

## ALLTRISRTA PLASTICS PLASTICS, LLC CERTIFIED UNDER THE ISO 13485:2016 STANDARD

**ABOUT ALLTRISTA PLASTICS PUERTO RICO LLC.** During the year 2017 Alltrista Plastics Puerto Rico, LLC, initiated its operations in Carolina as Jarden Plastics, for the manufacturing of plastics bottles and closures for pharmaceutical industry and precision plastic injection molded parts for non-active medical devices.

**THE CHALLENGE.** Alltrista Plastic's customers, medical devices and pharmaceutical manufacturers, continuously demand higher standards and that their suppliers operate under a formal quality system. Alltrista Plastics Puerto Rico, LLC, realized that their quality management system needed to be upgraded in order to meet international standards. Since the company's personnel had participated in various activities sponsored by PRiMEX, part of the MEP National Network™, management contacted PRiMEX again for assistance to evaluate and improve their quality system in order to meet the high customer standards.

**MEP CENTER'S ROLE.** On December 2019 Alltrista Plastics Puerto Rico, LLC, contacted PRiMEX to request guidance, support services and trainings to obtain the ISO 13485:2016 certification. Upon PRiMEX's initial visit, it was confirmed that ISO 13485:2016 standard certification was required to meet most actual and potential customers demands. An initial formal introduction to ISO 13485:2016 training was conducted for management and key personnel that would be supporting the certification process.

After this initial training, Alltrista Plastics Puerto Rico increased the efforts towards making sure the company quality management system met ISO 13485:2016 requirements. All required supporting activities were improved or initiated, including employee's commitment to meet quality standards. Internal auditor training was also conducted. Internal audits and management review were initiated and finally, Alltrista Plastics Puerto Rico, LLC, was audited by a certification body and received on April 2021 the ISO 13485:2016 certification with PRiMEX's continuous support.

"We have always recognized that having a good quality system is essential for the proper functioning of a company. Certifying Alltrista Plastics Puerto Rico, LLC, under the ISO 13485:2016 standard has been one of our goals since the beginning of our operations. During December 2019 we contacted PRIMEX and Eng. Rafael Pagan, PRiMEX performance consultant, was introduced to the company as a representative of PRIMEX. He helped us in all areas and was with us in each stage until we obtained the ISO 13485:2016 certification. We are very grateful for the commitment that PRIMEX has with its clients and for being open to share its vast experience in the industry."

-Joel Castro, PE, MEM, Quality Manager

## RESULTS



\$6,500,000 in increased or retained sales



10 jobs created



ISO 13485:2016 certification



New business opportunities with Pall Medical, Abbot Medical & Ethicon

## CONTACT US



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