CIRCUIT NEWS 3.1

JAN 2024...***Happy New Year!***

Navigating International Standards for Manufacturing

What is a standard? Think of a standard as a formula that describes the best way of doing something. Standards are the distilled wisdom of subject matter experts that know the needs of the organizations they represent.
What are the benefits of standards? Per the International Organization for Standardization (ISO) it's the best way of ensuring that the end user or customer of a product or service will have confidence it is safe, reliable and of good quality.
NOTE: ISO standards apply internationally.

ISO Compliant vs. ISO Certification - The term 'compliant' can be misleading. Companies can claim to be compliant, meaning they have set up an internal system based on ISO, but there is no independent external auditing of their internal systems which is required to obtain ISO Certification by an approved external certification entity.

Let's look at a few key standards more closely:

- ***ISO 9001:2015 -*** This standard specifies a set of standardized requirements for a Quality Management System (QMS) regardless of what the user organization does, its size or whether it is in the public or private sector. Please see... ISO - ISO 9001 and related standards - Quality Management
- ***ISO 13485:2016 -*** This standard specifies requirements for a Quality Management System where the organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and regulatory requirements. For more information... ISO 13485:2016 - Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
- ***AS 9100D -*** This standard is a management system for the Aerospace Industries. The standard provides suppliers with a comprehensive quality system for providing safe and reliable products. For additional information go to... AS9100 - Wikipedia

Other related relevant regulations to consider:

- ***AS 5553 -*** AS5553D: Counterfeit Electrical, Electronic, and Electromechanical (EEE) Parts; Avoidance, Detection, Mitigation, and Disposition - SAE International
- ***ITAR -*** For a company that is involved in the manufacture, sale or distribution of goods or services covered under the United States Munitions List (USML) or a component supplier of goods covered under (USML), the contractual or requirement of being ITAR compliant means that the company is registered with the State Department's DDTC... International Traffic in Arms Regulations - Wikipedia

Article sources include ISO.gov, SAE International and Wikipedia

ISO Standards in Action!

Prior to the onset of the recent COVID pandemic, SoPark was part of the solution to our medical device OEM customers by being ISO 13485:2016 certified for the manufacture of printed circuit board assemblies that are used in their medical device products.

During the pandemic, our ISO 13485:2016 certification helped to further ensure our customers that the necessary quality levels were being met, and regularly independently audited, adding yet another layer of confidence to their medical products at a very critical time of need.

Check our website for past Circuit News issues…

Quick link:

News | SoPark | Electronics Contract Manufacturer

Or contact us below...

Email: sales@sopark.com Phone: 716.822.0434 www.sopark.com 3300 South Park Avenue, Buffalo, NY 14218