**Mohammed H. Nayel**

**Master of Science in Bioorganic Chemistry (Leiden University)**

**U.S. Citizen**

Silver Spring MD

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**OBJECTIVE:**

Seeking a challenging position that utilizes my expertise and advances my knowledge in Synthetic Organic Chemistry (Drug Design and Synthesis), Generic Drugs Analysis (Raw Material of API), Quality Assurance, and Project Management

**Work Experiences:**

**04 Mar 2019 to Present (Glen Research)**

**R&D Scientist:**

* Propose and evaluate new products for potential inclusion in product portfolio
* Conduct scientific search for organic chemistry utilizing different tools such as SciFinder
* Write scientific article for the Glen Research Report
* Quality Assurance Scientist: Review all the QC batches (product quality, and ISO process). Release and reject QC batches based on their analytical data (HPLC, LC-MS, NMR, TLC) matching analytical specifications.
* Review experimental data for new batches of existing products for release
* Design and execute experiments to determine optimum synthesis and deprotection conditions for Phosphoramidites synthesis
* Document, Interpret, and troubleshoot all experiments with upmost scientific rigor
* Actively participate in internal and external scientific discussions
* Follow latest advancements in filed by means of thorough and regular survey of relevant literature and scientific conference attendance
* Provide expert technical support to Quality Control and end-users

**22 October 2018 to 01 Mar 2019 (Chenega Corporation/ FDA OMPT/CDER/OPQ/OS/DQSA/QDAB)**

**Data Analyst:**

* Support the Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), Office of Pharmaceutical Quality (OPQ), Office of Surveillance (OS), Drug Quality Sampling and Testing (DQSA) with post-market drug products surveillance activities.
* Collect sample information and laboratory testing results from multiple sources into a database.
* Conduct scientific reviews for scientific or regulatory issues involving the chemical properties of substances and evaluates the results.
* Sort and clean-up collected data using DQSA procedures.
* Check the calculations for testing results accuracy and perform data analysis on the verified testing results (dissolution, content uniformity, Impurities, etc.) for approved drugs active ingredients (API) and for the over the counter (OTC).
* Assist in writing comprehensive statistical and analytical reports from scientific investigations studies and projects
* Prepare word summary report or Power Point presentation on data review or tracking when requested by program lead.
* Apply chemistry knowledge and experience to the assessment of regulated products to assure their safety and effectiveness.

**02 January 2012 to 19 October 2018 (Fisher Bio Services (FBS), Germantown MD)**

**Project Manager, Acquisitions, Analytical Lab Manager (National**

**Cancer Institute -Chemotherapeutic Agents Repository) NCI-CAR Contractor: $75K**

* Develop Analytical Method (i.e. HPLC, TLC, IR) to study the composition, molecular structure, chemical properties, and purity of the, pre-drugs, antibiotics, agricultural chemicals, immunogenic agents, biological products, environmental agents, hazardous and toxic substances
* Project Manager for the Developmental Therapeutics Program (DTP) for NIH-NCI (Fisher BioServices Contractor).
* Manage the Acquisitions department and the Analytical Lab (PM and calibration, etc...), and manage the Analytical method development for HPLC and other analytical instruments.
* Train chemists at HPLC method development and FT-IR, and complete analytical method validation
* Acquiring of Investigational New Drug (IND) and facilitate their testing
* Communicate with the potential anti-cancer drugs suppliers and medicinal chemists oral and written and update the testing results of their compounds
* Provide full analytical report to NCI including purity, and impurity profile for small organic molecules
* Participate in the structure determination of the new synthesized compounds and suggest the suitable analytical method to determine the required information by NIH-NCI
* Coordinate with Suppliers and NCI staff the progression of testing of the potential antic-cancer drugs
* Develop and update SOPs for the Analytical Department and Acquisitions Department
* Confirm adequacy of packaging and storage, prevent and resolve any possible customs/regulatory related shipment delays
* Participate in the recommendation of the modification of existing Developmental Therapeutics Program (DTP) Policies to facilitate the registration and testing of the potential chemotherapeutic agents
* Served as a liaison among the suppliers (domestic and international) and NCI staff
* Implementing the root cause analysis tools
* Propose and implement PPI projects to enhance the efficiency of the lab tasks and the operation overall
* Develop and modify analytical methods or research projects to study the composition, molecular structure, chemical properties, and chemical reactions of substances to assist NIH-NCI for structure determination for potential Chemotherapeutic Agents
* Member of Quarterly Impact Award and Inspire Award at Thermo Fisher Scientific
* Identified chemicals hazardous utilizing 29 CFR 1910.1200 OSHA Hazard Communication).
* Generate and assist suppliers with the Toxic Substances Control Act (TSCA) Form for the newly synthesized chemicals

**27 December 2010 to 31 December 2011 (Fisher BioServices (FBS), Rockville MD)**

**NCI/NIH Contractor Chemist:**

* Reviewing and processing submissions for potential human anti-cancer drugs to NCI/NIH
* Coordinating with suppliers, recipients, and shipping companies to prevent and resolve customs/regulatory related shipment delays
* Review the chemical composition of the submitted compounds and the analytical methods that utilized to determine the structure and the purity of the final compound
* Evaluate, classify, and prepare documentation for chemical disposal activities

**28 August 2013 to present (Montgomery College, Takoma Park / Silver Spring Campus)**

**Adjunct Faculty (Part-time):**

* Teaching organic and analytical chemistry principals and techniques such as:
* (NMR, IR, and GC)
* Stereochemistry
* Distillations
* Organic reactions (SN1 and SN2)
* Teaching organic and inorganic compounds physical properties determination (i.e. melting point)
* Prepare the final exams and provide finals grades to the Chemistry Department

**16 April 2007 to 26 December 2010 (Thermo Fisher Scientific (TMO) Genomics, Milwaukee**

**Process development/Manufacturing Chemist:**

* Scaling up organic reactions from gram scale to kilogram for Phosphoramidites synthesis
* Developed and supervised the review and analysis of chemical processes involved in the manufacturing and scale-up of RNA and DNA Phosphoramidites
* Develop, modify, and analyze methods or research projects related to organic molecules
* Transfer technology from R&D to the manufacturing
* Developed suitable analytical methods to characterize in process (intermediates) products and final products using analytical methods (HPLC, LC-MS, and NMR)
* Cross training with nucleotides department for AKTA purification
* Perform item qualification for reagents and solvents
* Oversee final product packaging and storage
* Assist with the selection and evaluation of production equipment
* Process development troubleshooting
* Writing, reviewing and training chemists in manufacturing methods/ deviations
* Perform scientific review, conduct oral and written evaluations of the literature
* Writing Safety Data Sheet (SDS) and Certificate of Analysis (C of A)
* Assisted with writing comprehensive, authoritative statistical and analytical reports from scientific investigations studies.
* Participate in developing analytical methods and extending their application to other substances.
* Work with the customer in the determination of the final product for RNA and DNA Phosphoramidites

**05 September 2005 to 31 December 2006 (Monomer Sciences, Inc., New Market AL)**

**Senior Synthetic Organic Chemist (R&D Chemist): $55K**

* Design - synthesis of modified nucleosides, RNA and DNA Phosphoramidites (Therapeutic RNA and molecular diagnostics reagents) and organic dyes. Scale up organic reactions.
* Develop analytical methods to determine the purity of the raw materials, intermediates and final products

**07 March 2005 to 03 September 2005 (Qualitest Pharmaceutical (Vintage Pharmaceutical Co.,) Huntsville AL)**

**R&D Analytical Chemist:**

* Develop, review and analyze chemical formulations involved in the manufacturing of human generic drugs
* Develop analytical methods and extending their application to other substances designing new sampling and sample preparation procedures and validation and collaborative studies.
* Worked with drug substance raw materials sampling, testing (IR, UV, HPLC, UPLC, and the entire test for the raw materials) for API quality vs.USP standards following the FDA regulation to release raw materials for formulation
* Implement and incorporate latest developments in methods for drug analysis under the applicable quality and safety regulations
* Communicate review of the drug analysis outcomes with senior managers through oral and written communication.
* Transfer developed Analytical Method from Research and Development to Quality Control Department and train QC chemists in the developed Analytical Method

**EDUCATION:**

**2001-2004 Master of Science in Bioorganic Chemistry (Three years)**, Track: Design and Synthesis, Faculty of Mathematics and Natural Sciences, Leiden University, Leiden, Netherlands

**1993-1996 Bachelor of Science in Chemistry and Zoology (Four Years)**, (Physics and Mathematics, Chemistry, Zoology, Botany and Scientific English), University of Khartoum, Khartoum, Sudan

**TRAINING COURSES:**

* Current Good Manufacturing Practice regulations training (Fisher BioServices Jan 2018)

Corporation

* Analytical Method Development Workshops Columbia, MD (MAY 2017) by Waters Corporation
* Master Control Advanced User Training (November 2016)
* Developing Frontline Leaders (This training is targeted towards managers of people with at least 1 year of management experience (6-7 June 2016)
* Root Cause Analysis Tools Thermo Fisher Scientific (TMO), 10/ 2013
* Practical Process Improvement/ Process Champion (Mangers): TMO, 02/ 2013
* Certified Trainer: FBS, 08/2012
* 49 CFR General Awareness and Familiarization, Hazardous Materials Table, (EPA-Hazardous Waste, OSHA- First Responder Awareness, General Requirements for Shipments and Packaging): FBS, 07/ 2011
* Chemical Development & Scale-Up in the Fine Chemical and Pharmaceutical Industries**:** Scientific Update, 05/ 10-12/ 2010
* Leadership Development**:** TMO Genomics 2/2010
* Effective Time Management**:** TMO Genomics, 12/07/2009
* Practical Process Improvement:TMO, 11/ 2008-02/ 2009
* 1100/1200 Series LC Troubleshooting & Maintenance: Agilent Technologies, 07/8/2008
* Project Management (Tools, Principles, Practices): The Lewis Institute Project Management Systems, 11/6-8/2007

**MEETINGS:**

* IRT-XVII International Round table on Nucleosides, Nucleotides and Nucleic Acids. *Bern-Switzerland, September 3-7, 2006*
* BAA (Biotechnology Association of Alabama) Annual Meeting, *Birmingham, Alabama US, February 3, 2006*

**AWARDS:**

* Best Practical Process Improvement (PPI) Project for Q3, for my role as Team Leader for this 28 Nov 16 (TMO – MD)
* Moments of Excellence Award - Customer Allegiance (TMO 28 Sep 16)
* Employee Recognition Award, for replacing explosive material (HOBt) with alternative substance as an activator in Amidite Synthesis (TMO 06/16/2010)
* Employee Recognition Award, for expedited schedule, delivery and cost improvement on Project “Dye Amidite synthesis” (TMO 08/01/2008)
* Employee Recognition Award, for exemplifying the Thermo Fisher value of Innovation by developing a method to convert 2’-OMe-U into another key raw material (2’-OMe-C). (TMO Genomics 12/05/2008)