



ESS Industry Profile

Infor Cloudsuite: ERP Designed for Medical Device and PPE Mfgs

Manufacturers of FDA Regulated products are faced with an evolving set of regulatory standards with which they must comply. The Infor CloudSuite Industrial (CSI) Solution is built to specifically address the nuanced requirements for this regulated sector. With lot and serial traceability, the solution supports full Device History Record (DHR) creation and querying, complemented by a totally integrated and stringently maintained Device Master Record (DMR). Recognizing the critical sensitivity, privacy, and security of data, the FDA Extended solution helps to maintain proper data governance with complete audit trail capability.



Maintaining strict quality management and detailed product documentation to meet customer specifications and regulatory requirements is necessary in an FDA regulated industry. In addition, special production techniques, materials, and packaging for medical products force companies to keep stringent control over engineering and shop floor operations. With the proper ERP system in place, our clients have the resources to create detailed work orders and access to real-time data to maintain tight control over manufacturing processes. Plus, they get accurate, reliable information about operations, customer histories, and costs to keep up with regulations and bring products to market quickly.

Industries Served by CloudSuite Industrial

- Medical Devices
- Compound Pharmaceutical
- Organ Regeneration
- Cosmetic Products
- Food & Beverage
- Ophthalmic Products
- Environmental Safety Equipment
- Stem Cell Solutions
- Diagnostic Testing Solutions
- Physical Rehabilitation Equipment
- Personal Protective Equipment

In an FDA compliant environment, Infor's FDA regulated clients benefit from well-established protocols and validation scripts that meet regulatory requirements for computer systems in compliance with the FDA's 21 CFR Part 11.

***Essential Software Solutions is a 100%
Canadian owned ERP implementation firm
doing business in Canada for over four
decades.***



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