M-Clarity™ Program

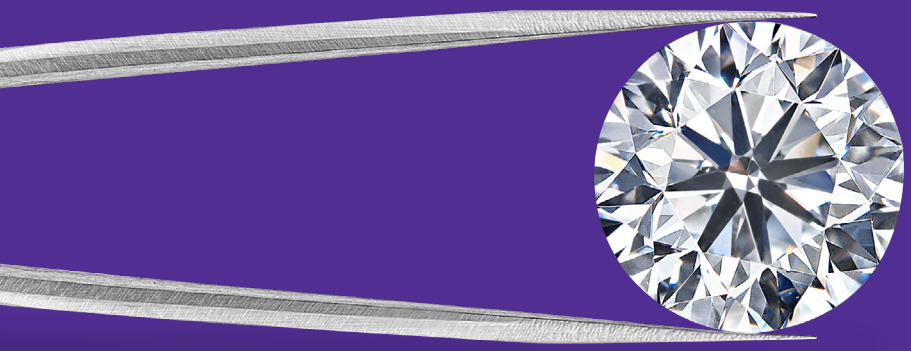
Your Guide to Quality and Portfolio Transparency

The Life Science business of Merck operates as MilliporeSigma in the U.S. and Canada.

Align quality to criticality

The development and manufacture of products in the Life Science industry has become progressively more challenging in recent years. Because of the increasing complexity of the processes, regulatory requirements and local standards, it is crucial to understand, assess and manage risks while ensuring business continuity.

In this dynamic context, we present the **M-Clarity™ Program** which defines product quality segments and improves product and service transparency throughout our broad Life Science portfolio.



select

the right product to meet your needs

The M-Clarity™ Program includes the majority of our Life Science products. Chemicals and consumables are classified into 6 Quality Segments (MQ100-MQ600), equipment is classified into 4 Quality Segments (EQ1-4), and spare parts into two Quality Segments (SP1-2):

- Each segment provides specific documentation and services.
- The segments have increasing attributes to meet your application and regulatory requirements.
- Transparency allows you to select the right product for your needs.

1

Move

smoothly through product development phases

Developing and manufacturing products is a complex process involving multiple suppliers and raw materials. Minimizing disruptions when moving from development to manufacturing requires a clear risk assessment.

The M-Clarity™ Program provides the perfect tool to guide the process of choosing components and raw materials, allowing for comparison of quality support and documentation, and ultimately minimizing costs and delays.

2

ensure

compliance by informed product selection

Quality Segments provide transparency in the attributes of materials to support your control requirements.

The decision regarding the most relevant quality profile is driven by your specific need for controlled and verified or validated processes as appropriate.

Leverage the M-Clarity™ Program to choose the appropriate products to develop your own risk assessment.

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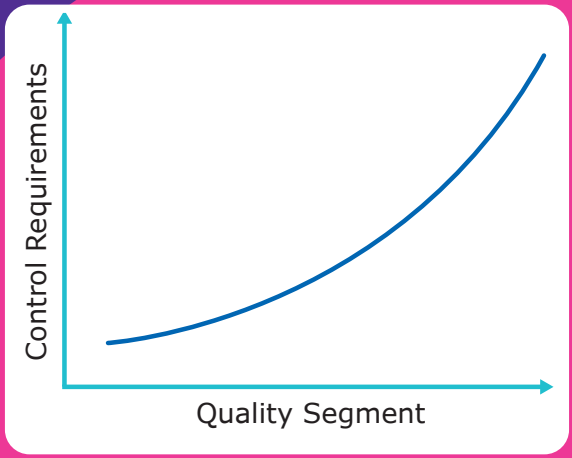

Higher Quality Segments address increasing control requirements.

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

All segments overview

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
	CNC*				
		Quality Agreements			
			Quality Declarations (TSE/BSE Statement, Cert. of GMO etc)		

Equipment and Spare Parts

EQ1	EQ2	EQ3	EQ4	SP1	SP2
Discriminating Attributes according to Equipment/Spare Part characteristics					
		CNC*	CNC*		CNC*

*CNC - Change Notification Commitment

For more information go to **SigmaAldrich.com/M-Clarity**

Quality Segments and Discriminating Quality Attributes

Chemicals and Consumables

Discriminating Attribute	Description	MQ 100	MQ 200	MQ 300	MQ 400	MQ 500	MQ 600
Quality Standard ISO 9001	ISO 9001	●	●	●	●	●	●
	FSSC 22000*			●	●		
	IPEC or ISO 13485					●	●
	ICH Q7 or 21 CFR medical device						●
Specifications available		●	●	●	●	●	●
Certificate of Quality or Certificate of Analysis available		●	●	●	●	●	●
Release testing is performed using established protocol		●	●	●	●	●	●
Written SOP for process control		●	●	●	●	●	●
Supplier approval process in line with corporate quality programs		●	●	●	●	●	●
Change notification available as an opt-in for individual products. Notifiable events differ between Quality Segments			●	●	●	●	●
Release testing is performed using established or published protocol			●	●	●	●	●
Site quality self-assessment available			●	●	●	●	●
Shelf life/expiration date is identified if applicable				●	●	●	●
Audits can be requested by customer				●	●	●	●
Product can be added to a Quality Agreement				●	●	●	●
Analytical method is verified					●	●	●
Analytical method may be shared upon request					●	●	●
Quality declarations as required by regulation or product application					●	●	●
Process control is verified					●	●	●
Supplier approval by paper audit or questionnaire					●	●	●
Original manufacturer disclosure may be requested with signed confidentiality commitment					●		
Controls for subcontracting are established					●	●	●
Primary packaging component control					●	●	●
Original manufacturer disclosure available with signed confidentiality commitment						●	
Analytical method is validated						●	●
Process control is validated						●	●
Supplier approval by on-site audit for critical suppliers						●	●
Shelf life/expiration date is defined by stability study						●	●
Risk based approach to controlled conditions for warehouse & shipping						●	●
Original manufacturer disclosure available without confidentiality commitment							●

*For selected product groups

Quality Segments and Discriminating Quality Attributes *(Continued)*

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		●

For more information go to **SigmaAldrich.com/M-Clarity**

Change Notification Commitment

Our Life Science business sector serves customers across academia, the biopharmaceutical industry, and the industrial sector, including food & beverage, with a broad portfolio of more than 300,000 products and solutions. To ensure that we provide the most-up-to-date product information, we have a best-in-class Change Notification Program based on our M-Clarity™ Program to inform customers about important changes that could impact their development or production processes.

Customer benefits from our Change Notification Program:

- You choose the product according to the appropriate Quality Segment for your application, and opt-in for Change Notification.
- The amount of information given in the Change Notification is transparent with respect to the Quality Segment of the product
- Customers define their Change Notification requirements: products on which they would like to receive notifications, persons to be informed, required e-mail and postal addresses
- Standardised, easily understandable Change Notification letters and follow-up documentation

Notifiable Changes

Our customers have the option to be informed about relevant changes that might affect the performance of our product and subsequently impact the customer's processes or products. Change Notifications on one hand, must contain all necessary information, while on the other hand, must be relevant to our customers. Our M-Clarity™ Program ensures we keep this balance and customers get exactly the amount of information needed for the intended use of the product.

The M-Clarity™ Program defines various product Quality Segments with appropriate quality attributes and notifiable changes provided for each segment. According to our M-Clarity™ Program, products with different Quality Segments get a different extent of Change Notification.

Matrix of Notifable Changes

Chemicals and Consumables

Notifiable Change	Change Notification Commitments Supported per Quality Segment					
	MQ 100*	MQ 200	MQ 300	MQ 400	MQ 500	MQ 600
Discontinuation of ISO certifications (e. g. ISO 9001, ISO 14001, ISO 13485, FSSC 22000 where applicable)		✓	✓	✓	✓	✓
Change to published/analytical release specification acceptance criteria (excluding compendial specifications)		✓	✓	✓	✓	✓
Obsolescence - catalog number is discontinued		✓	✓	✓	✓	✓
Releasing QC testing Site		✓	✓	✓	✓	✓
Downgrade of Quality Segment or change of Quality Segment category		✓	✓	✓	✓	✓
Revision of Discriminating Quality Attribute/Matrix of Notifiable Changes		✓	✓	✓	✓	✓
Shelf Life (expiration date or recommended retest date)			✓	✓	✓	✓
Change of our immediate supplier - no disclosure of source			✓			
Change to primary manufacturing and/or repackaging/downfilling site			✓	✓	✓	✓
Change in test method (non-compendial) and those affecting quality document (CoA/CoQ or label)			✓	✓	✓	✓
Changes in the manufacturing process impacting specification, where process uses a substantially different route of synthesis or manufacture (chemicals)			✓	✓	✓	✓
Primary packaging materials and/or container closure/ Change in materials of construction (not including customized packaging)			✓	✓	✓	✓
Change to raw materials affecting the CoA or CoQ or specification				✓	✓	✓
Labeling - Change to item name or number/ Changes in the labeling regarding product name, specification, shelf-life or storage				✓	✓	✓
Change in the nature of the raw materials with TSE/BSE relevance resulting in an increased risk for the finished product with respect to EMA/410				✓	✓	✓
Changes in the manufacturing process impacting specification, or intended use, form/fit/function (disposable/devices/single use items only)				✓	✓	✓
Change of Original Manufacturer (OM) - disclosure of OM not guaranteed (Confidentiality Commitment required in case of disclosure)				✓		
Changes to the equipment - impacting the manufacturing process, specifications or intended use				✓	✓	✓
Change in GMP Status					✓	✓
Change of Original Manufacturer (OM) - disclosure with Confidentiality Commitment					✓	
Change of general transport conditions					✓	✓
Changes to instructions for use and change in risk level						✓
Change of Original Manufacturer (OM) - disclosure w/o Confidentiality Commitment						✓
Change of CEP revision						✓

*Notifiable changes are not applicable for the quality segment MQ100

Equipment and Spare Parts

Notifiable Change	EQ1*	EQ2*	EQ3	EQ4	SP1*	SP2
Obsolescence of product			✓	✓		✓
Downgrade of Quality Segment or change of Quality Segment category			✓	✓		✓
Revision of Discriminating Quality Attribute/ Matrix of Notifiable Changes			✓	✓		✓
Changes requiring retrofit			✓	✓		
Major software changes				✓		
Changes affecting form, fit or function						✓
Changes to raw materials in contact with the fluid path						✓

*Notifiable changes are not applicable for the quality segments EQ1, EQ2 and SP1

For more information go to **SigmaAldrich.com/M-Clarity**

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