



Dear Customer,

Thank you for contacting Cell Signaling Technology, Inc. about our products and services. To assist with requests to complete customer questionnaires, CST has compiled the following information that highlights the elements of our ISO9001:2015 Quality Management System. We hope that you will find this information sufficient for your continuing assessment of CST as a supplier but, if necessary, we welcome any additional questions or comments. For additional information please contact Quality@cellsignal.com or visit www.cellsignal.com.

Our Company

Cell Signaling Technology (CST) is dedicated to providing the world's highest quality, innovative research products to accelerate biological understanding. A privately-owned company headquartered in Danvers, Massachusetts, USA. Founded in 1999, CST employs over 600 people worldwide.

Our Mission

Founded by scientists, CST is dedicated to providing the world's highest quality research and diagnostic products that accelerate biological understanding and enable personalized medicine. Our four core values are the basis for our decision-making, leadership, and culture. They are the principles that the company was founded on and continue to guide our path.



Innovative Science

We believe in the power and promise of science to solve the challenges we face as a global community. Innovation and collaboration are the tools we use to advance life sciences.



Engaged Employees

We believe in creating a stimulating environment that engages all employees, drives innovation, and fosters a culture of inclusion and respect.



Best-In-Class Products

We believe that by empowering scientists and clinicians with best-in-class tools and an excellent customer experience, we can accelerate new discoveries that lead to a better understanding, diagnosis, and treatment of disease.



Social Responsibility

We believe that business must be more responsible, working in partnership with local communities and seeking to minimize its environmental impact.



Corporate Commitments

In addition to the brief overview of CST's mission, we would like to share some additional information on our corporate culture and values.

To continually support our global employees, CST adheres to all local and state labor laws. In addition, CST aligns with current Privacy Regulations. To learn more about your region please visit [CST's Privacy Policy](#) page.

As a part of CST's strong Environmental Social Responsibility program, our employees are engaged partners in our communities. Additional information may be found on our [Environmental Social Responsibility](#) page.

As a partner and leader in signaling research, CST is committed to understanding and finding answers to critical questions about diseases. Our protocols for common lab techniques may be accessed by visiting our [learning and support page](#).

Quality Management Systems (QMS)

CST is an ISO9001:2015 certified company. This certification attests to the rigor of CST's Quality System, a comprehensive approach to achieving the highest possible quality, lot-to-lot reproducibility, and continuous improvement in product development, manufacturing, quality assurance, documentation, and customer support. Link to certification: [ISO9001:2015 FM592035](#)

Quality Policy: Cell Signaling Technology is committed to developing and producing the highest quality products and services that enable and support our customers while complying with relevant standards and/or regulatory requirements for research use only (RUO) materials, through the continued effectiveness of our Quality Management System.

Quality Scope: Manufacture and distribution of antibodies, assay kits, and companion products.

CST is open to discussion on providing appropriate and relevant documents for review during a mutually agreed upon onsite visit or audit. Below are some of the fundamental processes that are documented within CST's ISO 9001:2015 Quality Management System:

- CST Quality Manual
- Management Review
- Document Control
- Employee Training
- Records Control
- Internal and Process Auditing
- Nonconformance Process
- Supplier Evaluation & Management
- Corrective Action and Preventative Action
- Customer Complaint Handling

Sincerely,

DocuSigned by:

Brian McDonough

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Brian McDonough
Sr. Manager, Quality Systems

Updated 22JAN2024



General Business Information									
Company Name:		Cell Signaling Technology, Inc.				Years in business:		~30	
Address:		3 Trask Lane, Danvers, MA 01923							
Description of Products and Services:		Manufacturer and supplier of a complete range of research use antibody, assay kits, and companion products.							
Employees	Total:	~600 Globally	Quality:	2	Manufacturing:	~120	Logistics:	~35	
Tax Identification Number:		04-3485744			Dunn and Bradstreet Number:		12-513-1669		
Customer Payment Remittance Address:			PO Box 3843, Boston, MA 02241-384						
Customer Service Department: Hours: 8:30 AM to 8:00 PM (EST) Phone: 978-867-2388 Fax: 978-867-2488 Email: orders@cellsignal.com Invoice requests: invoicerequests@cellsignal.com					Technical Support: Hours: 8:00 AM to 6:00 PM (EST) Phone: 877-678-8324 Email: support@cellsignal.com Website: www.cellsignal.com				
Quality Contact Information									
Contact:	Brian McDonough, Sr. Quality Manager			Email:	Quality@cellsignal.com		Phone:	978-867-2388	
Facility Information									
Research and Development		3 Trask Ln. Danvers, MA 01923			Manufacturing and Distribution		32 Tozer Rd. Beverly, MA 01915		
Total Space		212,000 ft ²			Manufacturing Space		~45,000 ft ²		
Warehouse Space		~1,600 ft ²			Lab Space		~72,000 ft ²		
Facilities					YES	NO	Comments:		
Is there a documented, planned preventative maintenance program for facilities equipment?					<input checked="" type="checkbox"/>	<input type="checkbox"/>	SOP-00246		
Is access to the facility controlled by electronic and/or physical security?					<input checked="" type="checkbox"/>	<input type="checkbox"/>			
Is there a documented pest control program?					<input checked="" type="checkbox"/>	<input type="checkbox"/>			
Is there a documented cleaning program?					<input checked="" type="checkbox"/>	<input type="checkbox"/>			
Separate air handling systems to prevent contamination, system for controlling air pressure and temperature?					<input checked="" type="checkbox"/>	<input type="checkbox"/>			
Does your company have a business continuity plan					<input checked="" type="checkbox"/>	<input type="checkbox"/>	SOP-20016		
Are eating, drinking and smoking limited to designated areas?					<input checked="" type="checkbox"/>	<input type="checkbox"/>			
Do your manufacturing locations have Good Manufacturing Processes certification?					<input type="checkbox"/>	<input checked="" type="checkbox"/>	Not required for RUO products		
Are your sites inspected by the FDA or national health authorities?					<input type="checkbox"/>	<input checked="" type="checkbox"/>	Not applicable		
Quality Management System					YES	NO	Comments:		
Are you certified to a standard?					<input checked="" type="checkbox"/>	<input type="checkbox"/>	Yes, ISO9001:2015 FM FM592035		
Is there a separate Quality group within your organization?					<input checked="" type="checkbox"/>	<input type="checkbox"/>			
Do you maintain a Quality Manual?					<input checked="" type="checkbox"/>	<input type="checkbox"/>	POLICY-00046		
Is there an Electronic Quality Management System?					<input checked="" type="checkbox"/>	<input type="checkbox"/>	Qualityze eQMS		
Are monitoring and measuring instruments calibrated and maintained on set intervals					<input checked="" type="checkbox"/>	<input type="checkbox"/>	SOP-00248		
Are monitoring and measuring instruments calibrated to known standards?					<input checked="" type="checkbox"/>	<input type="checkbox"/>	As applicable		
Do you maintain records of calibration?					<input checked="" type="checkbox"/>	<input type="checkbox"/>	SOP-00024		
Is there a documented preventative maintenance program for equipment used in production					<input checked="" type="checkbox"/>	<input type="checkbox"/>	SOP-00246		
Do you have a formal documented employee training program?					<input checked="" type="checkbox"/>	<input type="checkbox"/>	SOP-00011		
Are training records maintained?					<input checked="" type="checkbox"/>	<input type="checkbox"/>	Within the eQMS		
Are personnel evaluated periodically to determine competence?					<input checked="" type="checkbox"/>	<input type="checkbox"/>			

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Are there written procedures for manufacturing processes?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Are manufacturing procedures reviewed and approved by subject matter experts, area management and the quality group?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SOP-00001
Is there a formal document revision review and approval process?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SOP-00001
Are documents and records maintained?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Retention varies by document type SOP-00024
Are procedures reviewed on periodic basis?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SOP-00001
Are there established criteria for the release of new materials (lots/batches)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Are all lots/batches tested or inspected to ensure they meet established criteria?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Are inspection or test records for released lots retained?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
If required, can you provide material origin information (human origin, animal origin, etc.)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Upon request to Quality@cellsignal.com
If required, can you provide a Certificate of Analysis?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Located on the website product page
Is there a system or procedure for addressing customer complaints?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SOP-00040
Is there a process for handling nonconforming materials?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SOP-00009
Is nonconforming material segregated and/or identified to prevent unintended use?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Is there an internal audit program?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SOP-00031
Are internal audits conducted on a set schedule?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Are internal audit records maintained?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Is there a documented CAPA process?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SOP-00026
Is there a system to verify the effectiveness of CAPAs	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SOP-00026
Does senior management periodically review the performance and effectiveness of the organizations systems and processes?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Annually at minimum during Quality Management Review
Is there a formal change control management system in place?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SOP-00260
Supplier Management	YES	NO	Comments:
Are suppliers qualified prior to purchases?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SOP-00037
Is an Approved Supplier List maintained?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Is there a supplier corrective action system in place?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SOP-00009
Are incoming raw materials inspected prior to use?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SOP-00717
Are inspection records maintained?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Are Certificate of Analysis or Conformity reviewed for incoming raw materials?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Are incoming materials handled, identified and stored in a manner that will prevent damage, contamination, mix-up and loss?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Does CST have reliable sources of supply for key components?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Does CST require notification of changes in critical processes or materials from suppliers?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Maintained in Supplier Quality Agreements
Does CST track supplier performance, on-time delivery and quality?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Customer Notification	YES	NO	Comments:
Will CST notify customers of changes to form, fit or function of product?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	As required. SOP-00654
Are customer returns handled through a formal and written procedure?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SOP-00040
Are customers notified and is corrective action taken if necessary?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Product Management	YES	NO	Comments:
Are there documented procedures for new product approval and release?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SOP-00136
Are there procedures in place for translating customer requirements into design requirements?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	



Are any production processes subcontracted?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Are there established criteria for the release of new materials (lots/batches)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Are products manufactured on dedicated equipment?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Not applicable for RUO
Are lot/batch numbers defined? How?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	The majority of CST lot numbers are system generated and are sequential
Is there an inventory tracking system used for lot traceability?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Is there traceability to all raw materials and component lots that are used in the finished product?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Does the facility have adequate space to prevent mix-ups and permit material segregation?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Is nonconforming material segregated and clearly labeled?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Are final products released by quality?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Final products are approved and released by the applicable Production Director and applications expert (as required)
IT/Data Security	YES	NO	Comments:
Is CST compliant with 21CFR Part 11	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Not compliant with 21CFR Part 11 but electronic records are maintained.
Are systems regularly backed up at set intervals?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Systems are backed up nightly
Is data archived electronically?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Is data information retained? For how long?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Retention time varies upon the nature of the data
Is there a written information security policy?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	POLICY-80001
Is there a written patch management policy?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	POLICY-80002
Is there a written email access policy?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	POLICY-80003
Sustainability Practices	YES	NO	Comments:
Does your company have a written mission statement that includes a commitment to a positive environmental impact?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	See website: https://www.cellsignal.com/about-us/environmental-and-social-responsibility
Do you have corporate Sustainability goals and are they mapped to the UN's Sustainable Development Goals?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Does your company monitor water usage with the goal of reducing use?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Does your company have a recycling program?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Does your company utilize eco-friendly packaging materials?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Does your company have or are you working toward achieving any Green/ Sustainability certifications (LEED, etc.)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Certain areas are certified by My Green Lab
Does your company have policies or plans for reducing energy consumption or greenhouse gas emissions?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Does your company utilize renewable energy onsite at your facilities?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Does your company consider sustainability scores when choosing suppliers?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Have you implemented any green chemistry practices?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Does your company have ISO 14001 certification?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Does your company participate in any sustainability assessment programs?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Ecovadis ID#: QA338467
Diversity, Equity, and Inclusion (DEI)	YES	NO	Comments:
Is your company considered minority owned?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	



Does your company have a program/policy on Corporate Social Responsibility?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Does your company have programs or policies addressing Diversity, Equity and Inclusion?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Does your company have an internal committee to oversee DE&I strategy?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Does your company have DE&I policies that are explicitly designed as recruiting and retention tools?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Does your company offer employee groups that foster inclusion among minorities within the organization?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Does your company have metrics in place to monitor the success of your DE&I initiatives?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Does your company have a supplier diversity program in place?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Fair Working Conditions, Health and Care	YES	NO	Comments
Does your company have written personnel policies in place for hiring, salary, benefits, termination, and retirement practices to prevent discrimination based on age, disability, gender, nationality, race, color, religion, social or ethnic origin, sexual orientation, health condition, political opinion, etc.?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Does your company have a formal, written policy that clearly states a commitment to prevent harassment and abuse in the workplace?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Does your company have policies that prohibit forced labor and child labor?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Does your company offer accessible and affordable healthcare for all employees?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Are labor, health, and safety policies, practices, and expectations communicated to all employees and suppliers in local or appropriate languages?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Does your company have procedures to ensure appropriate machinery is well-maintained and equipped with the necessary safety devices?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Are all your employees trained on relevant health and safety matters, such as personal protection equipment, machine safeguarding, hazardous materials handling, emergency management, etc.?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	



Cell Signaling Technology High Level Organizational Chart

