FAQ Sheet

# 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 levels, making choosing the right product for your application or regulatory need simple and transparent. |
| **What does MQ mean?** | Merck Quality Segment. Under the M-Clarity™ Program, life science products are classified into one of six quality segments, MQ100 - MQ600, 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 MQ Segment?** | Please contact your local sales partner |
| **Where can I find the MQ Segment?** | The MQ -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?** | 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. |
| | 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. |
| **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 |
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| **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), MQ 200-600 products; no need to re-submit requests for change notification already in place. |
| **Why not change notification at MQ200 for supplier?** | MQ 200 products are designed for technical and research application where traceability is not required. The flexibility in supply chain supports the product offer. |
| **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 (CofO) 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. |
| **Can MQ 100 or MQ 200 products be included in a Quality Agreement?** | No, only products >= MQ 300 can be covered by a Quality Agreement. The content of a 321` Quality Agreement is defined by industry standards/guidelines and applicable regulations. MQ 100 and MQ 200 products do not fulfill the necessary Discriminating Quality Attributes required to meet these standards. MQ 100 and MQ 200 products are designed for technical and research applications, while Quality Agreements are required for regulated products, products used in cGMP manufacturing, and products used in human/veterinary applications. MQ 200 products will still qualify for a Change Notification Commitment. |

## To place an order or receive technical assistance

In Europe, please call Customer Service:

France: 0825 045 645
Germany: 069 86798021
Italy: 848 845 645
Spain: 901 516 645 Option 1
Switzerland: 0848 645 645
United Kingdom: 0870 900 4645

For other countries across Europe, please call: +44 (0) 115 943 0840
Or visit: **MerckMillipore.com/offices**
For Technical Service visit: **MerckMillipore.com/techservice**

**MerckMillipore.com**

Merck KGaA
Frankfurter Strasse 250
64293 Darmstadt, Germany



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