M-Clarity™ Program

Discriminating Quality Attributes List

Discriminating Attribute	Description	MQ 100	MQ 200	MQ 300	MQ 400	MQ 500	MQ 600
Quality Standard	ISO 9001	✓	✓	✓	✓	✓	✓
	IPEC GMP or HACCP or FSSC 22000 ISO 13485 (Different classes)					✓	✓
	ICH Q7						✓
Specifications available		✓	✓	✓	✓	✓	✓
Certificate of Quality or Certificate of Analysis available		✓	✓	✓	✓	✓	✓
Release testing - 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 MQ levels.			✓	✓	✓	✓	✓
Release testing - performed using established or published protocol			✓	✓	✓	✓	✓
Site quality self-assessment available			✓	✓	✓	✓	✓
Shelf Life/Expiration date is identified if applicable				✓	✓	✓	✓
Physical 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							✓

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