NEWS on diagnostics

2023 Volume 3

In this issue....

Welcome to the third issue of News on Diagnostics for 2023. Quality is a key topic in IVD manufacturing and can help guide your choice of the right product for your application. What can Merck do to support your critical (and non-critical) raw material choices?

This volume of News on Diagnostics helps to answer that question.

Quality

As a global leader in the Life Sciences industry, we are committed to high-quality products and services, manufacturing effectiveness, and meeting our customers' expectations.

Quality is embedded in everything we do, meaning we provide quality, compliance, and business support in the most effective and efficient way for the entire portfolio of our life science business.

We foster a quality culture based on:

- Highly qualified and proactive professionals
- An environment of customer centricity and continuous improvement
- Robust and standardized processes
- Integrated risk management and global tools
- Measurements aligned with customers' expectations and regulatory needs.

The M-Clarity™ Program

In highly regulated Life Science industries, robust quality programs from suppliers help to support manufacturing-driven needs, such as risk mitigation. The quality segment of the M-Clarity™ Program provides transparency so that you can choose, with confidence, suitable products that meet your needs with respect to:

- Compliance with the appropriate quality and regulatory standards
- Portfolio transparency
- Change notification support
- Documentation support

Initially, the M-Clarity™ Program focused on chemicals and consumables, with six quality segments (MQ100-MQ600), differentiated by both application and quality attributes.

Chemicals and Consumables

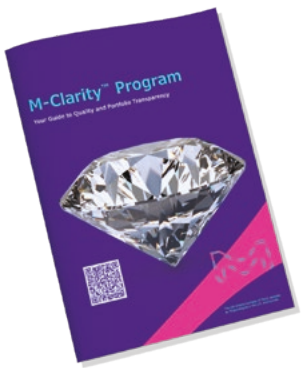
MQ100	MQ200	MQ300	MQ400	MQ500	MQ600
For non regulated laboratory applications, with no change notification requirements	For research, and non regulated industrial applications, with limited change notification requirements	For products used in applications requiring enhanced change control and quality agreement	For critical products and applications driven by high expectations for manufacturing control and requiring verified process control	For highly regulated applications requiring a validated process control	For highly regulated applications under regulatory surveillance
6 Attributes	**9 Attributes**	**12 Attributes**	**20 Attributes**	**25 Attributes**	**27 Attributes**
	CNC*				
		Quality Agreements			
			Quality Declarations (TSE/BSE Statement, Cert. of GMO etc)		

To make this program even more relevant and useful for our customers, Merck has expanded this program to include some equipment (segmented as EQ1-EQ4) and spare parts (segmented as SP1-SP2).

Equipment and Spare Parts

EQ1	EQ2	EQ3	EQ4	SP1	SP2
	Discriminating Attributes according to Equipment/Spare Part characteristics				
6 Attributes	**10 Attributes**	**12 Attributes**	**14 Attributes**	**3 Attributes**	**6 Attributes**
		CNC*	**CNC***		**CNC***

*CNC - Change Notification Commitment



Again, these products are segmented by type (equipment/spare part) and discriminating quality attributes (DQA).

For more information about our expanded M-Clarity™ Program, please visit **SigmaAldrich.com/mclarity**

You can also download information about the DQA, Change Notification, and the M-Clarity™ Matrix on this page.

The table below describes the DQAs for each type of product that have been recently added to the program

Equipment and Spare Parts

Discriminating Attribute	EQ1	EQ2	EQ3	EQ4
Quality Standard ISO 9001	•	•	•	•
Supplier/subcontractor approval process in line with on-site audit corporate quality program	•	•	•	•
Product specifications/data package available	•	•	•	•
Certificate of Conformity or Quality or Certificate of Analysis available (where applicable)	•	•	•	•
Release testing - performed using established protocol	•	•	•	•
Site quality self-assessment available	•	•	•	•
Audits at our Life Science site can be requested		•	•	•
Equipment maintenance provided as service		•	•	•
Release test data available during an audit		•	•	•
User guide		•	•	•
On-site equipment qualification (IQ/OQ) is provided as a service			•	•
Change Notification available as an opt-in for individual products			•	•
Release test data available upon request				•
Factory acceptance test offered as a service				•

Discriminating Attribute	SP1	SP2
Quality Standard ISO 9001	•	•
Supplier/subcontractor approval process in line with on-site audit corporate quality program	•	•
Site quality self-assessment available	•	•
Product specifications/data package available		•
Certificate of Conformity or Quality or Certificate of Analysis available		•
Change Notification available as an opt-in for individual products		•

The Elevate Dossier is available upon request.

In the Dossier, you will be provided information on:

- Site Quality Survey self-assessment
- ISO 9001 certificate
- Product Specifications
- Declarations / Statements (animal origin content, latex content, BSE/TSE, phthalates, RoHS, etc.)

Request your product dossier **here**

Quality Management Systems

Merck utilises a robust Quality Management System for our processes across our Life Science business with the aim of continuously improving our systems and performance.

Our dedicated Life Science Quality Management Systems & Audit team responsibilities include:

- Continuously gathering information from the experiences of customers using our products
- Providing a management system for resolving customer issues or complaints
- Taking corrective actions when necessary
- Ensuring continuous improvement through self-assessment

Most of our Life Science sites are certified to the ISO 9001:2015 standard, with additional relevant certification where required. Visit the overview of our ISO certified Life Science sites where you can download our ISO certificates.

SigmaAldrich.com/ISOCertificates

Customer Support – Quality Services

In a highly regulated market, such as IVD manufacturing, a manufacturer must ensure their suppliers provide products that are fit for purpose throughout the product lifecycle, from design and development through to supply to the end-user.

Our Quality Services team is responsible for quality-related elements of Customer Inquiries and Customer Communication. We partner with our Technical and Customer Services teams to ensure a seamless support network. In addition, we push industry standards forward and add value to our customers by providing superior quality and regulatory services.

Visit our Customer Quality Services page to find out more about how we support your quality requirements.

SigmaAldrich.com/QualityServices

Did you know...

We believe sustainability is rooted in responsibility?

We'll keep you updated on sustainability topics, webinars, new product introductions and offers.

See more at **SigmaAldrich.com/gogreener**

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