GLADYS OSIS

WORK EXPERIENCE

09/01/2018 – Present ***Eurofins CRL Inc. , Piscataway, NJ***
Manager, Photobiology

- Manage Photobiology staff including hiring
- Act as Principal Investigator for studies, when appropriate
- Prepare documentation necessary for IRB submission
- Prepare study-related documents, such as Source Documentation forms, Informed Consent Forms, and Case Report Forms as required
- Maintain source documentation, including obtaining medical histories, informed consent and raw data.
- Assist in the preparation of test articles
- Supervise the conduct of study procedures as specified in the study protocol and assist in the conduct of the study procedure as required
- Assist study physicians with examinations and assessment
- Record observations, test results and physical measurements as required
- Review test results with PI to provide conclusions and summaries.
- Perform specialized procedures as qualified by training and evaluation of proficiency
- Interact with Sponsors to assist, as needed, in clinical protocol design.
- Assure that study protocol meets all requirements of Sponsor.
- Designate the study project manager and assume the primary responsibility for the conduct of a study.
- Provide daily work direction, training and guidance to all directly reporting staff.
- Respond to Sponsor or Client Service Rep, requests for information, study timelines and interim results.
- Conduct *in vitro testing* following FDA 2011 and ISO 24443 monographs

01/2016 – 08/31 /2018 Clinical Research Laboratories, LLC, Piscataway, NJ
Manager, Photobiology

- Manage Photobiology staff including hiring
- Act as Principal Investigator for studies, when appropriate
- Prepare documentation necessary for IRB submission
- Prepare study-related documents, such as Source Documentation forms, Informed Consent Forms, and Case Report Forms as required
- Maintain source documentation, including obtaining medical histories, informed consent and raw data.
- Assist in the preparation of test articles
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- Assure that study protocol meets all requirements of Sponsor.
- Designate the study project manager and assume the primary responsibility for the conduct of a study.
- Provide daily work direction, training and guidance to all directly reporting staff.
- Respond to Sponsor or Client Service Rep, requests for information, study timelines and interim results.
- Conduct *in vitro testing* following FDA 2011 and ISO 24443 monographs

12/2014 – 12/2015 Clinical Research Laboratories, Inc., Piscataway, NJ
Senior Study Coordinator, Photobiology

- Supervised Photobiology Dept. Staff

<u>WORK EXPERIENCE</u> (CONTINUED)

- Conduct *in vitro testing* following FDA 2011 and ISO 24443 monographs
- Maintain source documentation, including obtaining medical histories, informed consent and raw data.
- Assist in the preparation of test articles

- Conduct study procedures as specified in the study protocol
- Assist study physicians with examinations and assessment
- Record observations, test results and physical measurements as required
- Assist in the tabulation of test results, calculations and summaries
- Perform specialized procedures as qualified by training and evaluation of proficiency
- Designate the study project manager and assume the primary responsibility for the conduct of a study.
- Provide daily work direction, training and guidance to all directly reporting staff.

9/2011 – 12/2014 **Clinical Research Laboratories, LLC, Piscataway, NJ**
Study Coordinator, Photobiology

- Assisted in conducting photobiology, phototoxicity, and general SPF studies.
- Recruited test subjects in conformance with requirements as specified in the study protocol
- Scheduled panelist's visits to the clinic
- Assisted in bookkeeping duties by obtaining medical histories, consent forms and questionnaires
- Assisted in the preparation of test articles
- Assisted in conducting clinical trials as specified in the study protocol under the supervision of the Study Director, Medical Director, or Project Manager/Study Coordinator

6/2011 – 9/2011 **Clinical Research Laboratories, LLC, Piscataway, NJ**
Laboratory Technician, Photobiology

- Assisted in conducting photobiology, phototoxicity, and general SPF studies.
- Recruited test subjects in conformance with requirements as specified in the study protocol
- Scheduled panelist's visits to the clinic
- Assisted in bookkeeping duties by obtaining medical histories, consent forms and questionnaires

WORK EXPERIENCE (CONTINUED)

- Assisted in the preparation of test articles
- Assisted in conducting clinical trials as specified in the study protocol under the supervision of the Study Director, Medical Director, or Project Manager/Study Coordinator

- Recorded observations, test results and physical measurements where required
- Assisted in the tabulation of test results, calculations and summaries.
- Performed specialized procedures as qualified by training and evaluation of proficiency

5/2007 – 6/2011 **Dental Health Associates, North Brunswick, NJ**
Dental Office Assistant
- Front desk and insurance verification in a dental practice.

3/2005 – 12/2006 **Dr. Alok Goyal, MD , Perth Amboy, NJ**
Phlebotomist
- Phlebotomy and EKG in a Medical Practice

4/2002 – 3/2005 **Maureen Fraser, DDS In Perth Amboy, NJ**
Medical Office Assistant
- Responsible for reception and insurance verification

4/1998 – 4/2001 **Fertility and Reproduction Clinic, Lima, Peru**
Medical Technologist
- Performed immunological, biochemical and hematological tests.
- Microscopic exam on blood and other body fluids as well as cross match of blood samples for transfusion.

4/1995 – 4/1998 **Montesur Clinic in Lima-Peru**
Medical Technologist in Clinical Laboratory
- Performed immunological, biochemical and hematological test
- Microscopic exam and culture of blood and other body fluids.

EDUCATION

1995 Bachelor of Science in Medical Technology Clinical Laboratory
San Marcos University, Lima, Peru

2002 Patient Care Technician, Phlebotomy and EKG
Caliber Training Institute, New York, NY

CERTIFICATION

2007 Certified Medical Technologist

American Medical Technologist

VOLUNTEER

2006 Outpatient Laboratory in RBMC in Perth Amboy, NJ