

MICROBIOLOGY RESEARCH ASSOCIATES - COMPREHENSIVE SUPPORT FOR HOME INFUSION USP <797> COMPLIANCE

From Program Design to Training, Environmental Monitoring, Implementation and Remediation, MRA is your Home Infusion Resource Partner.

COMPLIANCE FOR HOME INFUSION

With sterile compounding regulations for pharmacies and hospitals becoming more stringent, it is imperative to utilize a company with USP <797> expertise and testing.

To assist our clients with their installation, operational and performance qualification needs, Microbiology Research Associates, Inc. offers a broad range of comprehensive environmental monitoring tests and analysis.

- Viable Surface & Air Sampling Non-Viable Particulates
- Evaluation of Aseptic Manipulation Skills
- MRA puts samples on test the same day they are received
- MRA is an FDA and DEA registered laboratory and our expertise is in contamination control for FDA regulated companies.



REQUIREMENTS FOR ACCREDITATION

Many commercial insurers require that infusion pharmacies be accredited* to serve their patients.

HOW MRA WILL HELP

MRA will work with you to validate the environmental controls and compounding processes in your facility to ensure they meet stringent requirements set by the FDA and to qualify for accreditation.

HOME INFUSION SERVICE OFFERINGS

- Routine Environmental Monitoring
- Gap Analysis
- Disinfectant Efficacy Studies
- USP <797> Compliance Educational Seminars
- Cleanroom Validation: Installation, Operational and Performance Qualification
- Fingertip, Gloving and Media Fill Proficiencies
- Interpretation of Reports

CONTACT US

Your partner in Microbiology testing services.

- Risk Assessment
- Remediation Assistance
- USP Compendial Testing, Including Sterility, Endotoxin and Bioburden

HOME INFUSION PHARMACIES ARE OFTEN ACCREDITED BY ORGANIZATIONS SUCH AS:

- The Joint Commission (www.jointcommission.org)
- Accreditation Commission for Health Care (www.achc.org)
- Community Health Accreditation Program (www.chapinc.org)
- Healthcare Quality Association on Accreditation (<http://www.hqaa.org/>)
- National Association of Boards of Pharmacy (<http://www.nabp.net/>)
- The Compliance Team (www.thecomplianceteam.org/)

Accreditation standards ensure the quality of infusion services and help prevent and detect critical issues including, but not limited to, adverse drug reactions, errors and patient/family noncompliance.

MRA has been in business for over 25 years partnering with businesses to help with compliance and microbiology testing. MRA will set up a USP <797> compliant environmental monitoring program including standard operating procedures, sample site maps, action levels, frequency, room conditions, growth promoted media, CAPA, calibrated air samplers and particle counters. Also includes validated incubation, laboratory analysis, colony counts, Genus ID and coagulase testing for staphylococcus spp.



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ABOUT US

Microbiology Research Associates, an Analytical Lab Group company, is a reliable partner and consultative extension to the cGMP microbiology and testing industry with expertise in USP <797> from the East Coast to the West Coast.

For more than 25 years, MRA has partnered with CMOs, CDMOs, medical device, biotechnology, compounding pharmacy, cosmetic and healthcare industries to provide FDA compliance expertise and testing solutions.

CONTACT US



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**YOUR PARTNER
IN COMPLIANCE
FOR HOME INFUSION
PHARMACY**

MRA
Microbiology Research Associates, Inc.

MRA PUTS SAMPLES ON TEST THE SAME DAY THEY ARE RECEIVED

- + Samples can be shipped to MRA for laboratory analysis or MRA can provide qualified microbiologists to perform E/M on-site.
- + Our experts have extensive experience in cGMP microbiology consulting and testing.
- + MRA is an FDA and DEA registered laboratory and our expertise is in contamination control for FDA regulated companies.

WHY CHOOSE US

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WHAT WE DO

Complete Support for US <797> Compliance for Home Infusion from Program Design to Training, Environmental Monitoring, Implementation and Remediation.

- + Routine Environmental Monitoring
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- + USP <797> Compliance Educational Seminars
- + Cleanroom Validation: Installation, Operational and Performance Qualification
- + Fingertip, Gloving and Media Fill Proficiencies
- + Interpretation of Reports
 - Action items
 - Recommendations
- + Risk assessment
- + Remediation Assistance
- + USP compendial testing including sterility, endotoxin and bioburden