



Miguel D. Castellanos

SUMMARY

Experienced cGMP Quality Assurance (QA) / Quality Control (QC) Manager and Analytical R&D Project Manager / Scientist, with 15 years of pharmaceutical experience and 23 years of total experience.

Hosted/participated in 3 FDA cGMP Audits, with 3 different companies & from 3 different positions, for which received no Warning Letters, 483s or Objectionable Items.

Developed, implemented and managed the entire GMP system (Operations, QA & QC) for a start up Contract Research Organization (CRO) / Contract Manufacturing Organization (CMO) and successfully passed FDA inspection with no observations.

Experienced in the following regulations and guidelines: ICH: Q1, Q2, Q3, Q6, Q7, Q9 & Q10. 21CFR: 210, 211, part 11. EMEA. USP, BP EP, EPA. TQM. ISO. OSHA.

MS in Analytical Chemistry.

Fluent speaker/writer in Spanish.

EXPERIENCE

COMPLIANCE INSIGHT, INC. 8/09 to present.

COMPLIANCE SPECIALIST

- **2011** - Acting QA Manager of a Mid-West Health Care Products contract manufacturer. In 3 months, co-lead the team that executed a plan to have the company increase their Quality Score with a major client by 40%, saving the company from dire financial downfalls. This plan consisted on about 700 action items spread throughout all areas of operations of the plant (manufacturing, packaging, warehousing).
- **2009-2010**: Acting QA Supervisor of a Mid-West pharmaceutical company under FDA Consent Decree (commercial operations were shutdown in Jan-09). Providing GMP guidance to one of the four manufacturing sites (tablets, liquids & creams) to effectively correct the FDA observations in order to bring back the company to GMP compliant status and resume commercial operations. Part of the investigation team (deviations) performing on-site investigations and developing CAPAs (in all manufacturing sites).
- **2010**: Performed a Gap Analysis for a Mid-West company in order for them to set into operations their own QC laboratory.
- **2010**: GMP consulting for a Contract Analytical Laboratory (Mid-West): resolved issues with FDA Warning Letter and 483s. Modified Environmental Monitoring Program, designed master protocol and evaluated temperature mapping of incubators, autoclaves, refrigerators and freezers; wrote investigation reports on several issues related to the Warning Letter and 483 findings.

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GIRINDUS AMERICA, INC., (Member of Solvay Organics Strategic Business Unit) 11/2001 – 7/2009
CRO/CMO for Clinical Trials and Commercial applications.

QUALITY ASSURANCE MANAGER, 10/2004 – 7/2009

- Hosted the first ever FDA GMP Site Inspection: NO Warning Letters, 483s or Objectionable Items (Feb 2007)
- Member of the Operational Team (OPS) which oversees and manages operations for the 5 companies (3 in Europe & 2 in the USA) of Solvay Organics Strategic Business Unit (SBU).
- Member of the Quality Team developing the Global GMP Program for the 5 GMP companies of the SBU.
- Second in Facility's Chain of Command, behind President-COO, until 2007 when the Production Manager position was created
- Project and System Manager for the design and validation of the WFI system.
- Team Member of the Supply Chain Management team.
- Direct Supervisor of 3 QA Associates & QC-Manager and 9 QC chemists.
- Performing of management functions such as hiring, performance reviews & employee guidance.
- Responsible for upgrading the GMP systems to cover Phase III and Commercial applications. Author of dozens of SOPs and Master Plans.
- Participated and directed the QA/QC team to be technical experts in audits of quality & technical operations at suppliers, contractors, and collaborators.
- Identified areas of potential risk, using statistical analysis, and executed CAPA programs
- Developed/managed Quality Performance Indicators in order to evaluate GMP compliance of the site.
- Conducted the GMP monthly training.
- Responsible for development/execution of the GMP system for clean room operations (Class 100,000); validation of the new suites and performing environmental monitoring.
- Hosted an average of 30 visits/year by clients. Hosted an average of 15 client's cGMP audits/year with 100% success rate.

QUALITY ASSURANCE OFFICER, 11/2001 – 10/2004

- Only QA Associate on-site. Responsible for all QA functions.
- Developed the Site's GMP program, per ICH Q7a guidelines
- Authored more than 150 SOPs for Phase I/II
- Developed and implemented the company's ICH stability program.
- Maintained oversight of daily quality operations within the manufacturing and facilities departments.
- Responsible for the Process Change/Deviations/CAPA programs
- Performed batch record review final release of GMP APIs.
- Investigated, assessed the impact of customer audits and resolves minor, major and critical deviations. Responsible for OOS, Deviations, IQ/OQ, Internal audits, GMP training & Batch records review
- Responsible for GMP training for the entire site.
- Creator of Process Action Teams (PAT), cross-functional teams in order to improve operations
- Responsible for coordinating site visits and audits
- Third in Facility's Chain of Command behind President-COO-Site Manager and Operations Manager.



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DURAMED PHARMACEUTICALS, 7/2000 – 10/2001.

CHEMIST III – Lead Investigator - Analytical Services 4/2001 – 10/2001

- Performed over 100 investigations concerning Out-of-Specifications (OOS), aberrant or unexpected results. The FDA audited all investigations with no Warning Letters, 483s or Objectionable Items.
- Interacted with Vendors, Manufacturing, Pharm R&D and AS personnel in order to conduct investigations following the FDA guidelines.
- Performed/reviewed USP/NF changes to analytical methods concerning Duramed's products.
- Performed/reviewed current Duramed's analytical methods discovering improvement schemes
- Supervised another investigator

RESEARCH SCIENTIST III- Project Manager – Analytical Services, 7/2000–4/2001

- Responsible for development and validation of new analytical methods for new products.
- Supervision of the R&D lab with 10 reports

PHARMACIA 2/1998– 6/2000

QUALITY CONTROL MANAGER

- Responsible for department compliance with all FDA, cGMP, USP, BP and EP regulations.
- Conducted over 200 laboratory investigations for out-of-spec (OOS) lab results. All FDA inspected with no Warning Letters, 483s or Objectionable Items.
- Worked closely with Production to resolve production issues.
- Supervised QC testing of site's Water For Injection (WFI) system.
- Direct supervision and training of QC Group Leader and ten QC Lab Technicians.
- Controlled the QC Lab's \$5 M/year budget and Capital Expense account.
- Released Raw Materials, Stability, In-Process and Finished Products.
- Conducted pre-employment interviews and personnel performance reviews.
- Controlled personnel discipline, attendance and overtime.
- Improved the morale, professionalism, pride and the teamwork atmosphere in the QC Lab.
- Improved the relations between the QC Lab and other Departments, including Production.
- Designed and incorporated "Method's Notebooks" to be used by all QC Technicians to improve lab efficiency for completion of analytical testing.
- Created a new position in the QC Lab for a Laboratory Data Reviewer, improving Lab efficiency
- Troubleshooting of analytical equipment (GC, HPLC, and vacuum oven, UV/VIS).
- Conducted GMP Training about Lab Investigations for OOS results for the site
- Incorporated a tracking system of Production schedules, incoming samples and release of results for final products; and to keep Lab personnel informed of new tasks, priorities or decisions.
- Headed the GMP committee to establish company's Guidelines and SOP for OOS investigations.
- Developed an analytical method for determination of residual solvents using GC.

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DURAMED PHARMACEUTICALS, Analytical R & D, 10/1996–12/1997.

RESEARCH SCIENTIST II

- Method development/validation: GC, HPLC, UV/VIS, Dissolution, Assays, Content Uniformity, and Cleaning Validation. Solids, liquids and suppositories. Work under cGMP, ICH and USP guidelines.
- Calibration of laboratory balances, computer interfaces and maintenance of analytical equipment.
- Accomplishments:
 - 1) Modified SOP for trace GC analysis of alcohols reducing sample prep time and analysis cost/sample.
 - 2) Developed-validated: (a) HPLC methods for analysis in packaging and manufacturing equipment for Cleaning Validation; (b) HPLC & UV methods for analysis of suppositories

DYNCORP/TECHNOLOGY APPLICATIONS, INC. 5/1991 – 3/1996. EPA Contractor.

ASSOCIATE SCIENTIST

- Principal Scientist, R&D: method development-validation of the official USEPA method 245.7 for the determination of low level mercury in aqueous and sediment samples using CVAFS. Three publications.
- Worked under TQM and USEPA guidelines.
- Team Leader and Analytical chemist, Drinking Water R&D, Disinfection By-Products Division.
- Liaison between EPA's Work Assignment Managers and Divisions.
- Lab Supervision, training of technical personnel and maintenance of equipment and supplies.

COURSES ATTENDED

Food & Drug Law Institute (FDLI): Food Week Conference: Introduction to Food Law & Regulation (including food safety law); Food advertising, marketing & labeling; Cosmetics and Dietary Supplements; Food Safety Modernization Act; Washington DC; January 2011

Management Courses: Total Quality Management & The Seven Habits of Highly Effective People

"Pharmaceutical Water Systems" 3-day course given by the University Of Wisconsin Department Of Engineering, in Las Vegas, April-2007

ICH Q7A Symposium in San Juan, Puerto Rico (2002). Symposium was given by the Expert Working Group who developed, approved and implemented ICH Q7A

Three-day Conference on the Barr Decision in Florida

Two-day conference on "Global Stability Update" (2000) in San Juan, PR.

AWARDS

International Scholarship, Organization of the American States, Washington, DC

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EDUCATION

MS, Analytical Chemistry, Western Carolina University, NC, (with thesis)

BS, Chemistry, Universidad Autonoma de Santo Domingo, Dominican Republic, (with thesis)

REFERENCES

LinkedIn: http://www.linkedin.com/profile?viewProfile=&key=25115271&trk=tab_pro

Additional references available upon request.

RESEARCH & PUBLICATIONS

"Determination of Total Mercury for the Water quality Based Approach." Paper published as part of the Proceeding of the Seventeenth Annual EPA Conference on Analysis of Pollutants in the Environment; May 3-5, 1994. Register # EPA 821-R-95-08, January 1995, p. 317-332.

Introduction to the USEPA Method 245.7, Determination of Mercury by Automated Cold Vapor Atomic Fluorescence Spectrometry." Paper published as part of the Proceedings of the Tenth Annual Waste Testing & Quality Assurance Symposium, July 11-15, 1994, p. 344-350.

"Determination of Mercury in Water by Semi-Automated Cold Vapor Atomic Fluorescence Spectrometry." Official USEPA Method 245.7. Revision 1.1 (1994)

"D-Arabitol Metabolism in Candida albicans: Studies of the Biosynthetic Pathway and the Gene That Encodes NAD-Dependent D-Arabitol Dehydrogenase." Paper published by the Journal of Bacteriology, October, 1993, Vol. 175, No. 19, p. 6314-6320.

"Enantioselective Measurement of the Candida Metabolite D-Arabinol in Human Serum Using Multidimensional Gas Chromatography and a New Chiral Phase." Paper published by the Journal of Chromatography, 495 (1989), p. 21-30.