



Credence MedSystems Achieves ISO 13485 Certification, Marking Key Milestone Towards Ready-to-Supply Partnerships

ISO Certification reinforces Credence's commitment to quality, manufacturing readiness, and its mission to solve evolving injectable drug delivery challenges

MENLO PARK, CA, UNITED STATES, September 29, 2026 /EINPresswire.com/ -- Credence MedSystems¹, a developer of innovative drug delivery technologies for pharmaceutical and biotechnology companies, today announced that it has achieved ISO 13485:2016 certification for its Quality Management System.

For pharmaceutical and biotechnology companies developing combination products that include advanced drug delivery systems, a robust quality management system is an important element of supplier qualification and manufacturing readiness. The certificate was issued by BSI. [ISO 13485 certification](#) demonstrates that Credence has established a quality management system aligned with internationally recognized requirements for the design and manufacture of medical-device-related products.

"ISO 13485 Certification is an important milestone in Credence's evolution," said Lisa Caparra, Director of Quality Assurance at Credence MedSystems. "We have built our business around solving difficult drug delivery challenges, but innovation alone is not enough. Pharmaceutical companies need delivery technologies supported by the quality systems, manufacturing processes and supply infrastructure necessary to move programs toward commercialization. This certification is an important demonstration of our evolution as a ready-to-supply partner for our pharma and biopharma collaborators."

Innovation Without Change[®]

The injectable drug delivery landscape is evolving. Changes in formulation stability, viscosity, dose requirements, usability and manufacturing continuity are creating new challenges for pharmaceutical and biotechnology companies. At the same time, evolving therapies and patient needs are driving new requirements for how injectable medicines are delivered.

Credence addresses these challenges through ready-to-supply platform technologies that are customizable for specific application needs. The company's philosophy of Innovation Without Change[®] is based on a simple principle: innovation should solve drug delivery challenges without introducing unnecessary complexity and risk elsewhere.

Our customers are not simply looking for a device—they are looking for a solution to a drug delivery challenge... and a path to getting their therapy to the patients that need them."

— Sian Eden, Commercial Director

Credence designs its technologies around proven primary components and established manufacturing processes. This approach is intended to enable pharmaceutical partners to adopt new drug delivery capabilities that address their evolving needs while minimizing implementation risk and operational disruption.

Credence's drug delivery platform portfolio³ includes:

Companion[®] Platform — Passive Integrated Safety.

User-Preferred Drug Delivery.

The Companion[®] Platform is an advanced prefilled syringe system with intuitive usability and passive integrated needle safety across industry-standard 1 mL, 2.25 mL, 3 mL and 5 mL syringe formats. The expanded platform supports the industry's transition toward larger-volume injectable therapies while maintaining the benefits of the established Companion[®] architecture.

Dual Chamber Syringe Platform — Reconstitution & Sequential Drug Delivery.

The Credence Dual Chamber Syringe Platform enables reconstitution or sequential injection while keeping drug components separate prior to administration. The platform is designed to address complex injectable therapies where formulation stability or other drug-product requirements create challenges for conventional delivery approaches. Credence also supports the broader dual-chamber solution through filling, assembly, labeling and packaging capabilities enabled through its specialized partners.

Metered Dosing Platform — Precision Microliter Drug Delivery.

The Credence Metered Dosing Platform enables precision microliter dosing for single- or multi-dose applications in ophthalmic, aesthetic and other precision therapies. The platform is designed to provide guided, controlled delivery while supporting compatibility with established prefilled syringe components and filling processes.

Credence also develops specialized technologies for specific drug delivery challenges, including solutions designed to address needle clogging and the delivery of high-viscosity formulations.

From Innovative Technology to Ready-to-Supply Partner

ISO 13485 certification represents an important step in Credence's evolution from an innovative drug delivery technology developer toward a ready-to-supply partner for pharmaceutical and biotechnology companies.

For pharma, selecting a drug delivery technology requires more than demonstrating device functionality. It requires confidence in the supplier's quality systems, design processes, manufacturing capabilities and ability to support a program as it advances toward commercial supply.

"Our customers are not simply looking for a device—they are looking for a solution to a drug delivery challenge, a lever for market differentiation, and a path to getting their therapy to the patients that need them," said Sian Eden, Commercial Director at Credence MedSystems. "ISO 13485 certification strengthens Credence's ability to support that journey. It is another important building block in our emergence as a partner that can bring innovative drug delivery solutions together with the quality and manufacturing readiness pharma expects."

About Credence MedSystems

Credence MedSystems develops ready-to-supply platform technologies that solve injectable drug delivery challenges. Its technologies are customizable for specific application needs while leveraging proven primary components and established manufacturing processes wherever possible.

Credence's portfolio includes the Companion[®] Platform, Dual Chamber Syringe Platform and Metered Dosing Platform, along with specialized technologies addressing specific drug delivery applications.

Contact:

www.CredenceMed.com
info@CredenceMed.com

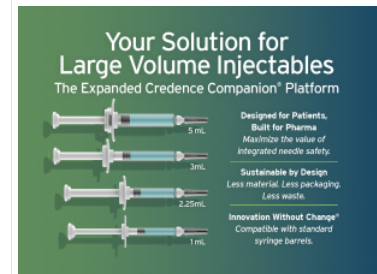
John Merhige
Credence MedSystems
+1 508-380-0602
[email us here](#)

Visit us on social media:
[LinkedIn](#)

WATCH NOW: The Platform of ready-to-supply drug delivery systems from Credence MedSystems. at <https://vimeo.com/1231071082?share=copy&fl=sv&fe=ci>



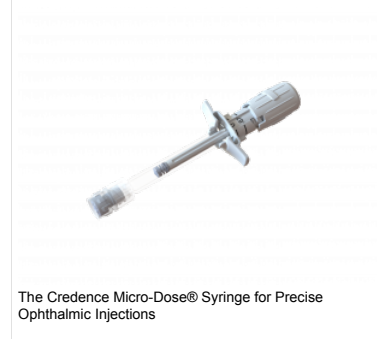
Credence MedSystems



The Credence Companion[®] Lineup: Passive, Integrated Safety from 1mL to 5mL



The Credence Dual Chamber Syringe allows for either reconstitution or sequential injection of two liquids.



The Credence Micro-Dose[®] Syringe for Precise Ophthalmic Injections



¹ <http://www.credencemed.com>

² <https://www.credencemed.com/products/>

³ <https://www.credencemed.com/products/>

This press release can be viewed online at: <https://www.einpresswire.com/article/945896163/>

Disclaimer: If you have any questions regarding information in this press release please contact the company listed in the press release. Please do not contact EIN Presswire. We will be unable to assist you with your inquiry. EIN Presswire disclaims any content contained in these releases.

© 1995-2026 Newsmatics Inc. All Right Reserved.