



## STATEMENT OF COMMITMENT TO FDA / cGMP STANDARDS



January 01, 2024

### **Subject: Inside Track Cabling Commitment and Compliance to FDA/cGMP Standards**

As a manufacturer of high quality cable and harness assemblies, some of which are utilized within the medical and medical device industry, Inside Track Cabling maintains strict compliance to the FDA Quality System (QS) Regulation/Medical Device Good Manufacturing Practices. Although the QS Regulation applies only to "finished device" manufacturers, ITC operates its facility and manufacturing process in complete accordance with FDA/cGMP Standards.

### **Current Good Manufacturing Practices (cGMP):**

cGMP is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use. Although cGMP is aimed primarily at diminishing the risk inherent in pharmaceutical production, as a manufacturer of high quality medical device cabling, it is essential that Inside Track Cabling adhere to these practices. We do this by executing the following responsibilities:

- Organize, maintain and operate our facility in a clean and controlled manner
- Validate our process and equipment
- Develop, implement and follow proper procedures
- Identify and specify responsibility throughout our organization
- Effectively document and record all manufacturing activities
- Continually train and develop our employees
- Practice good housekeeping and hygiene
- Perform timely preventive maintenance of our facility and equipment
- Design quality into the entire lifecycle of our products
- Perform regular calibration and auditing activities
- Maintain compliance to a recognized quality standard

We at Inside Track Cabling take quality and compliance matters seriously and are steadfast in our commitment to comply with FDA/cGMP quality standards. Although not currently registered with the United States Food and Drug Administration, our organization has maintained such registration in the past and will do so in the event that a customer requires the manufacture of product considered to be a "Finished Medical Device".

Sincerely,

A handwritten signature in blue ink that reads "David L. James".  
*Authorized Signatory*

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