

Dear Customer,

Thank you for contacting Cell Signaling Technology, Inc. (CST) 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 a privately-owned company headquartered in Danvers, Massachusetts, USA. Founded in 1999, CST employs over 600 people worldwide. CST prides itself in being a *different* kind of life sciences company—one founded, owned, and run by active research scientists, with the highest standards of product and service quality, technological innovation, and scientific rigor for over 20 years. We consistently provide fellow scientists around the globe with best-in-class products and services to fuel their quests for discovery.

#### **Our Mission**

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.

### **Best-In-Class Products**



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

### **Engaged Employees**



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

### **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**

As a good corporate citizen, CST is committed to conducting business with integrity, fairness, and in a sustainable manner. At CST, we believe in the power and promise of science to solve the challenges we face as a global community. We're a company of caring people driven by a devotion to facilitating good science—a company committed to doing the right thing for our customers, our communities, and our planet. For additional information regarding our mission please view our <u>Story Brochure</u>.

We recognize that people will always be our most important asset. As a commitment to our employees, CST provides a safe, inclusive and stimulating working environment that understands the importance of diversity and human dignity. We believe meaningful work is important. CST has established company policies that incorporate excellent health insurance, and pay benefits. Engaging our employees in committees and philanthropy that benefit the environment and our local communities helps maintain loyalty and long-term work relationships.

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 <u>Environmental Social Responsibility</u> page.

CST values the critical role its suppliers play in its operations and understands it cannot achieve its mission without their assistance. To review the minimum standards with regards to business ethics, labor, health, safety, and environmental responsibility please view our <u>Supplier Code of Conduct</u>. In addition, CST aligns with current privacy regulations. To learn more about your region please visit <u>CST's Privacy Policy</u> page.

#### Quality Management Systems (QMS)

CST is an ISO9001:2015 certified company. This certification attests to the rigor of CST's Quality System, our 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: <u>ISO9001:2015</u> <u>FM592035</u>

**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
- Document Control
- Employee Training
- Records Control
- Management Review
- Internal and Process Auditing
- Supplier Evaluation & Management
- Nonconformance Process
- Corrective Action and Preventive Action
- Customer Complaint Handling

Sincerely,

-DocuSigned by:

Brian McDonough

Giloc4B61AD304DB... Brian McDonough Associate Director, Quality Systems

|  | G                                      | eneral Bu                 | usine   | ss Inforn  | nation  |    |                        |   |                                   |        |  |
|--|--|---------------------------|---|--|---|----|------------------------|---|-----------------------------------|--------|--|
| Company Name:  | C                                      | Cell Signali              | ng Te   | chnology   | y, Inc.   |    | Years in business: ~25 |   |                                   |        |  |
| Address:   |  | Trask Lan                 | <u> </u>  | •  |   | I  |                        |   |                                   | ļ      |  |
| Description of Products and<br>Services:   | N                                      | Manufacturer and su       |   |  | supplier of a complete range of research use<br>s, and companion products.  |    |                        |   |                                   |        |  |
|  |  |                           |   |  | facturir  |    |                        | Logisti   | ~e•                               | ~35    |  |
| Tax Identification Number:   | 04-34857                               | ,                         | 2   |  |   | •  |                        | · · · ·   |                                   | 3-1669 |  |
| Customer Payment Remitta   |  |                           | x 384   |  | Dunn and Bradstreet Number: 12-513-1669<br>B, Boston, MA 02241-384  |    |                        |   |                                   |        |  |
| Customer Service Department:<br>Hours: 8:30 AM to 8:00 PM (EST)<br>Phone: 978-867-2388<br>Fax: 978-867-2488<br>Email: orders@cellsignal.com                |  |                           | Techn<br>Hours<br>Phone                           | Technical Support:<br>Hours: 8:00 AM to 6:00 PM (EST)<br>Phone: 877-678-8324<br>Email: <u>support@cellsignal.com</u> |   |    |                        |   |                                   |        |  |
| Invoice requests: invoicerequests@cellsignal.com   |  |                           |   | Websi  | Website: <u>www.cellsignal.com</u>  |    |                        |   |                                   |        |  |
| EU-Customer Support and Sales:<br>Hours: 8:30 to 18:00 (CET)<br>Call: 31 (0)71 7200 200<br>Fax: 31 (0)71 891 0019<br>Email: <u>order.eu@cellsignal.com</u> |  |                           |   | Hours<br>Phone<br>Email:   | EU-Technical Support:<br>Hours: 8:30 to 17:00 (CET)<br>Phone: +31 (0)71 7200 200<br>Email: <u>eusupport@cellsignal.com</u><br>Website: <u>www.cellsignal.eu</u> |    |                        |   |                                   |        |  |
|  | (                                      | Quality Co                | ontac   | t Inform   | ation   |    |                        |   |                                   |        |  |
| Contact: Brian McDonough, Associate<br>Director, Quality Systems Email:  |  |                           |   |  | uality@cellsignal.com   |    |                        |   | Phone: 978-867-2388               |        |  |
|  | ,                                      | Facili                    | ty Inf  | ormatio  | n   |    |                        |   |                                   |        |  |
| Research and<br>Development  | 3 Trask Ln.<br>Danvers, N              | ask Ln.<br>vers, MA 01923 |   |  | Manufacturing and<br>Distribution   |    |                        |   | 32 Tozer Rd.<br>Beverly, MA 01915 |        |  |
| Total Space  | 212,000 ft <sup>2</sup>                |                           |   |  | Manufacturing Space   |    |                        | ~45,000 ft <sup>2</sup>                             |                                   |        |  |
| Warehouse Space  | ~1,600 ft <sup>2</sup>                 |                           |   |  | Lab Space   |    |                        | ~72,000 ft <sup>2</sup>                             |                                   |        |  |
| EU - Distribution  | Dellaertwe<br>2316 WZ Le<br>The Nether | VZ Leiden                 |   |  | EU - Warehouse  |    |                        | Einsteinweg 5n<br>2333 CC Leiden<br>The Netherlands |                                   |        |  |
| EU - Warehouse Space   | ~200 m <sup>2</sup>                    |                           |   |  |   |    |                        |   |                                   |        |  |
|  | F                                      | Frequentl                 | y Ask   | ed Ques  | stions  |    |                        |   |                                   |        |  |
| F  | acilities                              |                           |   |  | YES   | NO |                        | Com   | ments:                            |        |  |
| Is there a documented, planned preventative maintenand program for facilities equipment?   |  |                           | ance  | $\boxtimes$  | 0   |    | SOP-                   | 00246   |                                   |        |  |
| Is access to the facility controlled by electronic and/or physical security?   |  |                           |   | $\boxtimes$  | 0   |    |                        |   |                                   |        |  |
| Is there a documented pest control program?  |  |                           |   |  | $\boxtimes$   | 0  |                        |   |                                   |        |  |
| Is there a documented cleaning program?  |  |                           |   |  |   | 0  |                        |   |                                   |        |  |
| Separate air handling systems to prevent contamination, system for controlling air pressure and temperature?   |  |                           |   | on,  | $\boxtimes$   | 0  |                        |   |                                   |        |  |
| system for controlling air pr  | essure unu i                           | remperaia                 | Does your company have a business continuity plan |  |   |    |                        |   |                                   |        |  |
| · · · ·  |  |                           |   |  | $\boxtimes$   | 0  |                        | SOP-  | -20016                            |        |  |

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| Do your manufacturing locations have Good Manufacturing<br>Processes certification?                                  | 0            | $\boxtimes$ | Not required for RUO<br>products                |
|--|--------------|-------------|---|
| Are your sites inspected by the FDA or national health authorities?  |              | $\boxtimes$ | Not applicable                                  |
| Quality Management System  | YES          | NO          | Comments:                                       |
| Are you certified to a standard?   | X            | 0           | Yes, ISO9001:2015<br>FM FM592035                |
| Is there a separate Quality group within your organization?  | $\boxtimes$  | 0           |   |
| Do you maintain a Quality Manual?  | X            | 0           | POLICY-00046                                    |
| Is there an Electronic Quality Management System?  | $\boxtimes$  | 0           | Qualityze eQMS                                  |
| Are monitoring and measuring instruments calibrated and maintained on set intervals                                  |              | 0           | SOP-00248                                       |
| Are monitoring and measuring instruments calibrated to known standards?  | X            | 0           | As applicable                                   |
| Do you maintain records of calibration?  | X            | 0           | SOP-00024                                       |
| Is there a documented preventative maintenance program for equipment used in production?                             | X            | 0           | SOP-00246                                       |
| Do you have a formal documented employee training program?   | X            | 0           | SOP-00011                                       |
| Are training records maintained?   | X            | 0           | Within the eQMS                                 |
| Are personnel evaluated periodically to determine<br>competence?   | X            | 0           |   |
| Are there written procedures for manufacturing processes?  | X            | 0           |   |
| Are manufacturing procedures reviewed and approved by subject matter experts, area management and the quality group? | X            | 0           | SOP-00001                                       |
| Is there a formal document revision review and approval process?   | X            | 0           | SOP-00001                                       |
| Are documents and records maintained?  | X            | 0           | Retention varies by<br>document type; SOP-00024 |
| Are procedures reviewed on periodic basis?   | $\mathbf{X}$ | 0           | SOP-00001                                       |
| Are there established criteria for the release of new materials (lots/batches)?                                      | $\boxtimes$  | 0           |   |
| Are all lots/batches tested or inspected to ensure they meet established criteria?                                   | X            | 0           |   |
| Are inspection or test records for released lots retained?   | $\boxtimes$  | 0           |   |
| If required, can you provide material origin information<br>(human origin, animal origin, etc.)?                     |              | 0           | Upon request to<br>Quality@cellsignal.com       |
| If required, can you provide a Certificate of Analysis?  | X            | 0           | Located on the website<br>product page          |
| Is there a system or procedure for addressing customer complaints?   | X            | 0           | SOP-00040                                       |
| Is there a process for handling nonconforming materials?   | X            | 0           | SOP-00009                                       |

## Cell Signaling

Is nonconforming material segregated and/or identified to  $\mathbf{X}$ 0 prevent unintended use? Is there an internal audit program? SOP-00031 Ο X Are internal audits conducted on a set schedule?  $\mathbf{X}$ 0 Are internal audit records maintained?  $\mathbf{X}$ Ο Is there a documented CAPA process? 0 SOP-00026  $\mathbf{X}$ Is there a system to verify the effectiveness of CAPAs? SOP-00026  $\mathbf{X}$ 0 Does senior management periodically review the Annually at minimum during performance and effectiveness of the organizations systems **Quality Management** X Ο and processes? Review Is there a formal change control management system in SOP-00260  $\mathbf{X}$ 0 place? Supplier Management YES NO Comments: Are suppliers qualified prior to purchases? SOP-00037 0  $\mathbf{X}$ Is an Approved Supplier List maintained?  $\mathbf{X}$ 0 Is there a supplier corrective action system in place?  $\mathbf{X}$ 0 SOP-00009 Are incoming raw materials inspected prior to use? 0 SOP-00717  $\mathbf{X}$ Are inspection records maintained?  $\mathbf{X}$ 0 Are Certificate of Analysis or Conformity reviewed for 0  $\mathbf{X}$ incoming raw materials? Are incoming materials handled, identified and stored in a manner that will prevent damage, contamination, mix-up and 0  $\mathbf{X}$ loss? Does CST have reliable sources of supply for key components?  $\mathbf{X}$ Ο Does CST require notification of changes in critical processes Maintained in Supplier  $\mathbf{X}$ 0 or materials from suppliers? Quality Agreements Does CST track supplier performance, on-time delivery and 0  $\mathbf{X}$ quality? **Customer Notification** YES NO Comments: Will CST notify customers of changes to form, fit or function of As required; SOP-00654  $\mathbf{X}$ 0 product? Are customer returns handled through a formal and written SOP-00040  $\mathbf{X}$ 0 procedure? Are customers notified and is corrective action taken if 0  $\mathbf{X}$ necessary? Product Management YES NO Comments: Are there documented procedures for new product approval 0 SOP-00136  $\mathbf{X}$ and release? Are there procedures in place for translating customer  $\mathbf{X}$ 0 requirements into design requirements? Are any production processes subcontracted? X Ο Are products manufactured on dedicated equipment?  $\mathbf{X}$ Not applicable for RUO 0

| Are lot/batch numbers defined? How?   |             | 0  | The majority of CST lot<br>numbers are system<br>generated and are<br>sequential   |
|---|-------------|----|--|
| Is there an inventory tracking system used for lot traceability?  | $\boxtimes$ | 0  |  |
| Is there traceability to all raw materials and component lots that are used in the finished product?              | $\boxtimes$ | 0  |  |
| Does the facility have adequate space to prevent mix-ups and permit material segregation?                         | $\boxtimes$ | 0  |  |
| Is nonconforming material segregated and clearly labeled?   | $\boxtimes$ | 0  |  |
| Are final products released by quality?   |             | X  | Final products are approved<br>and released by the<br>applicable Production<br>Director and applications<br>expert (as required) |
| IT/Data Security  | YES         | NO | Comments:  |
| s CST compliant with 21CFR Part 11  |             | ×  | Not compliant with 21CFR<br>Part 11 but electronic records<br>are<br>maintained.   |
| Are systems regularly backed up at set intervals?   |             | 0  | Systems are backed up<br>nightly   |
| Is data archived electronically?  | $\boxtimes$ | 0  |  |
| Is data information retained? For how long?   |             | 0  | Retention time varies upon the nature of the data  |
| Is there a written information security policy?   |             | 0  | POLICY-80001   |
| Is there a written patch management policy?   | $\boxtimes$ | 0  | POLICY-80002   |
| Is there a written email access policy?   |             | 0  | POLICY-80003   |
| Sustainability Practices  | YES         | NO | Comments:  |
| Does your company subscribe to a sustainability rating service?   | $\boxtimes$ | 0  | Ecovadis<br>EVID: QA338467   |
| Does your company have a written mission statement that includes a commitment to a positive environmental impact? |             | 0  | See website:<br>https://www.cellsignal.com/<br>about-us/environmental-<br>and-social-responsibility                              |
| Do you have corporate Sustainability goals and are they<br>mapped to the UN's Sustainable Development Goals?      | $\boxtimes$ | 0  |  |
| Does your company monitor water usage with the goal of reducing use?  |             | 0  |  |
| Does your company have a recycling program?   | $\boxtimes$ | 0  |  |
| Does your company utilize eco-friendly packaging materials?   | $\boxtimes$ | 0  |  |
| Does your company have or are you working toward achieving any Green/ Sustainability certifications (LEED, etc.)? |             | 0  | Certain areas are certified<br>by My Green Lab   |
| Does your company have policies or plans for reducing energy consumption or greenhouse gas emissions?             | $\boxtimes$ | 0  |  |

| Does your company utilize renewable energy onsite at your facilities?  |             | 0           |           |
|--|-------------|-------------|-----------|
| Does your company consider sustainability scores when choosing suppliers?  |             | 0           |           |
| Have you implemented any green chemistry practices?  | $\boxtimes$ | 0           |           |
| Does your company have ISO 14001 certification?  | 0           | $\boxtimes$ |           |
| Diversity, Equity, and Inclusion (DEI)   | YES         | NO          | Comments: |
| Is your company considered minority owned?   | 0           | $\boxtimes$ |           |
| Does your company have a program/policy on Corporate<br>Social Responsibility?   | $\boxtimes$ | 0           |           |
| Does your company have programs or policies addressing Diversity, Equity and Inclusion?  | $\boxtimes$ | 0           |           |
| Does your company have an internal committee to oversee<br>DE&I strategy?  | $\boxtimes$ | 0           |           |
| Does your company have DE&I policies that are explicitly designed as recruiting and retention tools?   | $\boxtimes$ | 0           |           |
| Does your company offer employee groups that foster inclusion among minorities within the organization?  | X           | 0           |           |
| Does your company have metrics in place to monitor the success of your DE&I initiatives?   | $\boxtimes$ | 0           |           |
| Does your company have a supplier diversity program in place?  | X           | 0           |           |
| Fair Working Conditions, Health and Care   | YES         | NO          | Comments  |
| Does your company have written personnel policies in place<br>for hiring, salary, benefits, termination, and retirement<br>practices to prevent discrimination based on age, disability,<br>gender, nationality, race, color, religion, social or ethnic origin,<br>sexual orientation, health condition, political opinion, etc.? | X           | 0           |           |
| Does your company have a formal, written policy that clearly states a commitment to prevent harassment and abuse in the workplace?   | X           | 0           |           |
| Does your company have policies that prohibit forced labor and child labor?  | $\boxtimes$ | 0           |           |
| Does your company offer accessible and affordable healthcare for all employees?  | $\boxtimes$ | 0           |           |
| Are labor, health, and safety policies, practices, and<br>expectations communicated to all employees and suppliers in<br>local or appropriate languages?   | $\boxtimes$ | 0           |           |
| Does your company have procedures to ensure appropriate machinery is well-maintained and equipped with the necessary safety devices?   | $\boxtimes$ | 0           |           |
| Are all your employees trained on relevant health and safety matters, such as personal protection equipment, machine   | X           | 0           |           |



## **Cell Signaling Technology High Level Organization Chart**

