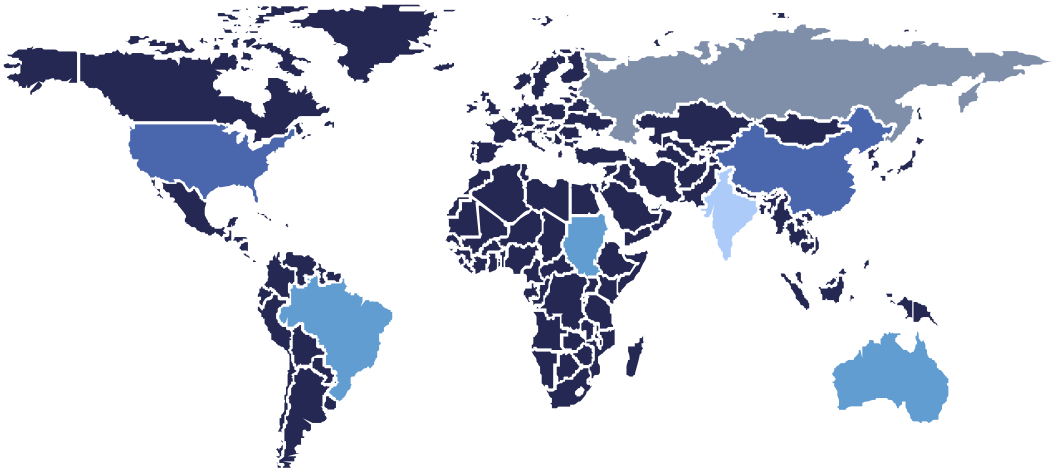
achieving success through expertise

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

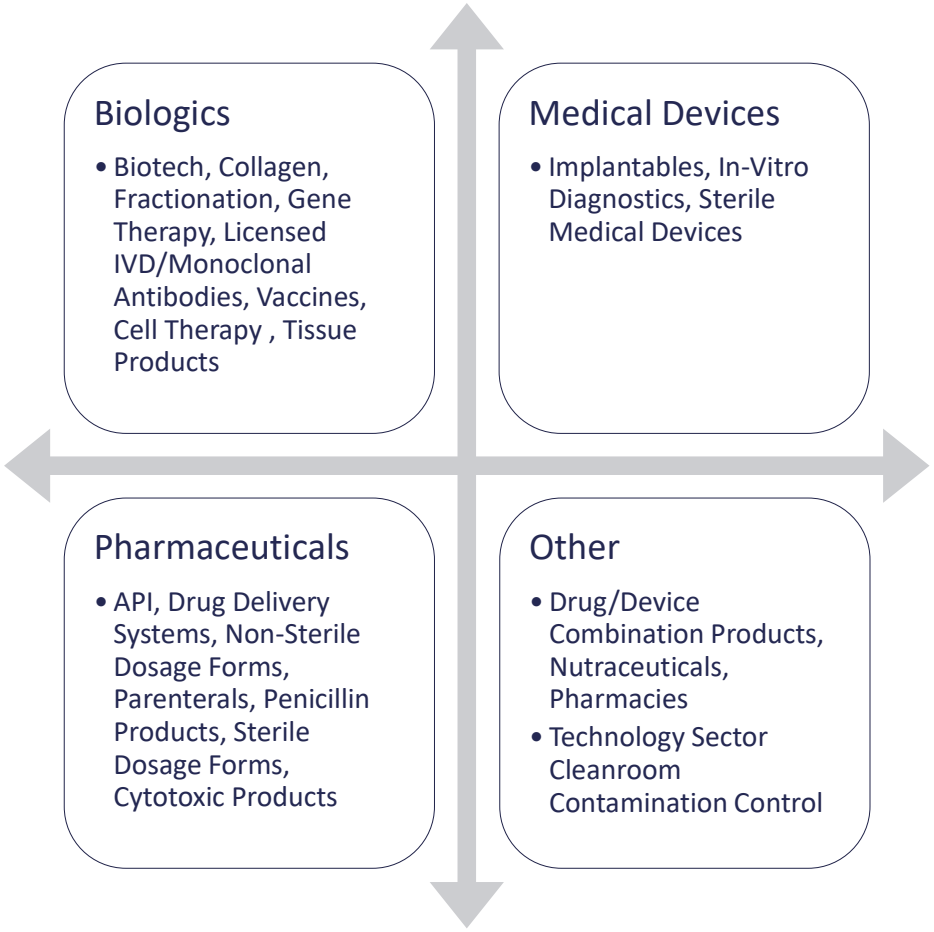
Ziva Abraham is the CEO and Founder of Microrite, Inc. Ziva has over 35 years of academic, research, clinical and industrial experience in microbiology, and quality assurance. Ziva has received her Master's Degree in microbiology and has conducted research on developing microbial insecticides using entomogenous 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"

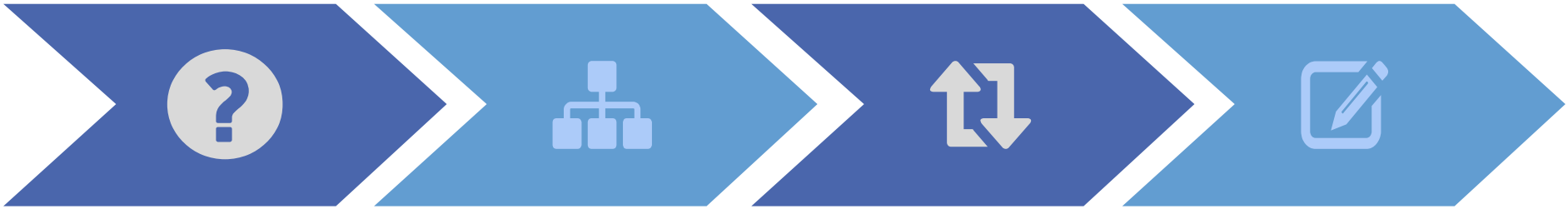
Microrite Expertise

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



Microrite Process

A comprehensive methodology to resolving challenges



Communicating

Planning

Executing

Reporting

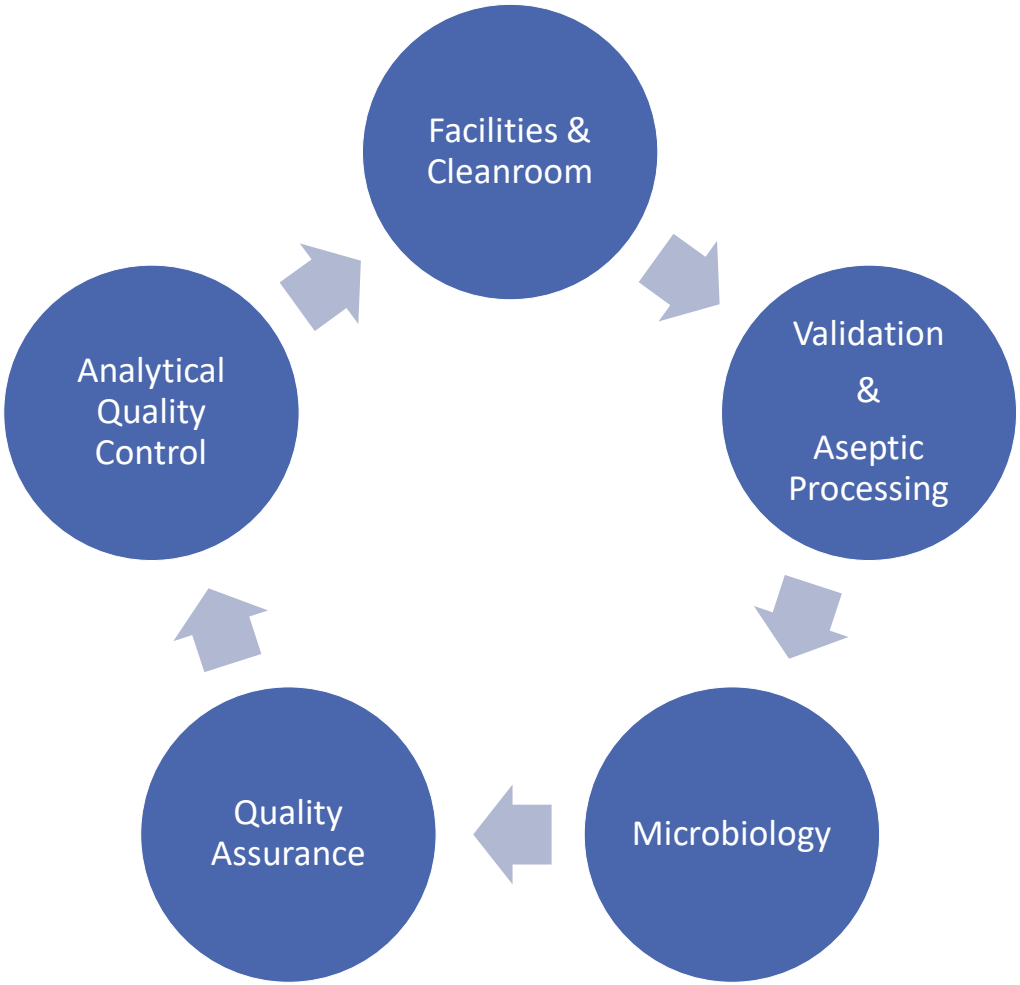
Communicating with the client to clearly understand their needs and requirements is the first step towards resolving challenges. Only after undestanding such a key factor can planning occur.

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.

Microrite's Core Competencies



What is a Holistic Contamination Control Strategy

The contamination control strategy (CCS) is a document that identifies and assesses risk, explores the mitigating options and defines the preventive actions that may be associated with the full range of sources of particulate and viable contamination of aseptically produced and terminally sterilized products

A Contamination Control Strategy (CCS) is implemented across the facility in order to assess the effectiveness of all control and monitoring measures employed by a company

Science is no longer isolated; it is living across the lifecycle of the product/process within a Quality Management System

Why is a Holistic Contamination Control Strategy

Aspects of contamination control strategy include a better overview of how all processes interact, how each process affects another

It helps removal of redundancies, increasing the possibility to proactively influence changes and strategies in elements related to contamination control, identify potential gaps, and to avoid product loss

Benefits of a Holistic Contamination Control Strategy

A well thought out and implemented CCS should help a site reduce the risk of product quality defects

A well thought out CCS will demonstrate to a regulatory inspector or auditor that a site is aware of its specific risks to products and how these have been mitigated

The Microrite Process for Developing a CCS

By working in conjunction with the various client departments to draft the policy as a team; Microrite creates companywide awareness on the importance of contamination control

This collaborative process by Microrite's subject matter experts and the company's own personnel helps the client understand address and mitigate contamination and be well prepared for regulatory visits

Key Aspects of the Holistic Contamination Control Strategy

Important aspects of a documented contamination control strategy are developed per current regulatory thinking as outlined in the current EU Annex 1:

- Pharmaceutical Quality Systems
- Design of both the plant and process
- Equipment and facilities
- Personnel
- Utilities
- Raw materials control
- In-process controls
- Product containers and closures
- Vendor approval
- Process risk assessment
- Process validation
- Preventative maintenance
- Cleaning and disinfection
- Monitoring systems
- Continuous improvement

CCS Implementation Strategy

Microrite's role

- Perform review of various elements
- Perform gap assessments per EU / USFDA / ICH requirements
- Providing solutions/risk mitigation plans for all identified gaps
- Assist, review and finalize white papers in conjunction with client
- Assist, review and finalize contamination control policy
- Training of process team for updated requirements

Client role

- Provide access to all necessary documentation in a timely manner
- Perform gap assessment per checklist prepared by SME's
- Identify action items
- Perform risk assessment for identified gaps
- Implement any corrective actions
- Initiate white papers for various review elements
- Initiate contamination control policy document

Benefits of the Risk Based Approach

This risk-based approach will help the client in achieving:

Why Microrite for Developing your CCS

Microrite team has developed contamination control strategies for many years saving clients from regulatory citations.

- Microrite has all expertise required, starting from facility design to product release
- While developing a CCS for a client Microrite equips the client for science based justification and imparts knowledge on real life contamination control
- A CCS developed by Microrite helps client personnel the basis for defending their CCS
- A CCS developed by Microrite is a tool that beyond regulatory expectations becomes a continuous improving pathway

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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