



# GMP-Conforming Pilot Plants and Production Facilities

- Planning
- Design
- Maintenance

by  
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San Diego, CA

To be announced

For a newly discovered product it is important that it reaches the market early to **secure market share**. It is equally important that it can be manufactured at an affordable cost to **ensure profitability**. These goals require not only a **well coordinated process development program**, but also a **well planned facility design and construction effort**.

This course will present **state-of-the-art solutions** to facility design issues. Because the pharmaceutical industry is highly regulated, this course will also examine the impact of **Good Manufacturing Practices** and **safety and environmental issues** upon facility design. The course will further highlight the **synergistic interaction of architecture and engineering** in producing facilities that are **cost-effective** and provide a **pleasant and efficient work environment**.

Because facilities must meet not only the **process requirements and user expectations**, but also meet the **project budget**, this course will also examine approaches to **controlling project scope and budgets**.

Participants will benefit by a better understanding of the many aspects of pharmaceutical facility projects, from the **planning, design, and engineering** to the **construction, commissioning and validation** of the facility.

## Course Content:

- **Project Definition**
- **Design Approach**
- **Regulatory Considerations**
  - Current Good Manufacturing Practices
  - International GMP's
  - Safety and Biocontainment
- **Architectural, Site and Layout Considerations**
  - Site Selection
  - Masterplanning
  - Unidirectional Flow
  - Schematic Design
  - Building and Site Security
  - Architectural Finishes
- **Pharmaceuticals**
  - Pharmaceutical Fine Chemicals
  - Aseptic Liquid Filling
  - Oral Dosages
  - Specific Facility Requirements

- **Biotechnology**
  - Fermenters and Bioreactors
  - Equipment for Recovery, Purification, Formulation, Filling and Packaging
  - Specific Facility Requirements
- **CIP and SIP Design**
  - Equipment Design Details
  - Sterile Piping Designs
- **Instrumentation and Controls**
- **Utility Systems**
  - Purified Water
  - Pure Steam
  - Biowaste Inactivation
  - Mechanical Building Utilities
- **Cleanroom and HVAC Design**
- **Facility Maintenance**
- **Building and Site Security**
- **Warehousing**
- **Project Planning and Scheduling**
  - Specifications
  - Cost Estimating
- **Procurement**
- **Construction**
- **Commissioning and Start-Up**
- **Validation**

## Course Faculty:

**Kim L. Nelson, Ph.D.** is Sr. Director of Bioprocess Technology with CRB. He has more than ten years of experience in the design and operation of bio-pharmaceutical facilities, working with such companies as SmithKline Beecham, Genzyme, Amgen, Hoffmann-La Roche, Connaught, California Biotechnology (Scios Nova), Syntex, Amvax, Serono Laboratories, Interpharm Laboratories, and Ciba Corning Diagnostics.

Kim received B.S. degrees in Chemical Engineering and Biochemistry from Oregon State University and his Ph.D. in Chemical Engineering from the University of Delaware. He taught for several years in the Department of Chemical Engineering at Arizona State University before entering industry where he headed the cell culture and fermentation process development groups at Otsuka Pharmaceuticals Ltd. and Flow Laboratories. In these positions he did large-scale anchorage dependent and suspension cell culture and pilot plant recombinant E. coli fermentation scaleup work.

Kim's engineering design experience prior to joining CRB include Life Sciences International, Quasar Engineering and United Engineers & Constructors. In his current position he continues to do conceptual and schematic design of biotech and (bio)pharmaceutical projects and consulting on process development, biocontainment and Good Manufacturing Practices. He has attended numerous FDA preconstruction meetings on the behalf of clients.

Kim is also co-editor of the book *Bioprocess Engineering - Systems, Equipment and Facilities*, Wiley Interscience, 1994.

## You will profit from this course, if you belong to the

engineering, process development, project management, validation, quality assurance, manufacturing, maintenance or regulatory compliance department of an FDA-regulated company.

Vendors to the health care industry, contractors and anybody who needs a more thorough understanding of the current validation issues and expectations will also greatly benefit from this course.

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for comprehensive information on all CCE-courses.

## Venue:

To be announced

When making your hotel reservation, please mention the **Center for Continuous Education** to receive the **special group rate!**

## Course Schedule:

Each Course Day:  
8:00 a.m. to 4:00 p.m.

## Fee Schedule:

\$1,695 for early payment  
\$1,795 for payment received by closing date  
\$1,895 for payment received after closing date

**To assure your participation, REGISTER EARLY!**

## For Registration...

we only need your **name, affiliation, postal address, and phone and fax numbers** together with the **course title**. You can **call, fax or e-mail** us the information or you can register through our **web site**.



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## The Unavoidable Small Print!

The course fee includes a **comprehensive course book** containing the complete presentation material. It also covers **continental breakfast and refreshments** served in the course room and **lunch** on course days. Course participants will receive a **certificate** confirming 1.8 CEU's.

Course acceptance is based on a **first come, first served basis**. To hold your place as a confirmed participant, CCE must receive your **payment made with check or major credit card by the course closing date**. CCE must have received your payment at the latest 5 business days prior to course start.

90% of the paid fee is refundable, if participant cancels before the course closing date. 50% of the paid fee is refundable for cancellation received not later than two weeks prior to course start. **No refund** can be made for cancellation after that date. However, **confirmed participants may send a substitute participant at any time**.

CCE reserves the right to cancel the course or to replace faculty at any time. In case CCE needs to cancel the course, participants will receive a full refund of fees paid to CCE. CCE will not be responsible for any other costs incurred due to course cancellation.

Course participants and their companies agree to these terms by making their payment to CCE.

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