DELHY MARIA ARIAS

Highly-motivated & adaptive regulatory professional with experience in Quality Assurance, Quality Control, Production and R&D in Tissue Banking, Medical Device, and Biologics Industries; Possesses strong work ethics, effective communication, and a positive attitude; Supporting FIU BME Department as Adjunct Faculty for Cell & Tissue Engineering

EDUCATION **FLORIDA INTERNATIONAL UNIVERSITY (FIU)** **Miami, FL**

- Master of Science in Engineering Management August 2010
- Bachelor of Science in Biomedical Engineering (Minor in Chemistry) August 2005

PROFESSIONAL EXPERIENCE

BIOTISSUE HOLDINGS, INC. **Miami, FL**

Sr. Regulatory Affairs Manager 01/2023 – Present
Regulatory Affairs Manager 06/2018 – 01/2023

- Liaise with international regulatory consultants to support product registrations
- Compile, submit, and maintain product international dossiers
- Responsible for timely submission of State, Federal, and International tissue banking licenses, permits, and registrations for the FDA, Health Canada, NY State, California, Maryland, Illinois, and Washington, D.C.
- Manage regulatory assessments, departmental metrics, and training plans
- Support departmental procedural changes through the electronic QMS

Audit Program Manager 12/2015 – 06/2018

- Manage activities for conducting gap analysis, internal, vendor, and external audits
- Ensure timely submission of tissue bank permits & registrations at the state level
- Oversee and manage several Quality Assurance Functions: Tissue Receipt, Donor Eligibility, Final Product Release, and Environmental Monitoring
- Approved vendors, suppliers and IQ/OQ equipment documentation
- Coached and mentored QA Staff to help them strengthen technical skills and develop career paths
- Thorough understanding of FDA HCT/P and Medical Device Regulations, Health Canada CTO and Medical Device Regulations, AATB Standards

Quality Engineer 05/2013 – 12/2015

- Provided technical feedback to Production and R&D for establishing and improving product criteria
- Responsible for the release of all distributable products to ensure safety, quality, and compliance
- Assisted Director of Quality during external audits (FDA, ISO, AATB, NY State)
- Performed desk and site audits of vendors to ensure quality and regulatory compliance
- Responsible for reviewing and evaluating Validation Protocols/Reports and IQ/OQ documentation
- Ensured the timely renewal of state licenses, Health Canada, and FDA establishment registrations

QA/QC Specialist 09/2009 – 05/2013

- Developed appropriate and effective CAPAs through the use of Lean Six Sigma tools such as the Fishbone Diagram, Control Charts, Root Cause Analysis, and 5 Whys
- Developed Defect & Nonconformance trending database to track product nonconformances
- Investigated product, equipment, and supplier nonconformances as well as customer complaints

- Inspected final product during in-process and final process stages prior to product release
- Performed internal audits of various areas of the Technical Division and vendor desk audits
- Reviewed and trend Environmental Monitoring and product-related microbial results

GMP Documentation Supervisor 02/2009 – 09/2009

- Acted as liaison between BioTissue and procurement agency for the acquisition of donor charts
- Revised and implemented the GDP System throughout the Technical Division
- Processed human placenta tissue in clean room for research and production purposes
- Developed trending database for Environmental Monitoring results for ISO 7 clean room
- Coordinated the process flow of batch records from placenta procurement to product release
- Improved the Environmental Monitoring documentation for the ISO 7 clean room

BIOHEART, INC. **Sunrise, FL**

Quality Control (QC) Supervisor 02/2008 – 02/2009

- Supervised and maintained the cGMP Quality Control laboratory for the Randomized, Double-Blinded, Phase II/III MARVEL Clinical Trial
- Established open communication with Clinical, Manufacturing, Logistics, and Quality Assurance departments to ensure each MyoCell product is manufactured with the highest quality standards in the shortest timeframe
- Ensured technicians received adequate growth opportunities by coaching them in the development and implementation of new projects and tasks
- Performed & reviewed QC tests such as cell viability, CD56 and Desmin markers, Sterility testing using the BacT ALERT, Sterility testing using the membrane filtration method, Streak plate method of isolation, Endotoxin, Mycoplasma, Gram Stain, Trypan Blue Assay, Myotube Formation Assay, and Environmental Monitoring
- Accountable for the calibration and preventive maintenance of QC equipment such as the Guava PCA, Air IDEAL Sampler, BacT ALERT 3D System, EndoSafe Reader, Luminometer, and CO_2 Incubators
- Executed Nonconformance Reports for nonconformances (NCRs), deviations, and Out-of-Specifications along with applicable CAPAs

Sr. *Quality Control & Research Associate* 12/2006 – 02/2008

Research Associate 08/2006 – 12/2006

- Prepared the Quality Control laboratory for the initiation of the Bioheart MARVEL Phase II/III Clinical Trial
- Main on-site and off-site technical support of Quality Control issues for PharmaCell at Maastricht, Netherlands and trainer for PharmaCell QC technicians
- Designed and executed engineering runs with Sr. Manufacturing personnel to validate the production of human skeletal myoblasts in the ISO 7 clean room
- Designed and tested the use of electrical stimulation on human skeletal myoblasts in collaboration with Bioheart SAB member Dr. Juan Chachques
- Cultured primary human endothelial cells from adipose tissue and identified external & internal markers specific to this cell line
- Transfected cultured pig cells with SDF-1 adenoviral vector for research purposes

Laboratory Technician II 10/2005 – 08/2006

Laboratory Technician I 05/2005 – 10/2005

- Executed experiments aimed towards improving cell preservation and culture methods
- Performed immunohistochemistry stains and characterization utilizing Guava PCA
- Collaborated in the documentation of Standard Operating Procedures and Material Specifications
- Acquired experience in the isolation, culture, harvest, and freezing of human skeletal myoblasts

CERTIFICATIONS

- Facilitative Leadership 2023
- RAPS Dual Certificate Medical Devices and Pharmaceuticals 2022
- ASQ Certified Biomedical Auditor 2013
- ASQ Certified Quality Auditor 2012
- AATB Certified Tissue Bank Specialist 2012
- FIU Lean and Six Sigma Certification 2008

RESEARCH EXPERIENCE **FIU MARC U-STAR PROGRAM (NIH)**

Undergraduate Research Assistant 2003 - 2005

- Cultured C6 astrocytes and endothelial cells for the development of an In Vitro Blood-Brain Barrier Model for Analysis of Anti-Epilepsy Drugs under the supervision of Biomedical Engineer Professor Anthony McGoron

VOLUNTEERING

- FIU MS in Engineering Management Advisory Board Council 03/2023 – Present
  Position: Board Member
- American Association of Tissue Banks (AATB) 02/2023 – Present
  Position: Accreditation Committee Member
- AATB Quality Council 07/2022 – 07/2024
  Position: Secretary
- Toastmasters International, The Landing Club 2009 – Present