (CfPIE room rate of $141/night if booked 3 weeks in advance)

Club Quarters Hotels, Boston, MA (CfPIE room rate of $255/night if booked 4 weeks in advance)

DoubleTree by Hilton London - Victoria (CfPIE room rate of £199.00/night if booked 4 weeks in advance)

FIRST DAY

Introduction
• Agenda review
• Basic water chemistry
• Allowable drinking water contaminates
• Packaged water exercise

Classification of Water Purification Systems
• Potable water and process water (filtered, softened, etc.)
• Analytical water grades 1, 2, & 3
• Reagent water types I, II, III & IV (sub-groups A, B & C)
• Pharmacopeia water grades (Purified, Highly Purified, & Water for Injection)
• Clean steam (condensate)

Governing Regulatory Agencies
• Compendial specifications (USP, EP, & JP)
• FDA and European GMPS
• EPA, ASTM, CLSI, ISO, ICH, BS, WHO, ISPE, and others
• Exercise

Unit Operations
• Pretreatment component equipment and arrangement options based on feed water analysis
• Methods to control turbidity, particulates, hardness, metals, organic, and microbiological impurities
• Final treatment (reverse osmosis, vapor compression, single-effect and multiple-effect stills)
• Sampling, cleaning and sanitization requirements
• Energy/resource conservation measures

System Design Parameters
• Point of use criteria: temperature, location, time-of-day, and demand (GPM & GPD)
• Generation rate, storage capacity, peak demand limit, batched vs continuous operation, sanitization schedule, maintenance shutdowns
• Localized systems: packaged water, single or multiple POU bench top units
• Distributed systems: storage tanks (single, batched, secondary), distribution network (single pipe – one way flow, recirculating, hot loop, cold loop, POU temperature control, flushing and sanitization schemes, etc.)
• Exercise

Distribution System Components
• Materials of construction
• Types of stainless steel
• Sanitary and non-sanitary piping fittings
• Valve types and selection criteria
• Sample ports and steam coolers
• Exercise

Recap, Questions and Answers

SECOND DAY

Commissioning and Qualification
• Plan development and flow chart with controls – observations, exceptions, and variances
• Direct and in-direct impact assessment
• The importance of as-built documentation – ETOP
• Is the initial start-up commissioning?
• Risk assessment, team approach with SMEs – identification, probability, and impact
• Sampling plan – location, frequency and duration
• Validate emergency maintenance during typical failures
• Exercise

Operations and Maintenance
• Accountability, SOP’s, and training
• Preventative & predictive maintenance
• Daily inspection checklist, trend reports, alarms
• Cleaning, sanitization, rouging
• Consumables replacement, yearly shut-down
• Managing performance deviations and component failure (microbial limits, pH, distribution pump, vent filter, rupture disc, etc.)
• Startup challenges (initial and post shut-down)
• Exercise

Instrumentation Calibration
• Identification of critical, non-critical, and informational instruments
• Program set up and impact to operations
• Required actions for out-of-spec “as found” conditions

Control and Monitoring System Performance
• SCADA type systems, data historian, secure access
• Control set points – range and tolerances
• Alarms – alert, action, failure
• Conductivity, temperature, flow rate, pressure, CFUs, etc.
• Trend reports (analysis, problem identification, predictive value)
• Exercise

Recap, Questions and Answers

Course Evaluation