

## About MicroWorks

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MicroWorks, Inc. is a Microbiological consulting and training firm that was founded on the basis that pharmaceutical and medical device manufacturers and suppliers do not always have enough personnel to do all of the studies that need to be done within the facility.

MicroWorks is a hands-on consulting firm. We are not a company that tells clients what they need to do, but a company that does projects for our clients.

MicroWorks has expertise in all areas of Microbiology including: environmental monitoring program design, new method development, auditing, equipment validation, cleaning validation program design, and regulatory follow-up.

With the startup of our new lab, MicroWorks has the ability to extend its reach to also include contract testing and troubleshooting.

The MicroWorks Swab Sampling System (MSSS) is now available for quantitative surface sampling in cleanrooms and isolators. With the addition of these new capabilities, MicroWorks has become a full service organization for our clients.

MicroWorks, Inc.  
2200 West 97<sup>th</sup> Pl.  
Crown Point, IN  
46307

219.661.8620  
mwiconsulting.com

# MicroWorks Consulting

MicroWorks, Inc.  
Hands-On Consulting  
Phone: 219.661.8620



# Microbiologists with Real Life Experience

Do you need a Microbiologist to perform work for your laboratory without the commitment or hassle of hiring? Without the expense?

Do you need a consultant with the experience to do projects for you, not just tell you what you need to do?

Does your staff need technical training that your training personnel do not have the expertise to do?

Does your staff have the laboratory skills but lack the ability or time to design experiments, write procedures, protocols or reports?

Are you just temporarily swamped in your lab?

MicroWorks wants to help you get through these tough times without putting more stress on your already overloaded staff and without long term commitments.

## Laboratory Design

MicroWorks can design your new lab and assist you with getting it commissioned.

## Environmental Monitoring Programs

MicroWorks can design, implement, and validate an EM program for your controlled facility. We also trend data and evaluate alert and action levels.

## Protocols, SOPs, and Reports

MicroWorks can write SOPs and execute IQ/OQ/PQ protocols and SOPs for equipment operation and validation, hold time studies, investigative studies for laboratory and production equipment.

## Training Programs

MicroWorks can write training programs in Environmental Monitoring, Proper Cleanroom Techniques, Microbiology Laboratory Procedures, Good Manufacturing Practices, Preparing for an FDA Inspection, Aseptic Technique and much more.

## Testing and Validation of Rapid Microbiological Methods

We can help you evaluate the feasibility of utilizing the latest rapid methods for testing your products.

## Microbiology Method Development and Validation

We can develop and validate new methods for bioburden testing, sterility testing, Microbial limits, LAL testing, testing components such as stoppers and vials.

## Investigation of Results

We can help you with the tough investigations. We can be that fresh set of eyes you have been looking for. We can help you get caught up on those CAPAs or environmental excursion reports.

## Regulatory Response Follow-up

Our consultants have experience dealing with FDA issues and can help you with regulatory follow up and return of your facility to compliance.

## Microbiological projects of all types

## Auditing Suppliers

## New Product Development

## Cleaning Validation

## Vitek® V2C Validation Testing and Training

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2200 West 97<sup>th</sup> Place  
Crown Point, IN 46307

Phone 219.661.8620  
Fax 219.662.9805  
Email [ed\\_mciver@mwiconsulting.com](mailto:ed_mciver@mwiconsulting.com)  
[www.mwiconsulting.com](http://www.mwiconsulting.com)

