

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		●



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