

M-Clarity™ Program

General Program Questions

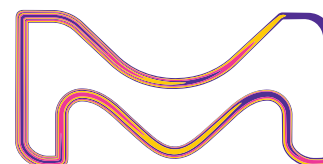
	Description
What is the M-Clarity™ Program?	The Merck M-Clarity™ Program is our quality system for our Life Science product portfolio. M-Clarity™ harmonizes the product quality classes across all of our Life Science portfolio in one transparent, best-in-class quality program. The M-Clarity™ Program uses defined quality attributes to place products within Quality Segment, making choosing the right product for your application or regulatory need simple and transparent.
What is a Quality Segment?	Under the M-Clarity™ Program, life science products are classified into 3 Quality Segments categories, MQ 100- 600 for Chemicals and Consumables, EQ1-4 for Equipment and SP1-2 for Spare Sparts, based on the level of documentation, services and regulatory support offered
Is the regulatory status of our products at authorities affected by M-Clarity™ program?	No, the M-Clarity™ program does not affect any information exchanged with authorities.
Have there been specification changes on material I am already using to fit into these new quality categories?	The purpose of M-Clarity™ Program is to offer one comprehensive quality program to our customers and to categorize our products into the appropriate segment. Changing existing product specifications is not part of the program.
Should I expect product price change because of M-Clarity™ program?	Price change is not part of the M-Clarity™ Program; however, price change may occur from time to time to reflect market demand and cost of good changes, independently from the M-Clarity™ Program.
Who should I contact if I have questions about M-Clarity™ Program?	Please contact your local sales partner
What do I do if I cannot find a product with the expected Quality Segment?	Please contact your local sales partner
Where can I find the Quality Segment?	The Quality Segment is shown only on the Web on the product data page.

Product Specification

	Description
Are you changing specs on material I am already using to fit into these new quality categories?	No. The purpose of M-Clarity™ Program is to offer one comprehensive quality program to our customers and to categorize our products into the appropriate segment. Changing existing product specifications is not part of the program.

Analytical Method

	Description
What is the difference between Analytical method tested to established or published protocol between MQ 100 and MQ 200?	A published protocol is for example ACS standard or a Compendial protocol. This was introduced into MQ 200 as an opportunity to differentiate products in different Quality Segments. Not every product has to comply to a published standard in MQ 200. The attribute describes only a possible discriminating attribute compared to MQ 100.
What is the difference between verified and validated?	<p>Verification is the process of documenting that a product, method, procedure, or system meets a set of pre-determined design requirements or specifications. This process does not provide a formalized reasoning but should provide a rationale that a product, method, procedure, or system meets the acceptance criteria for a specific use.</p> <p>Validation is the process of establishing documented evidence that provides a high degree of assurance that a specific product, method, process, procedure, or system will consistently produce a result meeting predetermined acceptance criterion.</p>
Are details of the verification or validation available for a customer?	No, such data are confidential data and cannot be shared with the customer.



Supplier Management

	Description
What does "Approved suppliers in line with corporate quality programs" mean?	Merck has a system to categorize all raw materials/finished goods and services suppliers.

Change Notification

	Description
What is the procedure to receive change notifications?	There is no change in access to the change notification service, Change notification is available upon request (Opt-In Program), MQ200-MQ600, EQ3-4, SP2 products; no need to re-submit requests for change notification already in place.
Why are change notification not available for all Quality Segments?	The Quality Segments MQ100, MQ200, EQ1-4 and SP1,2 do not address applications where information about changes is a standard requirement.
Are there prenotification timelines?	Under the M-Clarity™ Program there are no fixed pre-implementation timelines. Merck will notify customers to the best of our abilities regarding notifiable events for those customers who have opted-in for the change notification program or who have signed a Quality Agreement. Required timelines on customers assessment are considered with respect to the intended use of the products we offer.
How to handle requests for exception of notifiable changes?	There are no exceptions for notifiable changes. A product has to be upgraded if necessary, before the corresponding Change Notification Commitment can be issued.

Expiry / Shelf-Life

	Description
Is the expiry/shelf-life attribute changing existing dating statements?	No, shelf life is still defined based on specific product and regulatory requirements.

Certificate – Quality Declarations

	Description
What does Quality declaration mean?	For each product or product group we defined a set of available documents based on regulatory and quality requirements or market expectations. For example, a declaration refers to the pharmaceutical regulation that falls under the Quality Declaration starting at MQ400.
Where do Certificates of Origin (CoO) or Animal Origin (AO) statements fit in M-Clarity?	Whenever you miss a declaration please contact your local sales partner.

Eligibility for Quality Agreements

	Description
Will the existing quality agreements be affected by the M-Clarity™ program?	No, the existing quality agreements will be supported until they expire; amendments to existing contracts may be proposed if relevant. Full revisions of existing agreements and new Quality Agreements will be based on the M-Clarity™ Policies.
Why can Quality Segment products not be included in Quality Agreements (QAAs)?	Products at Quality Segments M300-MQ600 can be covered by a Quality Agreement. The content of Quality Agreements is defined by industry standards/ guidelines and applicable regulations. Attributes required to meet these standards and regulations. This is not fulfilled for MQ100- MQ200 , EQ1-4 and SP1-2.

To place an order or receive technical assistance

In Europe, please call Customer Service:

France: 0825 045 645

Spain: 901 516 645 Option 1

Germany: 069 86798021

Switzerland: 0848 645 645

Italy: 848 845 645

United Kingdom: 0870 900 4645

For other countries across Europe, please call: +44 (0) 115 943 0840

Or visit: [MerckMillipore.com/offices](https://www.MerckMillipore.com/offices)

For Technical Service visit: [MerckMillipore.com/techservice](https://www.MerckMillipore.com/techservice)

[MerckMillipore.com](https://www.MerckMillipore.com)

Merck KGaA
Frankfurter Strasse 250
64293 Darmstadt, Germany

