

WITH ISO9001 CERTIFICATION KORBER BREAKS BARRIERS TO
ENTRY TO NEW CUSTOMERS

ABOUT KORBER MEDIPAK SYSTEMS NA INC. Körber Pharma, Inc., is part of Körber, a German-based company and a worldwide leader in manufacturing of packaging equipment to pharmaceutical and medical companies. The packaging equipment, for instance syringe handling machines, is designed and built specifically to customer's specifications. In addition, Körber Pharma, Inc., offers advanced integration services, which provide a complete packaging line with all of the mechanical components and controls tied together seamlessly. Körber Pharma's Fargo, North Dakota, facility employs 137 people.

THE CHALLENGE. Körber Pharma's team was aware of significant opportunities to secure relationships and revenue with key clients that required ISO9001 certification. COO David Brown committed to a key client that their team would achieve their ISO9001 certification before end of the year to meet that client's needs. For expert help Korber Pharma's project leadership team of Jeremy Wentz, project manager, and Kelli Russillo, technical writer, turned to Impact Dakota, part of the MEP National Network™.

MEP CENTER'S ROLE. A meeting was set up on site at Körber Pharma, Inc., to perform a no-cost ISO9001 assessment and to share implementation plans. The Körber Pharma leadership team collaborated with Jodie Mjoen of Impact Dakota and identified areas where additional support would be needed in order to meet the ISO9001 requirements.

An ISO9001 project kickoff meeting was held on June 20, 2021, with all the Körber Pharma's leadership team. Break-out sessions were scheduled over the next several weeks with the various departments to perform a full gap assessment to the ISO9001 standard. The team determined where the company was compliant, where gaps existed and what actions could be taken to make current processes more robust to meet the standard. Using the resulting gap closure plan, the team trained their entire organization to the revised processes.

The collaborative team put their new quality management system (QMS) into motion to collect objective evidence of compliance, completing an internal audit and identifying their own internal corrective actions. The team then notified their Registrar Accreditation Board (RAB)-accredited third-party registrar the company was ready for certification and completed an ISO9001 stage 1 audit with the registrar at the beginning of November 2021. Körber Pharma then positioned themselves for the full ISO9001 stage 2 registration audit. Completed on December 20th 2021, just 6 months after the team kicked off this ISO9001 implementation project, Körber Pharma passed with a few minor corrective actions and completed their ISO9001 QMS certification.

"Impact Dakota provided a step-by-step process of preparing and guiding our company through the unknown to achieve our final goal of attaining ISO 9001 certification. Great resource to have in your corner no matter what your business needs."

-Jeremy Wentz, Senior Project Manager - Team Lead

RESULTS



Received ISO9001 certification



\$150,000 of new investment time and money



137 employees trained for ISO9001 QMS



1 new customer



Culture is more performance-driven by formalizing processes to drive actions

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