# **Debra Weigl, PMP**

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**PROFESSIONAL PROFILE**

Biochemist with extensive experience managing Regulatory Compliance, Quality Assurance and Process Development Projects within the healthcare industry.

**EDUCATION AND CERTIFICATIONS**

**University of Wisconsin-Madison**

Bachelor of Science, Bacteriology

**North Carolina Wesleyan College**, Rocky Mount, NC
Undergraduate Studies in Business and Information Systems

**North Carolina State University,** Raleigh, NC

Graduate Studies in Technical Writing and Editing

**University of Texas-Austin, Center for Professional Education**

Certificate in Process Management

**Project Management Institute (PMI)**

Project Management Professional (PMP) Credential

**EMPLOYMENT SUMMARY**

2017-2019 **Cytovance, Inc.**, Oklahoma City, OK
Quality Systems & Regulatory Compliance Manager

2013-2017 **The Clorox Company**, Kennesaw, GA
Quality Assurance Project Manager—Healthcare

2011-2013 **CSA-Soliance, Inc.**, Austin, TX
Senior Quality & Regulatory Projects Manager

2008-2010 **Tunnell Consulting**, King of Prussia, PA

 Senior Consultant (Contractor)

2003-2007 **Human Genome Sciences, Inc.,** Rockville, MD
Section Head—Analytical Compliance

2001-2003 **Diosynth Biotechnology RTP, Inc.**, Research Triangle Park, NC

 Senior Scientist/Project Team Lead—Process Development

**EMPLOYMENT SUMMARY, continued**

1992-2001 **Glaxo SmithKline, Inc.**, Research Triangle Park, NC
Senior Scientist—Biotechnology Product Development
Scientist—Protein Chemistry, Pharmaceutical Discovery

1985-1992 **Abbott Laboratories, Inc.**, North Chicago, IL

 Biochemist—Anti-infective Research, Pharmaceutical Discovery

**RELEVANT EXPERIENCE**

* As Quality Systems & Compliance Manager for a biopharmaceutical manufacturer, was responsible for the Document Control function. This involved review and approval of all corporate documentation, oversight of the electronic library system, and management of document issuance and change control processes.
* In response to an FDA action, was deployed to remediate compliance issues in a plant within my employer’s manufacturing network. Led a cross-functional project team in the evaluation and complete overhaul of the site’s quality system, comprising some 700+ documents. The result included redrafting ~50 core quality assurance procedures, reconfiguring all manufacturing batch records and eliminating about 200 unnecessary procedures.
* As a consultant, mapped the entirety of the manufacturing and distribution processes within an Over-the-Counter (OTC) drug/cosmetic manufacturer. A gap assessment was subsequently performed on the mapped processes for compliance with internal Quality System procedures, International Standard for Organization (ISO) standards and international regulatory requirements.
* Led a project team in the successful commissioning of a new medical (nanofiber suture) device plant. In addition to validating and documenting the operation of all equipment and processes, all Quality System documentation needed for compliance to FDA, ISO and European regulatory requirements was produced, reviewed, and approved for daily operations.
* Over a thirty-year career, have authored, reviewed, and/or approved numerous corporate policies, standards, standard operating procedures, work instructions, protocols, reports, master records, and forms. Have also been responsible for defense of these documents and the embodied Quality Systems in governmental regulatory inspections and stakeholder audits.

**PUBLICATIONS**

Coauthor of 19 Peer reviewed and invited scientific papers; a bibliography is available upon request.