



EMA and FDA guidelines

Method Development, Method Validation, MethodTransfer

Confirmatory testing process & Routine batch analysis

UPLC-MS/MS, GC-MS/MS & High resolution UHPLC-MS/MS

API & process related nitrosamines

STABILITY STORAGE & TESTING

ICH or custom climatic zones

Walk in stability chambers

Storage & testing or storage & return

Analytical services: Microbiological & Chemical testing in GMP certified laboratories

METHOD DEVELOPMENT & VALIDATION

Analytical method development

Validate and issue analytical methods according to EMA & ICH guidelines

Bespoke Method Development tailored to your needs



EXTRACTABLES LEACHABLES

Identification and Quantification

Comprehensive Analytical Techniques (GC-MS liquid and headspace injection, ICP-MS and high resolution LC-MS)

Container closure systems

Line materials or single use systems

Medical Devices

ENVIRONMENTAL MONITORING

Samples collected from key production sources, raw materials & products

Total DNA isolated & sequenced using NG\$

The full microbiome of each sample is revealed

A comprehensive microbiome map of the production environment is created

Comprehensive microbiome map of the production environment created

Expert insights, Detailed analysis, Suggestions for corrective actions

MICROBIOLOGICAL TESTING

Microbial Enumeration Tests

Microbial Identification & Pathogen Testing

Micro Suitability Studies – Method Validation

Preservation Efficacy Testing

Environmental Monitoring Program

Bioassay and MIC Studies

MICROORGANISM IDENTIFICATION

DNA or MALDI TOF Identification of bacteria - yeasts - fungi

Small turnaround time

Details on ecology, classification, growth conditions, and potential pathogenicity







QACS is a GMP & GLP certified, FDA approved and ISO I7025 accredited laboratory providing a comprehensive range of laboratory testing services to support the pharmaceutical industry. Laboratory Testing services are provided for Pharmaceutical QC, Design, Research and Development of proprietary medicines. Methodologies stay in accordance with EMA & FDA. Pharma Testing services include Microbiological, Chemical, Packaging, Molecular analyses & Monitoring services.



ONE STOP SHOP



24H EU PICK UP







