M-Clarity™ Program

Your Guide to Quality and Portfolio Transparency
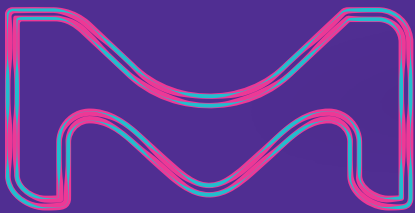
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align quality to criticality

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 levels and improves product and service transparency throughout our broad Life Science portfolio.*

select the right product to meet your needs

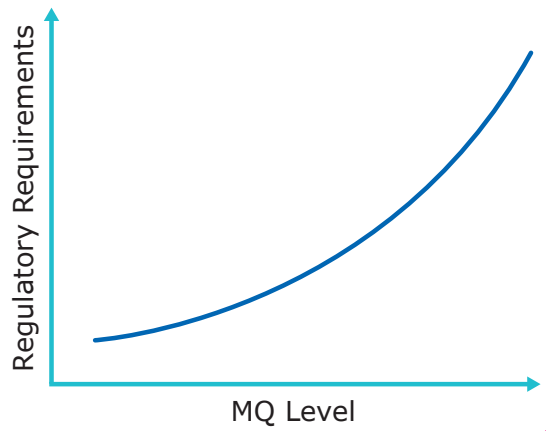**Move** smoothly through product development phases

ensure compliance by informed product selection

*Instruments, custom products, and contract manufacturing products are not part of the M-Clarity™ Program.

	Quality Segments	
	MQ100	**MQ200**
Application scope	For non-regulated applications with no change notification requirements	For non-regulated applications with limited change control requirements
Discriminating features	Standard control	Increased control
Quality systems	ISO 9001	ISO 9001, ACS
Quality attributes (e.g. specifications, Certificate of Quality)	●	●
Basic change control		●
Enhanced level of control		
Verified process		
Certified/validated process		
Highly regulated application		

Industry-driven regulations require that products of higher criticality or those used in highly-regulated industries, such as pharma or *in vitro* diagnostics manufacturing, need enhanced supplier quality support.

The MQ[†] levels of the M-Clarity™ Program provide 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 control notification support
- Documentation support

[†]MQ = Merck Quality

Increasing regulatory needs require higher MQ levels

Chart: Y-axis "Regulatory Requirements", X-axis "MQ Level" — an upward curving line.

	MQ300	MQ400	MQ500	MQ600
	For products used in applications requiring enhanced change control and quality agreement	For critical products and applications driven by high expectations and requiring verified process control or manufacturing control	For regulated applications	For highly-regulated applications under authority surveillance
	Enhanced control	Driven by customer expectation	Driven by authority regulations	Driven by authority regulations and surveillance
	ISO 9001, ACS	ISO 9001 and/or ISO 13485 and other controled processes	ISO 9001, and/or applicable standards IPEC GMP, HACCP FSSC 2200	ISO 13485 and/or ICH-Q7, 21CFR, cGMP
	●	●	●	●
	●	●	●	●
	●	●	●	●
		●	●	●
			●	●
				●

select

the right product to meet your needs

The M-Clarity™ Program includes the majority of our Life Science products, classified into 6 MQ levels, MQ100 to MQ600:

- Each level provides specific documentation and services
- The levels 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

MQ levels provide transparency in the attributes of materials to support your regulatory requirements. The decision regarding the most relevant quality profile is driven by your specific needs 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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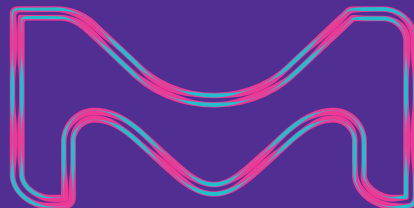
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For further information, please contact your local VWR organization or have a look at the VWR webpages:
vwr.com