

**MONICA J. CAHILLY**

July 2008

**PROFESSIONAL EXPERIENCE**

- ◆ 1992-present: Quality, Compliance, Validation Consultant; President of Green Mountain Quality Assurance, LLC, servicing:
  - ◆ Pharmaceutical
  - ◆ Biotechnology
  - ◆ Medical Device
  - ◆ Laboratories
  - ◆ Contract Research Organizations
  - ◆ Environmental Testing and Engineering
  - ◆ University R&D
- ◆ Regulatory Experience:
  - ◆ FDA GMP, GLP, QS Reg, GCP / ICH, VICH, Part 11
  - ◆ EPA GLP
- ◆ Consulting Activities:
  - ◆ 21 CFR Part 11 / Computer Systems Validation Compliance Global and Facility Program Development
  - ◆ Provide Training: Computerized Systems Validation, 21 CFR Part 11, GLP, GMP
  - ◆ Risk Management Program Development
  - ◆ GLP Compliance Program Development
  - ◆ Quality System Development for Clinical Pharmacogenomic Research Operations
  - ◆ GMP / Quality Systems Audits
  - ◆ In-Life GLP Toxicology Inspections and Data Audits
  - ◆ Bioanalytical Data and Laboratory Audits
  - ◆ Application Integrity Policy Audit / Data Integrity Investigations
  - ◆ Consent Decree Audits
  - ◆ 21 CFR Part 11 Compliance Assessments and Computer System Audits
  - ◆ Mock FDA Inspections of Quality Systems and Computerized Systems
  - ◆ Veterinary International Committee on Harmonization (VICH) Clinical Protocol, Report, and Study File Audits
  - ◆ Computer Systems Validation Audits
  - ◆ Analytical Data Audits
  - ◆ Method Validation Audits
  - ◆ Software Vendor Audits
  - ◆ Facility Inspections
  - ◆ Standard Operating Procedure Development
- ◆ 1990-1992: Quality Assurance Specialist, Lancaster Laboratories, Inc. Activities:
  - ◆ Responsible for implementation of laboratory-wide compliance program in Computer Validation.
  - ◆ Responsible for FDA GMP- and GLP-compliance program.
  - ◆ Assisted in implementation of Total Quality Management program.

- ◆ Wrote SOPs and Conducted Training in: Computer Validation, GMP, FDA and EPA GLP, Laboratory Statistics, Total Quality Management.

#### EDUCATIONAL QUALIFICATIONS AND ACCREDITATION

- ◆ RQAP-GLP, 1997, re-registration 2000, 2003, 2006—Registered Quality Assurance Professional, Good Laboratory Practice (GLP) Regulations
- ◆ M.S., (Genetic) Toxicology, 1986—Massachusetts Institute of Technology
- ◆ B.A., cum laude, Biochemistry, 1983—Dartmouth College

#### PUBLICATIONS AND LECTURES

- ◆ June 2008 (Framingham, MA), Presenter, Two-Day Workshop, *Quality Oversight of Electronic Data & Computerized Systems Compliance*, New England Regional Chapter of the Society of Quality Assurance
- ◆ May 2007 (Austin, TX), Lecturer, *Electronic Records, Signatures, and Systems Compliance Programs—Current Perspectives*, International Society of Quality Assurance Annual Meeting
- ◆ “Regulatory and Technical Challenges in Incorporating Surrogate Tissue Profiling Strategies into Clinical Development Programs,” Judith L. Oestreicher, Monica J. Cahilly, Deborah P. Mounts, Maryann Z. Whitley, Lisa A. Speicher, William L. Trepicchio, Michael E. Burczynski, Surrogate Tissue Analysis: Genomic, Proteomic, and Metabolomic Approaches, ed. Michael E. Burczynski, John C. Rockett, pub. Taylor & Francis Group, LLC, CRC Press © 2006, pp.249-261.
- ◆ *Validation of Computerized Systems*, Monica J. Cahilly, Process Validation in Manufacturing of Biopharmaceuticals, ed. Anurag Singh Rathore and Gail Sofer, pub. Taylor & Francis Group, LLC, CRC Press, © 2005, pp.395-449.
- ◆ “Clinical Pharmacogenomics and Transcriptional Profiling in Early Phase Oncology Clinical Trials,” Michael E. Burczynski, Judith L. Oestreicher, Monica J. Cahilly, Deborah P. Mounts, Maryann Z. Whitley, Lisa A. Speicher, and William L. Trepicchio, Current Molecular Medicine 2005, vol. 5, pp. 83-102.
- ◆ October 2004 (Norwich, CT), Lecturer, *Preparing for an FDA Inspection of Computerized Systems*, New England Regional Chapter of the Society of Quality Assurance.
- ◆ June 2002 (Arlington, VA), Lecturer, *Compliance Challenges in the Current Hybrid Environment*, “The Paperless Laboratory”, American Association of Pharmaceutical Scientists (AAPS).
- ◆ January 2002 (Washington, DC), Lecturer, *21 CFR Part 11 Compliance and preparing for an FDA Inspection of Computerized Systems*, Well Characterized Biologicals Program (WCBP) and FDA, Center for Biologics Evaluation and Research (CBER).
- ◆ January 2002 (London), Lecturer, *Preparing for FDA Inspections of Computerised Laboratory Systems*, Laboratory Equipment Validation, SMi.
- ◆ June 2001 (London) and April 2001 (Washington, DC), Lecturer, *Preparing for FDA Inspections of Computerized Laboratory Systems*, Institute of Validation Technology
- ◆ Nov 1999-2001, Columnist, “21 CFR Part 11 Compliance Corner”, quarterly NERCSQA newsletter.
- ◆ Nov 1999, Roundtable Co-Facilitator (Worcester, MA), *Validation of Office Applications Software*, NERCSQA.

- ◆ June 1999 (Mystic, CT), Lecturer, *Conducting Quality Assurance Inspections of Computerized Systems*, NERCSQA.
- ◆ Dec 1996-Feb 1998, Founding Editor, Northern Highlights, quarterly newsletter of NERCSQA.
- ◆ September/October 1992, Bretzin (Cahilly) Monica J. and Hess, M. Louise, *Quality Assurance of the Computer Validation Process in the Contract Laboratory*, Pharmaceutical Engineering, vol. 12, no. 5, pp. 8-14.

#### CONTINUING EDUCATION

- ◆ ISPE Conference, *GAMP® 5, Enabling Innovation*, February 2008
- ◆ FDA-DIA Webinar, *Companion to FDA Pharmacogenomics Guidance*, Nov 2007
- ◆ 2<sup>nd</sup> FDA Risk Congress, *Global Approaches to Risk Management throughout Product Life Cycles*, May 2007
- ◆ National Meeting of Society of Quality Assurance (SQA), May 2007
- ◆ *Bioanalytical Training: Biomarkers, Ligand-binding Assay Validation, Pharmacokinetics*, SQA Fall Training, Sept 2006
- ◆ *Assuring GLP Compliance Non-Clinical Medical Device Studies*, SQA Fall Training, Sept 2006
- ◆ *Co-Development of Drug, Biological, and Device Products*, FDA/DIA Pharmacogenomics Workshop, July 2004
- ◆ *Pharmacogenomics in Drug Development and Regulatory Decision-Making: The Genomic Data Submission (GDS) Proposal*, FDA/DIA, Nov 2003
- ◆ *5<sup>th</sup> Annual FDA and the Current Challenges of GMPs*, University of R.I. College of Pharmacy, July 2003
- ◆ *The Paperless Laboratory*, AAPS, Jun 2002
- ◆ Well Characterized Biological Program (WCBP), FDA CBER, Jan 2002
- ◆ *Laboratory Equipment Validation*, SMi, Jan 2002
- ◆ *Electronic Records; Electronic Signatures*, IVT, June 2001 and April 2001
- ◆ National Meeting of SQA, Oct 2000
- ◆ *Electronic Records; Electronic Signatures*, IVT, Aug 2000
- ◆ *Validation of Corporate IT Systems in the Pharma Industry*, SMi, Jul 2000
- ◆ *Technical Implementation of Part 11*, FDA and PDA, Jun 2000
- ◆ *Auditing Electronic Chromatography Data*, Biotechnical Services, Inc., Feb 2000
- ◆ *FDA Guidance on Computerized Systems Used in Clinical Trials*, DIA, Dec 1999
- ◆ *Analyzing and Validating E-Record and E-Signature Systems*, IIR, Sep 1999
- ◆ *Electronic Submissions and Electronic Record-Keeping Systems*, IIR, Sep 1999
- ◆ *Conducting Facility Inspections and Effective Meetings*, New England Regional Chapter of SQA (NERCSQA), Jun 1999
- ◆ *Introduction to Auditing Electronic Chromatography Data*, BSI, Apr 1999
- ◆ *21 CFR Part 11*, NERCSQA, Mar 1999
- ◆ *Computer Systems Validation—A Common Sense Approach*, IIR, Dec 1998
- ◆ *Validating Clinical Data & Assuring Quality Database Systems*, IIR, Dec 1998
- ◆ National Meeting of SQA, Oct 1998
- ◆ *GLPs and GCPs in Target Animal Studies*, SQA, Mar 1998
- ◆ *Facility Inspections*, NERCSQA, Nov 1997
- ◆ *Analytical Methods Validation*, SQA, Oct 1997
- ◆ National Meeting of SQA, Oct 1997
- ◆ National Meeting of SQA, Oct 1996

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- ◆ *Computer Validation*, taught by Martin Browning, US FDA, and Richard Johnson, US EPA, author of Good Automated Laboratory Practices (GALP), Oct 1991
- ◆ National Meeting of SQA, Oct 1991
- ◆ *GALPs: Good Automated Lab Practices*, MARSQA, May 1991

**MEMBERSHIPS AND PROFESSIONAL ASSOCIATIONS**

- ◆ International Society of Pharmaceutical Engineering (ISPE), 2008-present.
- ◆ Drug Information Association (DIA), 1999-2000; 2004-2005; 2007-present.
- ◆ Society of Quality Assurance (SQA), 1996-present.
- ◆ NERCSSQA, Dec 1996-present; Interim Vice-President, NERCSSQA, 1998-1999.
- ◆ Assn. of Clinical Research Professionals (ACRP), 2006-2007.
- ◆ Parenteral Drug Association (PDA), 2000-2006.
- ◆ American Association for the Advancement of Science (AAAS), 2001-2003.
- ◆ MARSQA, 1991-1992.