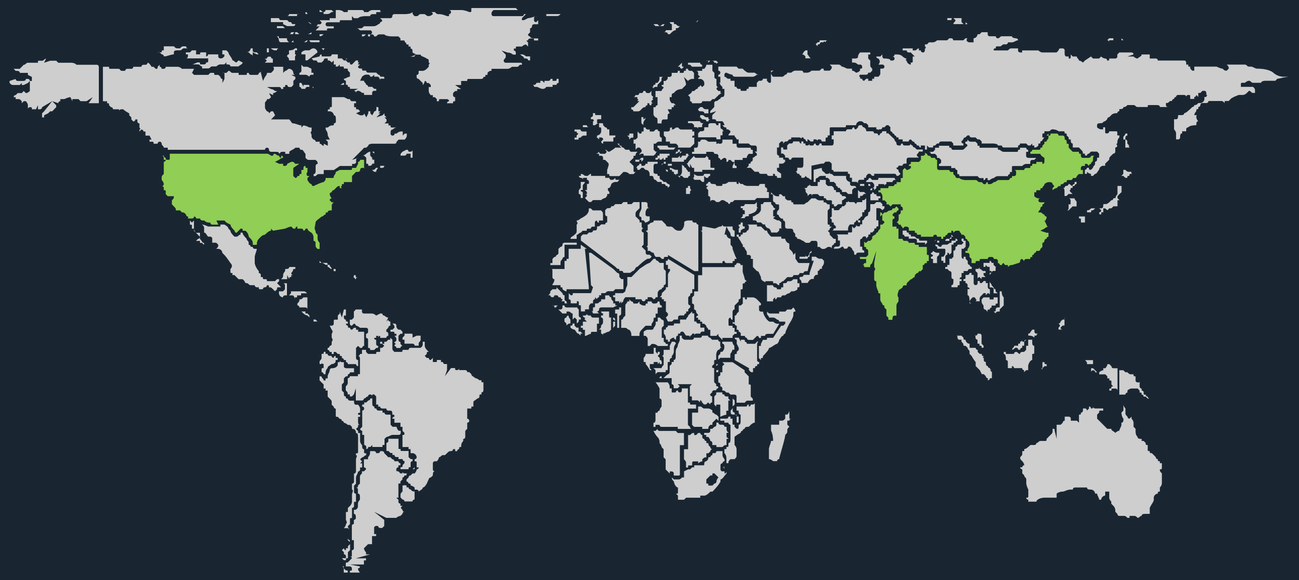
microrite, inc.

achieving success through expertise

Who We Are

Microrite strives to provide the highest standards of GMP consulting and training services for the pharmaceutical, biotechnology, and medical device industries



We provide a full spectrum of GMP services, and with consultants in the Americas as well as Asia we have global capabilities

Microrite is a USA based consulting and training Company helping pharmaceuticals, biotechnology, medical devices and other healthcare industries in the areas of facilities, validation, microbiology, quality assurance and quality control to ensure GMP compliance.

Our Founder

Ziva Abraham

CEO & Founder

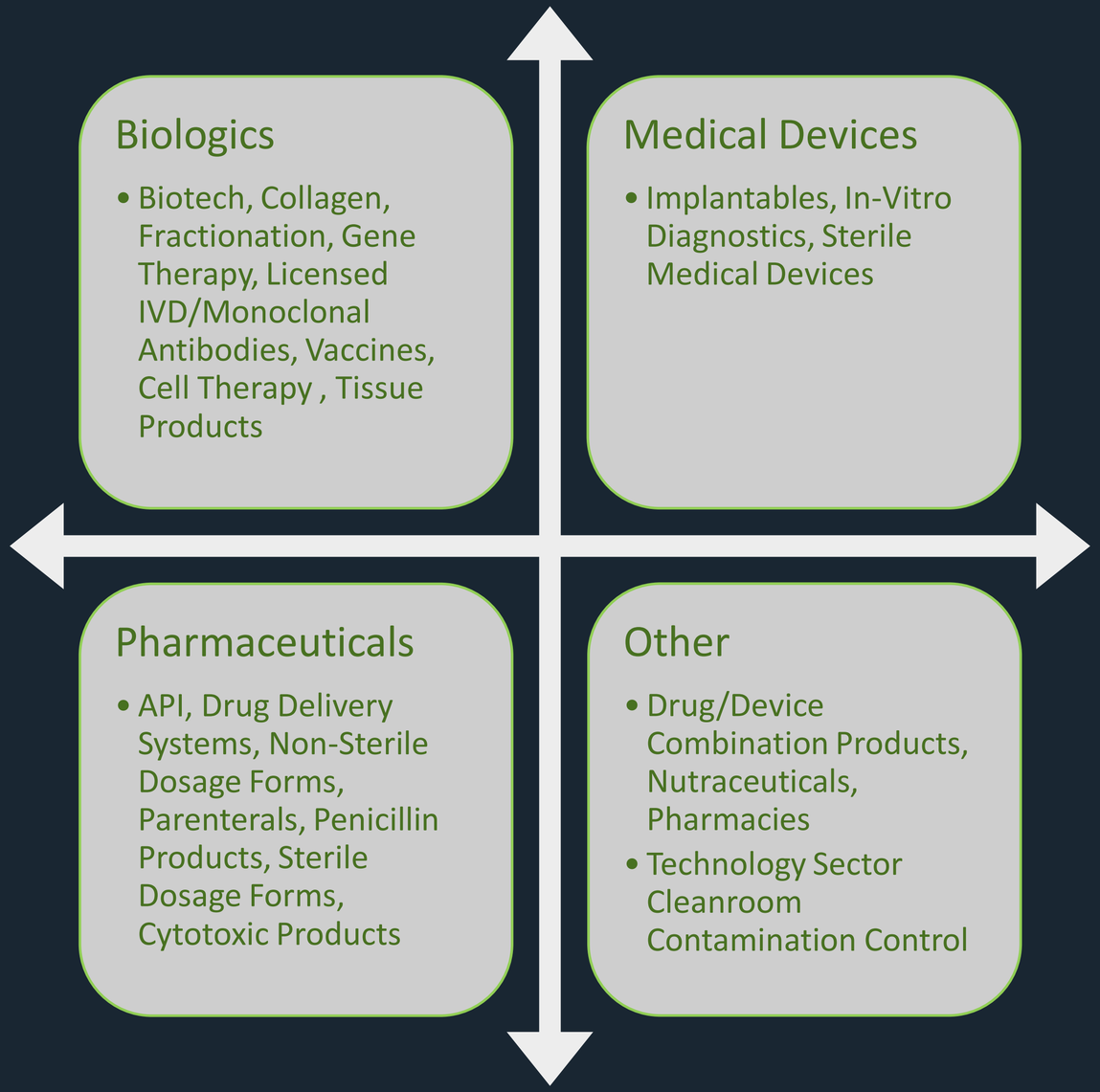
Ziva Abraham *is the CEO and Founder of Microrite, Inc. Ziva has over 30 years of academic, research, clinical and industrial experience in microbiology, and quality assurance. Ziva has received her Master's Degree in microbiology and has conducted research on developing microbial insecticides using entomogenous bacteria and fungi towards a Ph.D degree. Her career also includes founding and managing clinical laboratories for Maccabi Medical in Israel.*

After years of consulting, and assisting countless clients worldwide Ziva has developed a unique methodology towards addressing client needs utilizing a risk based approach.

Ziva founded Microrite because she noticed a true gap in expertise within the life science consulting industry. A hands-on approach was lacking, in her words; "you truly have to work with the client, hand in hand to impart your knowledge, to understand the clients needs and ultimate goal, to become part of the team"

Our Expertise

Our experts exhibit an intimate knowledge of US FDA and European regulatory body regulations in:



Our Process

A comprehensive methodology to resolving challenges

Communicating

Planning

Executing

Reporting

Communicating with the client to clearly understand their needs and requirements is the first step towards resolving challenges. Only after undestanding such a key factor can planning occur.

Considering regulatory requirements & implications, cost & compliance, timelines & deliverables, and ultimatly product quality as well as patient safety are some of the major components of our project planning strategy.

Project execution utilizing subject matter experts and technical project managment is key to successful project plans. Each expert plays an integral role, which when combined with other expertise forms a novel approach to project execution.

Reporting documentation, when combined with educating the client, guarantees continuous compliance with regulations and manufacturing of quality products.

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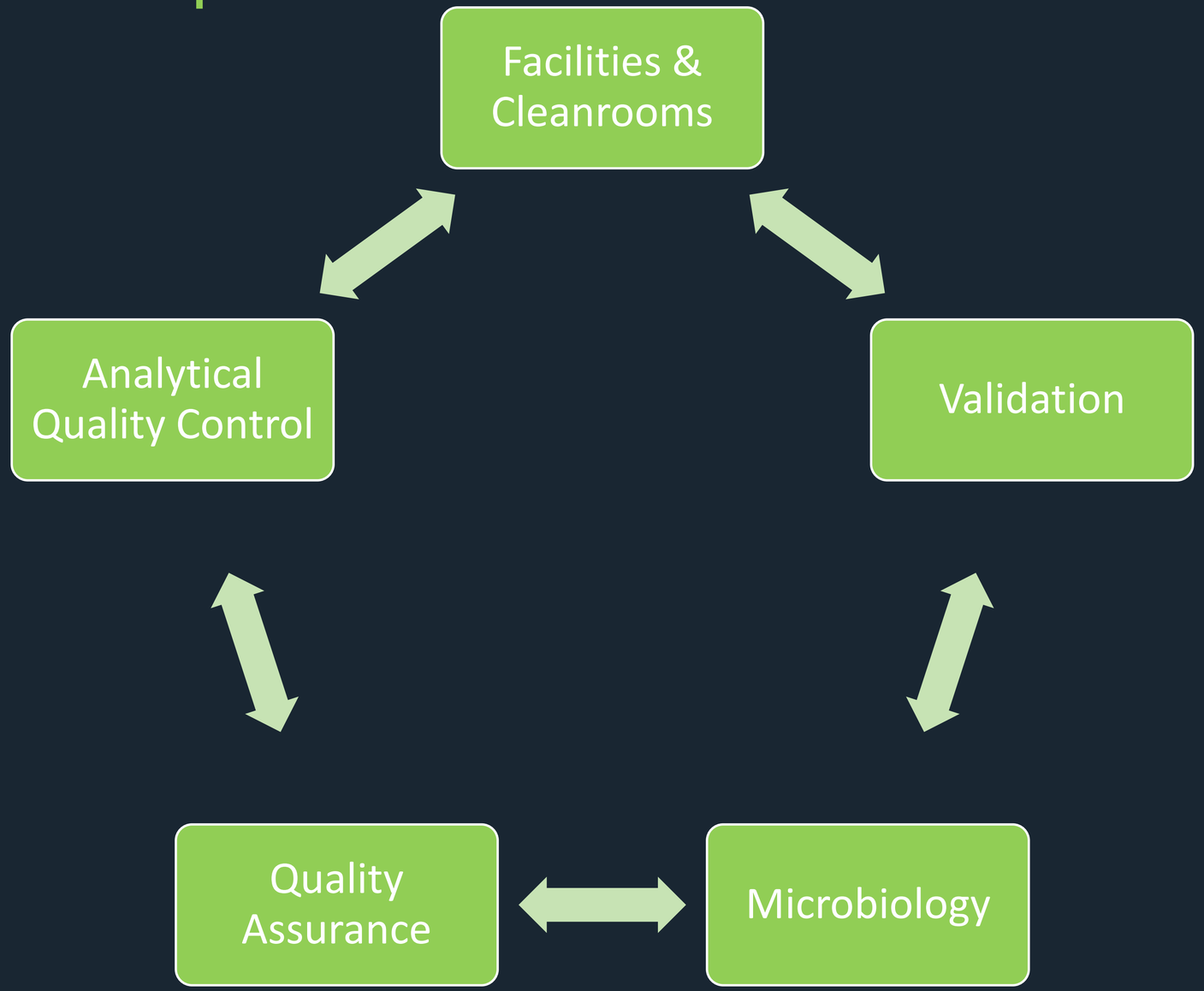
Our Core Competencies



Facilities & Cleanrooms

Microrite adopts a risk based comprehensive approach to GMP facilities from user requirement development through start-up and qualification. We ensure compliant design, construction and airflows per cleanroom standards. Our goal is to make certain that your facility is suitable for the type of product you manufacture. By leveraging expert knowledge in GMP facilities, we assist clients in:

- Site Selection & User Requirement Specifications
- Basis of Design Reviews
- Construction Management/Project Management
- Airflow Visualization/Smoke Studies/Computational Fluid Dynamics
- Electrostatic Contamination Control
- EH&S and Cleanroom Trouble Shooting
- Utilities and Equipment Selection Advice

Validation

Microrite’s experienced validation team has the technical aptitude to make our clients' projects successful. Through our validation services Microrite ensures that a specific process or system will consistently produce to the required specification in accordance with GMPs. Our team understands validation principles, implementation and practices for operational consistency in:

- Facility/Cleanroom, Isolator, RABs Validation
- Water Systems Validation
- Compressed Air/Gases Validation
- Manufacturing & Laboratory Equipment Validation
- Lifecycle Approach for Process Validation
- Media Fills/Process Simulation
- Cleaning Validation

Microbiology

Microrite takes pride in our unparalleled expertise in all areas of microbiological quality control and sterility assurance. With highly proficient subject matter experts, we offer clients confidence in the microbiological quality of their products. Our diverse team of microbiologists can help implement contamination prevention, control and remediation measures by:

- Total Microbiological Quality Control
- Risk Based Environmental Monitoring Program
- Scientifically Sound Cleaning, Disinfection & Gowning Programs
- Contamination Control Programs and Investigations
- Microbiological Methods and Procedures
- Microbiology Laboratory Audits
- Sterilization and Sterility Assurance

Quality Assurance

At Microrite we excel at development and implementation of phase appropriate quality systems. We support start-up as well as established companies to implement the framework for their quality program. Through quality system procedures and functions we ensure that GMPs are followed and maintained as required by regulations. We assure that the product manufactured is safe for human use by:

- Quality System Design and Procedures
- GAP Analysis
- Mock Audits
- Vendor/Supplier/CMO Audits
- Materials Management
- Regulatory Inspection Preparation
- FDA 483 Responses and Remediation

Analytical Quality Control

At Microrite, we assure that analytical methods are designed, developed and validated to provide consistent accuracy in product testing. We help develop integrated stability programs to verify that product quality remains unchanged through storage, shipping and shelf life. We achieve AQC through laboratory control of analytical performance by:

- Stability Program Development
- Analytical Method Development
- Analytical Method Validation
- Contract Laboratory Audit
- Analytical Technology Transfer
- Testing Protocols and Procedures
- Failure Investigations

Why Our Clients Choose Us

The Microrite team takes pride in their ability to cohesively engage with clients in order to resolve any challenges they may face, in a timely and cost effective manner.

Microrite's consultants are well published, and expert committee members for various standards committees and organizations such as:

- ISO Cleanroom Standards Committee – TC 209
- ISO Sterilization Standards Committee – TC 198
- IEST Board
- ASHRAE Board
- AAMI Standards for Sterilization
- United States Pharmacopeia
- Indian Pharmacopeia

Each of our consultants is a subject matter expert and has held key positions in industry.

Thank you for your time and consideration

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