# M-Clarity™ Program

## Quality Segments and Discriminating Quality Attributes

### Chemicals and Consumables

| Discriminating Attribute | Description | MQ 100 | MQ 200 | MQ 300 | MQ 400 | MQ 500 | MQ 600 |
|---|---|---|---|---|---|---|---|
| Quality Standard ISO 9001 | ISO 9001 | ● | ● | ● | ● | ● | ● |
| | FSSC 22000* | | | ● | ● | | |
| | 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 | | | | | | ● | ● |
| Risk based approach to controlled conditions for warehouse & shipping | | | | | | ● | ● |
| Original manufacturer disclosure available without confidentiality commitment | | | | | | | ● |

*For selected product groups

## 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



MS_FL12541EN Ver. 1.0
61781
05/2025