

Consulting Services

System and Software Compliance

Validation can often be a time consuming, complex activity that ties up valuable resources. Waters Professional Services can assist in the development of necessary validation protocols for your group based on existing industry expertise. Our services are designed to provide user acceptance testing in accordance with all current GMP (21 CFR Part 210, 211, 820), GLP (21 CFR Part 58), EU GMP Annex 11 & 15, EU Parliament – E-Signatures, IC Q7A and 21 CFR 11 regulations, as well as industry expectations.

BASIC VALIDATION SERVICES FOR NUGENESIS LAB MANAGEMENT SYSTEM (LMS)

Installation Qualification (IQ) and Operational Qualification (OQ) protocols

Standard built (as is) protocols and execution services are available for:

- Waters® NuGenesis® LMS (and Addenda)
- Data migration

ON-SITE CONSULTATION SERVICES FOR THE INFORMATICS SOFTWARE PRODUCTS SUITE

- On-site consulting and Performance Qualification (PQ) script writing services for the intended use of the system by the customer
- Custom test scripts may be developed in collaboration with the customer for Empower® and NuGenesis LMS. Some examples include, but are not limited to:
 - Verification of 21 CFR Part 11 requirements
 - Verification of system, project, group, and user-level privileges
 - Verification of electronic signature requirements
 - Verification of modules purchased in addition to Waters Empower software – system suitability and Method Validation Manager (MVM)
- On-site consulting includes collaboration, testing, and training with the customer on using and creating scripts
- Additional PQ consulting days to cover additional testing, configuration, script writing, or script customization can be purchased by the day

```
...mirror object to mirror
mirror_mod.mirror_object

operation == "MIRROR_X":
mirror_mod.use_x = True
mirror_mod.use_y = False
mirror_mod.use_z = False
operation == "MIRROR_Y":
mirror_mod.use_x = False
mirror_mod.use_y = True
mirror_mod.use_z = False
operation == "MIRROR_Z":
mirror_mod.use_x = False
mirror_mod.use_y = False
mirror_mod.use_z = True

selection at the end -ad
mirror_ob.select= 1
mirror_ob.select=1
context.scene.objects.act
("Selected" + str(modifi
mirror_ob.select = 0
bpy.context.selected_ob
data.objects[one.name].s
print("please select exact
OPERATOR CLASSES ---
types.Operator):
X mirror to the select
object.mirror_mirror_x"
mirror X"
context):
context.active_object is n
```

AUDIT SERVICES

Complementing compliance needs, this service offers an opportunity to review the Waters Technologies Software Quality Assurance Program covering our Software Development Life Cycle and Structural Validation Testing.

WHAT IS THE ADVANTAGE OF USING WATERS FOR VALIDATION CONSULTING SERVICES?

Simply put, Waters has the domain knowledge and years of experience in the area of Validation consulting. The Validation Consulting Team helps streamline the process for customers moving beyond vendor qualification by assisting in the development of critical validation documents and custom test scripts that define how they intend to use the Waters software.

WATERS PROFESSIONAL SERVICES

Your "Next Steps" Partner

We are a global network of project managers, informatics engineers, and application scientists dedicated to ensuring the success of your organization. We provide a comprehensive suite of tailored services to optimize efficiencies, lower costs, and maintain regulatory compliance in constantly changing markets.

WATERS GLOBAL SERVICES

Delivering world renowned services and support

Waters Service and Support offerings are tailored to optimize your laboratory productivity while addressing your budget realities. Our offerings help maintain system peak performance, minimize down time, address scientific application challenges, and support stringent compliance requirements. As your services and support provider, we are committed to the success of your laboratory and business.

Waters quality support and consultative services ensure your success wherever your laboratory is located in the world.



Waters has consecutively earned the ACE Award since 2001 for providing best-in-class technical knowledge, issue resolution, and process support.

Waters

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