

Form Name:
Submission Time:

Citizens Commission
April 1, 2019 5:23 pm

Name	Corina Casey
Address	<div></div> <div></div>
Phone	<div></div>
Email	<div></div>
Citizenship Affirmation	I am a U.S. Citizen
Residency Affirmation	I am a resident of the Commonwealth of Massachusetts
Statement of Intent	I intend to comply with and advance the policy established by this Act.
Statement of Interest	As a philosopher and a biochemist, I am strongly passionate about solving unique challenges using high quality, risk-based decision making.
Résumé or Summary of Qualifications Upload	https://s3.amazonaws.com/files.formstack.com/uploads/3282862/71887710/490419683/71887710_corina_casey_resume_2.pdf
Political Party Affiliation, if any, over the previous five years	Unenrolled
If multiple or other, please explain	Registered independent in Colorado from 2009-2016
City or Town where you reside	OXFORD
Employment Status	Employed
Occupation	Scientist
Employer	Takeda Vaccines

CORINA CASEY

PROFESSIONAL SUMMARY

My expertise in science and philosophy, in combination with my practical laboratory experience gives me a unique, innovative viewpoint that allows me to connect cross-functionally to collaboratively solve problems using a flexible approach in order to ensure product quality.

SKILLS

- Equipment, instrument, analytical method, and process transfer, qualification and validation
- Internal and external auditing
- Experience working under and managing quality systems (GMP, GLP, GCP, GCLP)
- Review of technical data/records
- Exceptional communicator
- SQL, HTML, python
- Highly skilled in Microsoft Office Suite (including excel and access)
- Expert Problem Solver
- Technical writing and presentations

WORK HISTORY

Specialist GMP QA, 01/2016 to Current

Takeda Vaccines – Fort Collins, CO

- Conducted internal audit and in-process inspection of in-house testing laboratory until transfer of activities to contractors.
- Provides oversight of GCLP/GLP activities relating to Serology and in-house clinical testing.
- Conducts reviews of GCLP contract method transfer, qualification, statistics and validation plans and reports.
- Developed methods relating to secondary packaging of vaccine drug product to ensure consistency of approach in quality oversight with other business units.
- Oversaw transfer of responsibilities for IMP QA secondary packaging to vaccines GMP QA.
- Conducts reviews and provides sponsor QA oversight of master production orders, executed batch records, master randomization tables, label design, and storage specification for finished drug product and packaged kitted drug product
- Coordinates deviation and CAPA management for IMP, drug substance, drug product and kitted product.
- Articulates audit findings, risks and detailed recommendations to upper management.

Research Associate II, 05/2013 to 01/2016

Takeda Vaccines – Fort Collins, CO

- Conducted internal audit and in-process inspection of in-house testing laboratory.
- Articulated audit findings, risks and detailed recommendations to upper management.
- Provided QA oversight of GCLP/GLP activities relating to Serology and in-house clinical testing.
- Conducted reviews of GCLP contract method transfer, qualification, statistics and validation plans and reports.
- Coordinated deviation and CAPA management for in-house testing laboratory.
- Managed transfer of quality systems during cross-regional harmonization initiative.
- Conducted QA reviews of clinical testing records and associated raw data.

Research Associate II, 08/2011 to 05/2013

Inviragen, Inc – Fort Collins, CO

- Evaluated and documented data relating to in-house clinical testing of human sera during phase I and II clinical trials.
- Competently utilize analytical and scientific software.
- Provide technical training to co-workers and new staff.

- Prepared specimens for analysis and established proper chronological priorities in testing.
- Carefully reviewed test results for accuracy.
- Properly calibrated and adjusted malfunctioning equipment to ensure precise test results.
- Developed process for right-first-time review of test records
- Developed quality systems for quality management of in-house clinical testing according to GLPs and GCLP regulations and recommendations.
- Managed local quality systems
- Conducted internal audit of quality systems.
- Conducted in-process inspections and internal audits of laboratories according to GLPs and GCLP.

Research Assistant, 05/2011 to 08/2011

Inviragen, Inc. – Fort Collins, CO

- Developed and troubleshooted RT-PCR method for in-house testing of human sera.
- Assayed clinical human sera by RT-PCR for phase I and II clinical testing.

Graduate Research Assistant, 08/2009 to 12/2010

Colorado State University – Fort Collins, CO

- Investigated the kinetics of the formation of polymerase initiation and elongation complexes in Polio virus RNA polymerase mutations.
- Developed methods for AUC, HPLC, SDS and polyacrylamide gel electrophoresis for use in enzyme kinetics, in-vitro transcription assays and PCR/plasmid cloning
- Studied the impact of cofilin during mitosis using UV/VIS spectrophotometry and confocal microscopy
- Analyzed data to create and organize graphs, charts, and documents for publications and presentation.

Undergraduate Research Assistant, 01/2007 to 01/2009

Wagner College – NY

- Investigated the regulation of Jadomycin B in *Streptomyces venezuelae* using PCR and Plasmid cloning.
- Analyzed data to create and organize graphs, charts, and documents for publications and presentation.

Teaching Assistant, 01/2008

Brown University – Providence, RI

- Developed behavioral experiments to study memory retention in high-school students
- Analyzed data to create and organize graphs, charts, and documents for publications and presentation.

Undergraduate Chemistry Assistant, 01/2007 to 01/2008

Wagner College – NY

- Prepared buffers/samples for chemistry department.
- Cleaned/sanitized laboratories.

Undergraduate Researcher,

Wagner College – New York, NY

- Bangladesh 2007 Collaboration project between Wagner College and Dhaka Community Hospital in Dhaka, Bangladesh.
- Interpreted test results and developed nonstandard tests.

Instructional Assistant, 04/2007 to 08/2009

Northern RI Collaborative – Lincoln, RI

- Assisted in the care and education of pre-K-12 students with Special Needs.

Shift Supervisor/Sandwich artist, 01/2005 to 01/2007

Subway Inc – Scituate, RI

- Managed five employees on second shift.
- Monitored food preparation and serving techniques to ensure that proper procedures were followed
- Inspected and cleaned food preparation areas to ensure safe and sanitary food-handling practices
- Prepared food items

EDUCATION

Master of Science: Biochemistry and Molecular Biology, 2010

Colorado State University - Fort Collins, CO

Bachelor of Science: Chemistry, 2009

Wagner College - Staten Island, NY

- Concentration in Biochemistry
- Concentration in Environmental Chemistry

Bachelor of Arts: Philosophy, 2009

Wagner College - Staten Island, NY

- Concentration in Gender Studies

AFFILIATIONS

- Parenteral Drug Association (PDA)
- American Chemical Society (ACS)
- Kappa Mu Epsilon, National Mathematics Honor Society
- Gamma Sigma Epsilon, National Chemistry Honor Society
- Alpha Sigma Alpha, Greek Sorority