

Jessica Claire

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SUMMARY

- Detail oriented Analytical Chemist and Laboratory Leader with over 15 years of successful quality management experience used to mentor and develop staff, form and strengthen cross functional relationships, assure an audit ready operation and realize cost savings through dedication to continuous quality improvement.

QUALIFICATIONS

- 15 years of Quality Management experience .
- BS/MS degrees in Chemistry
- Character driven collaborative leadership practice and style.
- Over 10 years of International Product Technical Transfer experience.
- Accomplished Project Manager. TQM and DMAIC/6Sigma green belt trained; Established track record implementing positive procedural change - Continuous Quality Improvement while providing exemplary support for existing operation.

EXPERIENCE

CONSULTANT

2010 to CURRENT

Icon | Knoxville, TN

8/2006-2/2008 and 1/2010-Current

Subject matter expert serving the legal, academia and industrial professions.

- Primarily telephone and on-line group meeting consultations providing Clients with scientific insights needed to make informed decisions.
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CONSULTANT, QA EMPLOYEE DEVELOPMENT AND PROJECT REVIEW

01/2013 to 2014

Janssen Biologics- J&J - Biopharmaceuticals | City, STATE

- Project technical data summary and review for BLA submissions, protocols, stability studies, raw material supplier evaluations and employee training and mentoring in the practice of the above.

INTERIM/CONTRACT QC LABORATORY MANAGER

2011 to 11/2011

Zoltek | City, STATE

- Temporary Manager while permanent QC manager was on personal leave; site of 30.
- Staff of 2 technicians supporting a 24/5 operation.
- Included raw material evaluation and approval, in process sample analysis, finished product release and customer complaints.

DIRECTOR OF QUALITY LABORATORIES

01/2008 to 2010

Biotech Pharmaceuticals - Biopharmaceuticals | City, STATE

- Responsible for manufacturing, R&D and Technical Transfer support
- Training, coaching and development of a staff of 45, 7 direct reports; 24hour 5day operation.
- Groups included Stability, Raw Materials, LIMS, Environmental Monitoring, Med Techs, Analytical methods development, QC in process and product lot release groups.
- Assured strict laboratory regulatory compliance, CAPA remediation and establishment and maintenance of audit ready operating groups.
- As established in my past, in addition to my management reports, two analytical development chemists also reported directly to me in order to maintain floor presence, aid in method development and trouble shooting for technical transfer projects.
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MANAGER II, QUALITY LABORATORIES

11/2003 to 05/2006

Baxter Healthcare - Biopharmaceuticals | City, STATE

- Received Six Sigma/DMAIC Green Belt training for Laboratory cycle time reduction projects and overall increased operational efficiency
- Responsible for the site quality laboratories including - raw materials, in process and finished goods analysis, technical services samples, validation, method development, stability, etc.
- Staff of appox. 45+ professionals. 6 direct, 24/7 support.
- Responsible for a budget in excess of \$7.5 MM annually.
- Hosted and supported monthly audits by US and foreign customers, 3 FDA audits, and various international regulatory bodies.
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ASSOCIATE DIRECTOR OF QUALITY LABORATORIES

05/2002 to 11/2003

Lonza Biologics - CMO, Biopharmaceuticals | City, STATE

- Responsible for the Raw Materials, analytical methods development, Quality Control, Biochemistry, Technical IS (LIMS) and EM laboratory programs (under cGMP)
- Staff of 70+ employees (analysts, supervisors and managers – 7 direct mgr and supervisory reports).
- One of seven Site Directors planning and implementing strategic initiatives supporting positive cultural growth at the Portsmouth NH site supporting a 460+ employee mammalian cell culture manufacturing facility.
- Managed a successful relocation project of all Quality Laboratories from 4500 sq.ft. to 17,000 sq.ft., including a LIMS deployment, while concurrently providing seamless manufacturing support, cutting the needed \$\$ from the budgeted 11MM to less than 8MM and requiring no additional head count (which was slated at 15 prior to my coming to this site).
- Reduced group operating cost by 25% in 10 months due to successful implementation of continuous quality improvement initiatives.
- Left during a company downsizing
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QUALITY CONTROL LABORATORY MANAGER

05/2001 to 05/2002

Genzyme Diagnostics - Medical Device/Biologics | City, STATE

- Supported the manufacture of test kits and the subsequent raw materials, including MAb, in process and finished product release.
- Management of the Quality Control and Technical Services laboratory - Medical device manufacturer
- Responsible for a group of 10 professionals in a cGMP compliant (CFR 810) QC/analytical laboratory
- Directed customer service/complaint resolution, stability programs, proficiency studies, raw material evaluations, equipment and instrument validations, etc.
- Left due to facility closure. Operations were moved from CA to MA.

QUALITY CONTROL LABORATORY MANAGER

05/1999 to 05/2001

DSM Catalytica Pharmaceuticals - CMO API Mfg | City, STATE

- Quality Control laboratory manager supporting a 24/7 pharmaceutical API contract production operation.
- Managed eight to twelve professional chemists and supervisors in a GMP compliant (CFR 210/211) QC/analytical laboratory.
- Drove the transfer and optimization of analytical methodology, assisted in the development and supported implementation of a site SPC/SQC program, production product release, development of plant and laboratory SOP's, raw material supplier assessments as a cost minimization project, etc.
- Reduced permanent and temporary staff turnover by approximately 90% through time investment, employee empowerment and a commitment to an investment in their future and success.
- Left after last batch was manufactured by Catalytica and processes were moved to NC after purchase by DSM.

SUPERVISOR , PRODUCT SUPPORT

05/1993 to 05/1999

GE Power & Water | City, STATE

Research Scientist / Supervisor– Corp. R&D, Product Support(1997 – 1999)

Senior Scientist – Corp. R&D, Product Support (1995 – 1997)

Scientist – Corp. R&D, Product Support (1993 – 1995)

- Managed Corporate Technical Services, Quality Control, remote Beaumont, TX Quality Control Laboratory and US contact for 3 international satellite laboratories (Widnes UK, Helsingborg Sweeden and Qualitno Italy).
- Direct reports included Laboratory Mgr, Process Chemist and Quality Control laboratory staff at the Beaumont TX facility and local QC laboratory in Trevose PA. Managed total team of five local and fourteen remote chemists/technicians
- Development and on site implementation of analytical/QC testing methods and SOP harmonization as well as implementation of technology and product transfer protocols for Global facilities.
- Supervised Corporate Technical Services Laboratory, responsible for investigation and disposition of product quality incidents for global raw materials, manufactured and purchased polymers and globally manufactured reaction products.
- Provided Quality Control support for Corporate R&D Organic Synthesis and Polymer Chemists. Support consisted of analytical and QC methods development (HPLC, GC, spectroscopic,etc.), analysis of all raw materials and finished good samples, transfer of specification requirements and methods to production sites, confirming data collection/reporting system