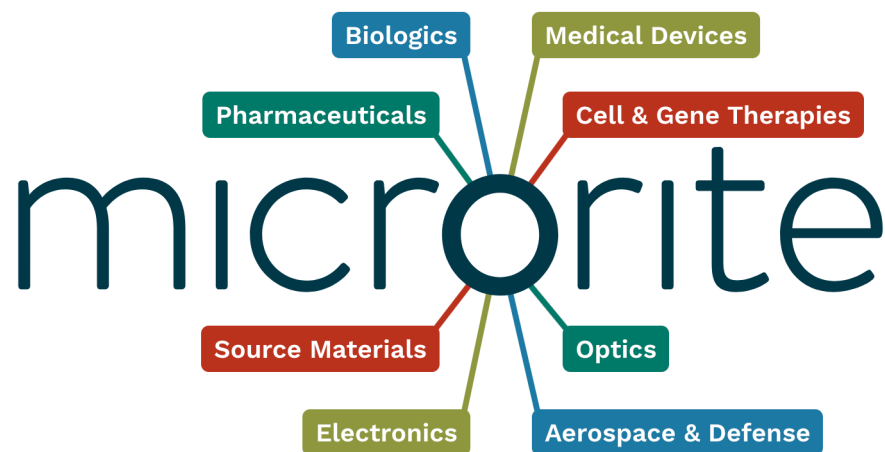


## WHO WE ARE

Microrite, Inc. is a cGMP consulting and training firm assisting companies globally. We strive to provide our clients with a comprehensive approach and unparalleled expertise in the areas of facilities, validation, microbiology, quality assurance and quality control.



## WHAT WE DO

Our goal is to prevent and control contamination to assist our clients in manufacturing quality products while adhering to relevant regulations and standards.

### FACILITIES

- Airflow visualization and recovery studies for cleanrooms
- Microbial, particulate, and static charge control
- Cleanroom cleaning plans and disinfectant qualification studies
- Gown choice, gowning and gown management programs

### VALIDATION

- Facility, utilities, and equipment validation (IQ/OQ/PQ)
- Isolator validation and decontamination cycle development
- Cleaning validation
- Sterilization validation

### MICROBIOLOGY

- Development of an overall contamination strategy for non-sterile and sterile products
- Risk based environmental monitoring programs
- Microbiology laboratory procedures, test methods, method validation
- Microbial audits of contract manufacturers, supplier and contract laboratories
- Failure investigations and establishing objectionable microorganisms
- Sterilization consulting: Gamma, EtO, E-Beam, Dry Heat, Steam and Chemical

### QUALITY ASSURANCE

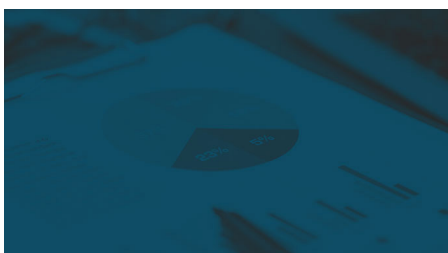
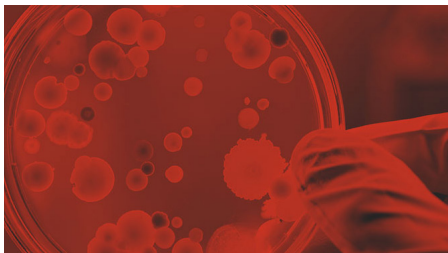
- GAP assessment
- Mock PAI audits/regulatory inspection readiness
- SOP development, batch record preparation and review
- Contract manufacturing organization (CMO) and vendor audits
- FDA 483 responses and remediation

### ANALYTICAL QUALITY CONTROL

- Procedure, method and stability program development and validation
- Analytical method transfer and analytical laboratory audit
- Failure investigations

## WHY MICRORITE

Our mission is to put our client and their needs first; Microrite's holistic approach allows our consultants to draw on the varied expertise of other SME's in our network and collaborate with client teams to achieve project goals. The Microrite team is highly experienced and well published. Our team members participate in industry standards and guidance committees such as IEST, ASHRAE, CETA, ISO, AAMI, USP and are well published.



To learn more or ask for assistance, write to us at [info@microrite.com](mailto:info@microrite.com) or call us at 408-445-0507

[www.microrite.com](http://www.microrite.com)

## HOW WE WORK



### COMMUNICATING

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



### EXECUTING

Executing projects utilizing subject matter experts and technical project management is key to successful project plans. Each expert plays an integral role, working congruently with client teams to complete projects in an efficient and effective manner.



### PLANNING

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



### REPORTING

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