M-Clarity™ Program

Frequently Asked Questions

General Program Questions	Description
What is the M-Clarity™ Program?	The M-Clarity™ Program is our quality system for the Life Science product portfolio. It harmonizes product quality classes across the portfolio into a transparent, best-in-class quality program. By using defined quality attributes, the M-Clarity™ Program categorizes products into clear Quality Segments, making it easier to select the right product for your applications and regulatory needs.
What is a Quality Segment?	Under the M-Clarity™ Program, Life Science products are classified into three Quality Segment categories, MQ100-600 for Chemicals and Consumables, EQ1-4 for Equipment and SP1-2 for Spare Parts, based on the level of documentation, services and regulatory support offered.
Is the regulatory status of our products at authorities affected by the 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 the 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 changes because of the M-Clarity™ Program?	Price changes are not part of the M-Clarity™ Program; however, price changes may occur from time to time to reflect market demand and cost of goods changes, independently from the M-Clarity™ Program.
Who should I contact if I have questions about the 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 available on the Web on the product detail page.

Product Specification

	Description
Are you changing the specifications on material I am already using to fit into these new quality categories?	No. The purpose of the 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 MQ100 and MQ200?	A published protocol is, for example, ACS standard or a Compendial protocol. This was introduced into MQ200 as an opportunity to differentiate products in different Quality Segments. Not every product has to comply to a published standard in MQ200. The attribute describes only a possible discriminating attribute compared to MQ100.
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
What does "Approved suppliers in line with corporate quality programs" mean?	Our company has a system to categorize all our suppliers for raw materials, finished goods, and services.

Change Notification

	Description
What is the procedure to receive change notifications?	A change notification is available upon request (through the Opt-In Program) for MQ200-MQ600, EQ3-4 and SP2 products.
Why are change notifications 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. However, to accommodate additional customer requests, we offer change notification services also for MQ200, EQ3, EQ4 & SP2.
Are there pre-notification timelines?	Under the M-Clarity™ Program there are no fixed pre-implementation timelines. Our company 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 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 into the M-Clarity™ Program?	Whenever a declaration is missing, 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™ Program policies.
Why can certain 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. The given attributes are required to meet these standards and regulations. This is not fulfilled for MQ100-MQ200, EQ1-4 and SP1-2.

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