

Capabilities for regulatory dependent industries

# LET'S CREATE REGULATORY COMPLIANCE. TOGETHER.



The life science business of Merck KGaA, Darmstadt, Germany operates as MilliporeSigma in the U.S. and Canada.

# WE ARE A LEADER IN LIFE SCIENCE

The Life Science business of Merck KGaA, Darmstadt, Germany brings together the world-class products and services, innovative capabilities, and exceptional talent of EMDMillipore and Sigma-Aldrich, to create a global leader in the life science industry. We operate as "MilliporeSigma".

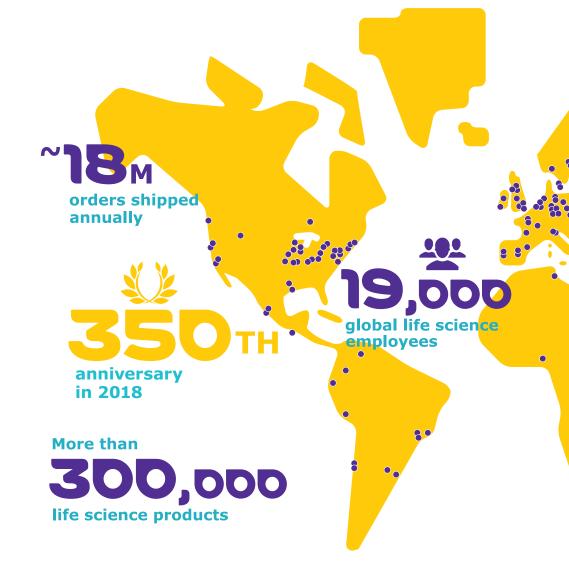
- We solve the toughest problems in the industry by collaborating with the global scientific community.
- We provide scientists with best-in-class lab materials, technologies and services.
- We can streamline your method development and productivity efficiently.

# We Can Make Your Life Straightforward and Help You with Risk Management and Regulatory Due Diligence:

- Products and services following the latest regulations to ensure compliance.
- Resources to meet your exact needs—customer-specific solutions.
- Warehouse and supply chain management with a one-stop shop for prompt delivery and local support.
- Support with applications and methods including value-added services.

#### We are More than Just a Distributor

- We are the manufacturer of most of the products we offer.
- You can be confident that quality and service are both as important to us as they are to you.



# Get the results as expected each and every time with our expanded offering

### **OUR STRENGTHS**

- Compliant manufacturing sites
- Breadth and value of portfolio with a complete workflow offer
- Global footprint
- Supply chain capabilities for reliable delivery, one-stop shop
- Widespread delivery capabilities from third party distributors

## **OUR KNOW-HOW**

- Active product innovation and strong R&D
- Quality and regulatory compliance with complete safety solutions
- Technical and regulatory expertise certifications (ISO 13485, cGMP, FSSC 22000 etc.)
- Data traceability and result reliability

### **OUR ASSETS**

- Reference materials and proficiency testing portfolio
- 24/7 technical support skills and best-in-class customer service
- Consistency and reliability across geographies



# SAFE SOLUTIONS FOR FOOD.

### 2

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SAMPLE LOG IN

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## PREPARATION

### ANALYTICAL SAMPLE PREP Instrumental Test Kits

- RQflex<sup>®</sup> 20
- Reflectoquant<sup>®</sup> Test Strips
- Lab Water systems
- Milli-Q®

### Chromatography sample prep

• Samplicity<sup>®</sup>, Millex<sup>®</sup> filters and SPE tubes and vacuum manifold, QuEChERS tubes and shakers **SPME** 

• SPME fibers



### Solvents

 $\bullet \ LiChrosolv^{\scriptscriptstyle (\!R\!)}$ 

### **Acids and Bases**

 $\bullet$  EMSURE  $^{\otimes}$  inorganic reagents and solvents

### MICROBIOLOGY SAMPLE PREP

- Homogenizer
- ESH Sample dilution
- DiluCult™
- Sample enrichment
- GranuCult<sup>™</sup>



# 3

### ANALYSIS

#### SAMPLE ANALYSIS Chromatography

HPLC, UHPLC and GC Columns
Thin Layer
Chromatography
TLC Plates
Lab Water systems
Milli-Q<sup>®</sup>
Titration
Titripur<sup>®</sup>, Titripac<sup>®</sup>

### Disinfection residue checking

- MQuant<sup>™</sup> test strips
- Reflectoquant<sup>™</sup> strips
  Move colorimeter and test kits

#### Spectrophotometry

 Spectroquant<sup>®</sup> spectrophotometers, test kits

### **Karl Fischer reagents**

### • Aquastar™

### Solvents

- LiChrosolv<sup>®</sup>
- Acids and Bases
- EMSURE® inorganic

### reagents and solvents

#### MICROBIOLOGY SAMPLE ANALYSIS

### Microbial air monitoring

- MAS-100<sup>®</sup>, MAS-100 Eco<sup>®</sup>
- Surface monitoring
- Contact plates and MVP ICON®
- Rapid pathogen detectionAssurance GDS<sup>™</sup> and
- PIPETMAX<sup>®</sup>

# Ready-to-use culture media

- ReadyPlate<sup>™</sup>
- **Dehydrated culture media**
- GranuCult<sup>™</sup> Media
- Lab Water Systems
- Milli-Q®



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# QA SUPPORT

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# Supporting Documentation

• Certificates of analysis, Safety data sheets and Validation Guides, Milli-Q System Validation

#### Standards and Certified Reference Materials

• Vitroids<sup>™</sup>, Lenticule<sup>®</sup>



# Microbial identification

ChromoCult<sup>®</sup> agar plates



### **WORKFLOW: BEVERAGES**

# SAFE SOLUTIONS FOR BEVERAGES.

## 3 ANALYSIS

### SAMPLE ANALYSIS

Chromatography
• UHPLC and HPLC and GC Columns
Thin Layer
Chromatography
• TLC Plates
Lab Water systems
• Milli-Q®
Titration
• Titripur® Titripac®

• Titripur<sup>®</sup>, Titripac<sup>®</sup>

# Disinfection residue checking

MQuant<sup>™</sup> test strips

- Reflectoquant<sup>™</sup> strips
  Move colorimeter and
- test kits

### Spectrophotometry

Spectroquant<sup>®</sup>
 spectrophotometers, test kits, CRM standards and accessories

Karl Fischer reagents
Aquastar<sup>™</sup>
Solvents
LiChrosolv<sup>®</sup>
Acids and Bases
EMSURE<sup>®</sup> inorganic reagents and solvents

### MICROBIOLOGY SAMPLE ANALYSIS

Microbial air monitoring • MAS-100<sup>®</sup>, MAS-100 Eco<sup>®</sup> Microbial membrane filtration

• EZ-Fit<sup>™</sup> filtration unit and EZ Family

Surface monitoring • Contact plates and MVP ICON<sup>®</sup>

#### **Rapid microbiology**

- EZ-Fluo™
- Ready-to-use culture media
- ReadyPlate<sup>™</sup>
- Dehydrated culture media
- GranuCult™
- Cell counting systems
- Muse<sup>®</sup> cell analyzer
- Lab Water systems
- Milli-Q®

# **QA SUPPORT**

#### Supporting Documentation

• Certificates of analysis, Safety data sheets and Validation Guides, Milli-Q System Validation

Standards and Certified Reference Materials

• Vitroids<sup>™</sup>, Lenticule<sup>®</sup>

# PREPARATION

ChromoCult<sup>®</sup>

RESULT

### ANALYTICAL SAMPLE PREP Lab Water systems

**INTERPRETATION** 

**Microbial identification** 

Milli-Q<sup>®</sup>
 Chromatography sample prep
 Samplicity<sup>®</sup>, Millex<sup>®</sup>, Vacuum
 Manifold

SAMPLE LOG IN







### WORKFLOW: FLAVORS AND FRAGRANCES

# LET'S INSPIRE SAFETY FOR FLAVORS AND FRAGRANCES. TOGETHER.



### **B** ANALYSIS

Our suite of analytical tools ensure your purity determination and composition verification tests are quick and accurate.

#### **Products**

- Sample preparation
- Separation
- Detection

## **2** FORMULATION

We know that successful formulations contain the perfect combination of highquality products you can trust. Our variety of organoleptics, pack sizes and FSSC 22000 certified ingredients were developed with you in mind.

#### **Products**

- Naturals & synthetics
- Kosher, halal, organic
- Food safe elite
- Food grade certified
- 170 organoleptic categories

# QUALITY & REGULATORY

Our products are supported by a dedicated regulatory and quality team. We provide easy-to-access online documentation for our products and facilities.

#### **Products**

- Specification Sheets
- Certificates of analysis
- Food grade certificates
- Kosher, halal, organic
- Follow IFRA Guidelines





### WORKFLOW: MEDICAL MATERIALS

# LET'S CREATE THE NEXT ELEMENTS FOR MEDICAL MATERIALS. TOGETHER.

# 5

### **FINAL PRODUCT TESTING & RELEASE**

#### Sterility testing (acc. to USP & EP) Endotoxins testing Polymer I.D

• By IR, LC-MS – solvents / columns **Residual ethylene oxide testing** (acc. to ISO 10993-7) **Leachable & extractables** (acc. to ISO 10993-17)

# Lab water systems Analysis

• SPE, SPME

Sample Preparation • Millex<sup>®</sup> syringe filtration

- CRMs & analytical standards
- ICP & AA
- Aquastar<sup>®</sup> Karl Fischer reagents
- GC capillary columns, UHPLC & HPLC columns etc.

# 2

### **RAW MATERIAL TESTING**

### **Sample preparation**

- Millex<sup>®</sup> syringe filtration
- SPE, SPME
- Lab water systems

#### Analysis

- CRMs & analytical standards
- ICP & AA standards
- Aquastar<sup>®</sup> Karl Fischer reagents
- GC capillary columns, UHPLC & HPLC columns etc.

# SERVICES

# Microbiological services method development:

- Method determination
- Method validation
- IQ, OQ, PQ testing

## FIT FOR PURPOSE RAW MATERIALS

#### Monomers

- Acrylamides
- Building Blocks
- Silanes
- Standard & customized
- Scalable, bulk
- PEGs

### Crosslinkers

Initiators UV Stabilizers, dyes Metals, salts, oxides, ceramics Nanopowders Solvents, acids, buffers

### **IN PROCESS TESTING**

#### Bioburden

- Membrane filtration
- Milliflex<sup>®</sup> system & EZ-family
- Ready-to-use culture media

### **Environmental Monitoring**

- MAS-100<sup>®</sup> air monitoring system and settle plates
   Surface Monitoring
- ICR contact plates & swabs



### WORKFLOW: COSMETICS AND PERSONAL CARE

# LET'S CREATE SAFER TESTING. TOGETHER.

### **3** EVALUATE PROTOTYPE

Testing of developed products for performance and compare to product specifications

#### **Products**

- Strat-M<sup>®</sup> Membrane Transdermal Diffusion Testing
- Duolink<sup>®</sup> technology for visualizing protein interaction
- Flow cytometry systems
- 3D cell culture
- Custom cell design studio
- Advanced gene editing technologies
- ADME/tox
- Genetic toxicology assays

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# 2

### **CREATE PROTOTYPE**

When developing the next great active ingredient or cosmetic product, we have the newest and largest breadth of products for you to innovate with, that meet ISO 9001 requirements

#### **Products**

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- IFRA fragrance ingredients
- Essential oils
- Solvents
- Inorganic reagents
- Catalysis & biocatalysis
- Monomers & polymers
- Nanomaterials
- Crosslinkers

# QUALITY PROFILE

Comprehensive portfolio for chemical and microbiological testing for clear and reliable results

#### **Products**

- Inorganic trace analysis
- Certified Reference Materials
- Aquastar<sup>®</sup> Karl Fischer reagents
- Rapid pathogen test kits
- Culture media
- Microbial filtration systems
- Environmental monitoring products
- Lab water systems



### 1) –

### **RESEARCH CONCEPT**

Our products for analysis will help our customers define desired organoleptics & product requirements

#### **Products**

- Analytical standards
- Analytical reagents
- Sample preparation SPE/SPME
- Separation columns GC / HPLC
- Spectroscopy UV/Vis, IR

# PARTNERING WITH US REDUCES TOTAL COST OF OWNERSHIP AND MITIGATES SUPPLY CHAIN RISK.

- Forecasting
- Procurement / e-commerce
- Manufacturing / off-the-shelf
- Packaging flexibility
- Shipping
- Tracking & traceability

Our global supply chain is designed to meet the highest quality service levels across your organization. From forecasting, to inventory and distribution planning, our advanced ordering process and resources are customized to anticipate and meet your business needs. We have developed a full range of e-commerce services designed to enable greater spend control for your procurement staff, and provide your researchers with ease of access to the products they've come to rely on.

If you're looking to reduce inventory, automate payments, increase procurement fiscal control, and/or reduce costs—we can tailor a convenient and cost saving e-solution to fit your needs.

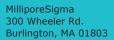
Discover how our website is making it easier for you to stay productive and conduct your daily activities in a more efficient manner.

SigmaAldrich.com/united-states/ ordering/e-Commerce-Solutions



# WHAT IF TRUST DIDN'T NEED TO BE QUESTIONED?

LET'S CREATE A RELIABLE AND SECURE SUPPLY CHAIN. TOGETHER.





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View additional product information, applications, real-time availability, ordering and contact information at SigmaAldrich.com

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