



Policy Owner/Sponsor: Regulatory Affairs and Compliance  
Review Date by Policy Review Committee: Jan 2017  
Supersedes: None

**Effective Date: January 1, 2017**

[To Be Completed by Policy Review Committee]

## Global Quality Policy

### PURPOSE

This policy provides the overarching framework which describes the commitment to ensure that the Quality Systems employed at our facilities are designed to support the integrity of the product, services, data and reports provided to our customers and clients.

### QUALITY POLICY

Charles River is committed to sustaining our reputation as a quality organization by upholding the standards and requirements of regulatory compliance and data integrity of all business units by:

- Assuring the quality and integrity of research products and services
- Assuring data integrity, data accuracy, precision, reliability and timeliness.
- Assuring the protection of human subjects and the welfare of laboratory animals
- Partnering with customers, vendors and employees to continually improve quality and meet regulatory requirements.

### SCOPE

This Global Quality Policy applies to all Charles River facilities and their employees as they are governed by their national standards, guidelines and regulations.

### DEFINITIONS

**Data Integrity:** The extent to which all data are complete, consistent and accurate throughout the data lifecycle.

	<p><b>Quality Risk Management:</b> means a systemic process for the assessment, control, communication and review of risks to the quality of CR products across the life cycle of those products.</p> <p><b>Quality Systems –</b> means a collection of business processes focused on consistently meeting customer requirements and enhancing their satisfaction. It is expressed as the organizational structure, policies, procedures, processes and resources needed to implement a Quality Management System.</p> <p><b>Management with Executive Responsibility:</b> senior employees of a testing facility or site who have authority to establish or make changes to the quality policy and quality system(s) at their test facility or site.</p> <p><b>SOPs:</b> Standard Operating Procedures</p>
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<h2 style="color: #0070C0;">RESPONSIBILITIES</h2>	
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	<p>Management, with executive responsibility, is ultimately responsible for the quality system at their testing facility or site and must establish policy and objectives for a quality system and a commitment to quality. Management is also responsible for ensuring that this quality policy is implemented and maintained at all levels of the organization.</p> <p>It is the responsibility of all Charles River employees to comply with the requirements of the Quality Policy and applicable procedures to continuously maintain and support a culture of quality that assures all business is conducted ethically and with integrity.</p> <p>It is the responsibility of management to review the suitability and effectiveness of the Quality Policy and associated procedures.</p> <p>Any questions related to the interpretation of this Policy and/or a subject matter included in this Policy shall be directed to the Corporate Senior Vice President of Regulatory Affairs and Compliance or the Associate Director of Global Quality Programs.</p>
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<h2 style="color: #0070C0;">REQUIREMENTS</h2>	
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	<p>The CR Quality System shall have the efficient and effective organizational structure, policies, procedures, processes and resources needed to implement the Global Quality Policy.</p> <p>The Quality System assures:</p> <ul style="list-style-type: none"> <li>• The quality and integrity of Charles River products and services</li> <li>• The protection of human subjects and the welfare of animals</li> <li>• Meeting or exceeding regulatory requirements</li> <li>• Data integrity and an elevated focus on continuous improvement</li> </ul>
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	<p>Where required, a Quality Manual (as required for GMP sites) and/or Standard Operating Procedures (SOPs) will be established for testing facilities or sites to identify the quality objectives of all applicable regulations, standards, and guidelines.</p>
	<p><b>RELATED DOCUMENTS</b></p>
	<p>None.</p>
	<p><b>REGULATORY REFERENCES</b></p>
	<p>This is not intended to be an exhaustive list:</p> <p>EudraLex - The Rules Governing Medicinal Products in the European Union - Volume 4</p> <p>European Union Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use</p> <p>ICH Q10 model, Section 2.2 Quality Policy</p> <p>ISO 17025:2005 Quality Manual Requirements</p> <p>ISO 9001: 2015 Quality Management System requirements</p> <p>ORA Quality Manual- FDA OFFICE OF REGULATORY AFFAIRS ASSOC. COMMISSIONER FOR REGULATORY AFFAIRS , document # ORA-QMS-POL-002, version 2.0, 3/19/2012</p> <p>Title 21 Food and Drugs CFR part 820.20</p> <p>USP ( United States Pharmacopoeia ) 1083.1 QMS</p>
	<p><b>DOCUMENT HISTORY</b></p>
	<p>New Document</p>