# URMI QUALITY MANAGEMENT CONSULTING PTY LTD

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UQMC QMS Consulting Services

Our mission is to help life science organisations (start-ups as well as traditional manufacturers) achieve sustainable compliance and operational efficiency.

At UQMC, we understand that QMS is not just about compliance, but also a powerful tool for improving overall business operations. Whether you are in drug development or traditional manufacturing, an effective QMS can help you achieve sustainable compliance as well as operational excellence.

With over two decades of experience within the ISO 9001 and Pharmaceutical Quality Systems, we have developed the "Customise-Simplify-Coach" framework that will assist you in establishing and improving your QMS. Our framework brings a fresh approach to not only identifying and implementing QMS requirements but also to employee training and skill development, ensuring that your team is equipped with the knowledge and expertise necessary to maintain a robust QMS.

Whether you are looking to implement new systems, improve existing ones, go digital or just want to understand how QMS can support your business operations, we are here to help.

#### Customize

Simplify > Comply

### Services offered – Early stage & Startups



<u>Phase-appropriate Quality Systems Implementation</u> - We provide tailored design & implementation of QMS procedures that are specifically suited to the stage of your drug or device development, ensuring applicable compliance as well as efficient project management.

<u>Documentation Review and QA oversight</u> - Our experts will review your documentation, including Quality Agreements, Batch manufacturing records and other critical documents, to ensure compliance.

<u>Audit Support</u> - Our consultant can audit your service providers, outsourcing providers as well as internal systems that support your development project.

<u>*Quality System Due Diligence*</u> - We offer Quality Systems Due Diligence services to help you evaluate potential acquisition targets, identify compliance risks, and asses the overall system quality.

### Services offered – Traditional Manufacturing



<u>Customised Quality Systems Assessment</u> - Our Customise-Simplify framework enables us to provide tailored QMS assessments that meet your unique needs. We evaluate your current QMS, identify areas of improvement, and provide actionable recommendations to enhance compliance and operational excellence.</u>

<u>Digital Transformation Support</u> - Our Digital transformation services include strategy development, planning, implementation support, training, and post-implementation effectiveness review.

<u>Tailored Training and coaching</u> - We offer customised training and coaching services on QMS and GMP related topics. See our "Training" section for details on our approach.

<u>Quality Culture Assessment and Improvement Plan</u> - Our Quality Culture Assessment and implementation service is designed to help you evaluate your current quality culture and develop a plan to enhance the culture, focused on continuous improvement and compliance



## **Bespoke Training**

<u>Assessment and Improvement Plan for Existing Training Program</u> - Our expert will assess your current training programs, identify gaps, and provide actionable recommendations for improvement.

<u>Design and Delivery of Annual QMS Related Training</u> - We will work with you to design and deliver annual QMS training programs that align with your organisation's goals and regulatory requirements. We can assist with design & development of immersive/interactive training content (use of VR/AR & AI)

All our training services are enhanced by 1:1 coaching to ensure trainees receive a comprehensive learning experience that drives long term compliance & boost employee engagement.



#### **Consultant Profile**

Our consultant, Antiksha Joshi, brings over 20yrs of rich experience in the quality management sphere of life science industries. Her diverse career spans across various types of organisations, from gelatin manufacturers to sterile injectable to biologics, and extends over three continents. She has been instrumental in implementing and enhancing Quality Management Systems (QMS), ensuring compliance and successfully navigating numerous regulatory audits (USFDA, MHRA, TGA).

Antiksha's expertise and passion are centred around assisting regulated industries in implementing bespoke quality systems. She leverages her deep understanding of Pharmaceutical Quality Systems, GMP, ISO 9001, and HACCP to provide tailored solutions to meet your unique industry needs. What sets her part is her ability to blend technical knowledge with interpersonal skills. Holding a Counselling Diploma in addition to a Master's in Microbiology, she designs and delivers personalised training and coaching programs. This unique approach ensures that our clients not only receive an effective QMS but also benefit from a people-centric implementation strategy