Quality Segments and Discriminating Quality Attributes

M-Clarity™ Program

Chemicals and Consumables

Discriminating Attribute	Description	MQ 100	MQ 200	MQ 300	MQ 400	MQ 500	MQ 600
Quality Standard ISO 9001	ISO 9001	●	●	●	●	●	●
	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						●	●
Original manufacturer disclosure available without confidentiality commitment							●
Risk based approach to controlled conditions for warehouse & shipping							●

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		●

MilliporeSigma
400 Summit Drive
Burlington, MA 01803

To place an order or receive technical assistance

In the U.S. and Canada, call toll-free 1-800-645-5476
For other countries across Europe and the world, please visit: **EMDMillipore.com/offices**
For Technical Service, please visit: **EMDMillipore.com/techservice**

EMDMillipore.com

MS_FL12541EN
49236
06/2023