JEFFREY D. DeCRISTO

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SUMMARY PROFILE

- Manufacturing, Quality Control, and Quality Assurance experience in the biotech, biologic, and medical device industries.
- Protein, RNAi, and bacterial cell culture production and qualification experience.
- Laboratory equipment metrology, maintenance, and troubleshooting experience.
- Laboratory oversight and upkeep experience.
- GMP controlled documentation usage, revision, and record management experience.
- Manual and electronic document control and training quality management system (QMS) software experience.
- Experience identifying and leveraging general and specialty software to meet business needs.
- Track record of identifying quality and business system needs and developing effective solutions to address the needs of internal/external customers.
- Experience identifying and managing projects.
- Strong proponent and facilitator of proactive rather than reactive processes and systems.
- Adept at working autonomously and collaborating with peers and groups (E/INTJ).
- Experience managing small groups (Three Step approach).
- Work history shows consistent success and increasing levels of responsibility.
- Salary Requirement – competitively affordable & negotiable.

Abilities:

- Regulatory (ISO, GLP, Q7A, cGMP) experience
- Biotech manufacturing, QC, & QA experience
- Laboratory operation & upkeep
- Laboratory equipment usage, calibration, maintenance, & upkeep
- Experience with:
  - Cell culture, protein mixtures, RNAi
  - Reverse phase, ion exchange, & P-11 HPLC chromatography
  - SDS-PAGE
  - UV-Vis & FTIR spectroscopy
  - Raw material qualification testing
  - Bacterial testing & endotoxin LAL
  - Karl Fischer
  - Nucleic acid synthesis
  - Handheld & robotic liquid-handling
- Controlled documentation drafting, usage, revision, review, & auditing
- Manual & electronic document control, training, & complaints software experience
- End user/employee training
- Project management
- Record and data management
- Microsoft InfoPath & SharePoint experience
- Equipment & software validation
- Creative & practical problem solving
- New tool & technology identification
- Scientific/technical reading & writing
- Effective written & oral communication
- Self-directed, collaborative, independent, idealistic, pragmatic, flexible, resourceful
- Microsoft Windows, Mac OS X, Microsoft Office 2010 Pro Plus experience

"Whatever is worth doing at all, is worth doing well." ~Philip Dormer Stanhope, 1746

PROFESSIONAL HISTORY & KEY ACCOMPLISHMENTS

THERMO FISHER SCIENTIFIC (Dharmacon), Lafayette, CO **2001 - 2013**

Founded in 1995, Dharmacon developed 2'-ACE RNA synthesis chemistry that led to the development and commercialization of siRNA products and technologies that are used globally by academic and commercial entities for gene research, drug discovery, and potential human bio-therapeutics. Fisher Scientific acquired Dharmacon in 2004, which then merged with Thermo Electron in 2006. Layoffs.

Senior Engineer, Business Systems (quality systems development focus), 2012-2013
Quality Assurance Manager (quality systems development focus), 2009-2012
Quality Assurance Supervisor (quality systems development focus), 2008-2009
Quality Assurance Associate Scientist II (quality systems development focus), 2006-2008
Quality Assurance Associate Scientist I (quality systems development focus), 2003-2006
Production Associate II, 2001-2003

- Development, implementation, and administration of:
  - Company asset and laboratory equipment inventory system
  - Equipment calibration and maintenance, and service contract scheduling software (Calibration Manager)
  - Calibration and maintenance methods for liquid-handling/volumetric, UV-Vis, mass, temperature, and CO_2 inspection, measuring, and testing equipment (IM&TE)
  - Manual/electronic document control and training system (QMS), and complaint software
  - InfoPath electronic, automated forms to streamline and optimize business processes
  - SharePoint intranet webpage configuration and content management
  - Site record management and retention of company records
  - Laboratory notebook scanning and archival for intellectual property protection
- Management and guidance of the Quality Assurance department including:
  - Metrology/calibration program and metrologist
  - Document control and employee training program, QMS software configuration, and Document Control Administrator
  - Raw material testing and analyst
  - Quality auditing program
  - Department goal/project planning and budgeting
- Other:
  - High-thoughput manufacturing and qualitative and quantitative product quality control
  - Quality/regulatory research and business infrastructure requirement determination
  - Current SharePoint, database and XHTML self-study

AMERICAN ALLIED BIOCHEMICAL, INC., Aurora, CO **2000 - 2006**

AAB is an independent laboratory that specializes in the manufacture, purification, and distribution of restriction endonucleases for an eclectic array of fields and applications. Company was sold in 2006.

Production, Inventory, & Customer Service Specialist, 2000-2006

- Cell culture media preparation
- Autoclaving of glassware & growth media
- Culture inoculation using aseptic technique
- Aerobic and anaerobic cell culture incubation
- Cell collection via centrifugation
- Cell lysis and endonuclease purification
- P-11 chromatography
- PAGE and λ DNA over-digest QC
- Buffer and reagent preparation
- Stock dilutions and inventory packaging
- Customer order processing and shipping
- Glassware washing and laboratory upkeep

SULZER BIOLOGICS, INC., Wheat Ridge, CO **1998 - 2001**

Research venture of Sulzer Medica to characterize and develop a bovine morphogenic protein mixture for orthopedic, dental, cardiac, and neurological applications. Company closed in 2001.

Analytical Services/Quality Control (ASQC) Laboratory Administrator, 2001
Lead Quality Control Analyst, 1999-2001
Quality Control Analyst, 1998-1999

- Product qualification, maintained laboratory equipment, wrote and revised SOPs/STMs
- Developed FTIR and USP raw material tests, coordinated department training, managed laboratory

WILEY CONSOLIDATED SCHOOL DISTRICT, Wiley, CO **1993 - 1998**

Science Department Chair and Teacher, 1993-1998

- Managed department, budget, inventory, orders, and teachers
- Developed curriculum and taught eight preps for grades 7-12

EDUCATION & PROFESSIONAL TRAINING

- ***Bachelor of Science (BS) degree, Biological Science***, Colorado State University, Ft. Collins, CO
- Colorado Secondary Science Education License, Colorado State University, Ft. Collins, CO
- The Practice of the Modern HPLC, 1999
- US FDA Regulatory Course on CBER Regulated Devices, 1999
- Directing, Controlling, and Managing Projects, 2000
- Writing SOPs to Meet cGMP Requirements, 2000
- cGMPs for the Pharmaceutical and Allied Industries, 2000
- Validation of Physical & Chemical Methods for Bio-Pharmaceuticals & Biological Methods Validation, 2000
- Statistical Analysis of Laboratory Data, 2001
- Fundamentals of Protein Chemistry, 2001
- Fundamentals of FTIR Analysis, Thermo Electron, 2001
- Independent Study: Quality Systems, Various, 2003
- Implementing and Auditing and ISO 9000 Quality System, 2004
- Independent Study: *The Practical Guide to People Friendly Documentation*, by Adrienne Escoe, 2004
- Independent Study: *The Metrology Handbook*, by Measurement Quality Division, ASQ, Jay L. Bucher, Editor, 2005
- Supervision: Core Competencies, MSEC, 2007
- Supervision: Your First 90 Days – How to Survive, MSEC, 2007
- *Practical Process Improvement*, R. Edward Zunich & Thermo Fisher Scientific, 2008
- Effective Project Management I – Foundations, MSEC, 2009
- Developing Presentation Skills, MSEC, 2009
- Communication Feedback – Know Thyself, MSEC, 2009
- Records Retention & Destruction, Fred Pryor Seminars, 2009
- Independent Study: Microsoft InfoPath, 2007-2012