



Pharmaceutical Water Systems

- Design
- Validation
- Operation
- Maintenance

Hubert Fleming, Ph.D.

San Diego, CA

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Water is the single largest volume product of the pharmaceutical industry. Because water comes into contact with product frequently during the manufacturing process and even can be part of the final pro-duct itself, its generation and use is highly regulated. Yet, water issues still rank second - after validation problems - on the list of objectionable findings in regulatory inspections.

This course teaches the current US, EU and Japanese requirements for water systems design, validation, operation and maintenance and discusses optimum design strategies based on specific case studies for new and renovated facilities, both, domestic and off-shore, meeting regulatory expectations.

Course Content:

Introduction to Water

- The Chemistry and Microbiology of Water

Regulatory Standards for Water

- Compdial vs. Non-compdial Water
- USP-Purified Water
- USP Water-for-Injection (WFI)
- The US, EU and Japanese Regulatory Requirements

Design of Water Purification Systems

- Source Water Requirements
- Treatment Options
- Pre- and Post-Treatment Issues
- Storage and Distribution System Strategies

Validation and Start-Up

- Regulatory Requirements
- Validation Program
- QA Protocols
- System Start-Up
- Sampling and Testing
- Setting of Alert and Action Limits
- Revalidation

Operational Considerations

- Operational Parameters
- SOP's
- Preventive Maintenance
- Troubleshooting
- Microbial Control
- Sanitization

Emerging Issues

- New and Upcoming Regulatory Requirements
- Novel Technologies

Course Faculty:

Hubert Fleming, Ph.D. is an independent consultant who is nationally and internationally recognized as an authority in water treatment. He received his master and doctorate in chemical engineering from Cornell University.

Hu has authored more than one hundred publications, eight book chapters, and sixteen patents in various aspects of chemical separations and purification. He is also the co-author of several books, including the *Membrane Handbook*, winner of the prestigious PSP Award for the Most Outstanding Work of Reference for 1992.

Hu is a former Adjunct Professor at Stevens Institute of Technology, Worcester Polytechnic Institute and Carnegie-Mellon University. He is past chairman of the *International Congress on Membranes and Membrane Processes*, and is a member of several international professional panels on separation science and technology, as well as the *ASTM D-19 Committee on Water Standards*, and the *Purified Water Working Group* of the Parenteral Drug Association (PDA).

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

engineering and maintenance staff, validation personnel, QA or QC staff, process development personnel, manufacturing department or regulatory compliance group of a FDA-regulated company.

Vendors to the FDA-regulated industry, contractors and anybody who needs a more thorough understanding of the technical aspects of the generation and maintenance of compdial water will also greatly benefit from this course.

This course is also available as an **in-house course** at your facilities!

Please contact us for details.

Visit

<http://www.cce-us.com>

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Venue:

Horton Grand Hotel
311 Island Avenue
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Fax 619.239.3823
www.hortongrand.com

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 payment received by **May 19, 2006**
\$1,795 for payment received by June 2, 2006
\$1,895 for payment received after June 2, 2006

**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 register through our website, www.cce-us.com, or you can **fax** or **e-mail** us this information.



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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 by the course closing date, June 2, 2006**. No payment can be accepted after 5 business days prior to course start.

90% of the paid fee is refundable, if participant cancels by June 1, 2006. 50% of the paid fee is refundable for cancellation received by June 9, 2006. **No refund** can be made for cancellation **after June 9, 2006**. 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.

Former Course Participant:

*"Excellent course and speaker.
Couldn't ask for more."*