**Oraya Therapeutics QA Manager:**

My role as the manager at Oraya Therapeutics 06/2008 – 08/2011 was as follows:

**Key Responsibilities:**

* Led the development, implementation, and maintenance of SOPs related to released QA documentation
* Served as the primary point of contact for all documentation-related inquiries and issues
* Collaborated with cross-functional teams to ensure compliance/regulatory requirements/industry standards
* Manage the DMS (Document Management System) to ensure its optimal performance and functionality
* Managed packaging validations in verifying processes and materials per specification requirement standards
* Oversaw the creation, review, approval, and distribution of all documents, including batch records, forms
* Implement continuous improvement initiatives to enhance documentation standards and processes
* Led training sessions for staff on documentation procedures and best practices
* Managed the serialization processes ensuring compliance and regulatory industry standards are upheld
* Led the team in gathering and submitting the required documentation for FDA review and approval
* Acted as the front room facilitator for quality audits from internal and external parties
* Provided leadership and guidance to a team of direct reports, ensuring plant coverage and support 24/7
* Participated in executive-level presentations on project status and daily operations
* In charge of managing calibration of industry standard tools as required
* Strong understanding of regulatory requirements (e.g., FDA, cGMP) pertaining to documentation management
* A proven track record of successfully leading documentation projects and initiatives
* My excellent communication, leadership, and interpersonal skills
* Ability to work effectively in a fast-paced environment and manage multiple priorities simultaneously
* Proficiency in Document Management Systems (DMS), Agile Database management
* Certification in Quality Management ASQ