

EzMed: a complete solution for growing companies in the medical devices and equipment industries

Comprehensive and affordable, EzMed is part of the SAP-certified EzLifeSciences family of solutions from Answerthink

EZLIFESCIENCES

EzMed is a preconfigured, rapidly deployable software and services solution that enables growth, regulatory compliance and the implementation of best business practices for the medical devices and equipment industries. Built on the world's leading enterprise applications from SAP, EzMed has been predefined by Answerthink to address the needs of small and midsize companies and can be up and running in only a matter of weeks.

EzMed is fully certified through our relationship with Arbour Group LLC.

As You Grow, The Challenges Become More Complex

Gaining and maintaining competitive advantage in the medical device and equipment industries has never been more challenging. Medical device companies are compelled to continually innovate, bringing products and technologies to market quickly without delays and development overruns. High quality standards must be coupled with cost containment. Operational excellence must co-exist with industry and securities regulations that impact the entire enterprise, including information technology systems.

Attempting to face off against these challenges is a daunting task without the benefit of timely reporting and data visibility, the use of industry best practices and a single, integrated enterprise software system that allows information exchange across your organization.

With EzMed, Answerthink and SAP have teamed up to deliver a rapidly deployable solution that allows growing companies in the medical device and equipment industries to improve business processes, rein in costs, maintain regulatory compliance and quickly ramp up operations upon the introduction of new products.

Industry best practices are built into the preconfigured solution. Hundreds of business processes, reports, forms and user roles are pre-built and delivered standard, along with end-user training and a master plan and template reports for vali-

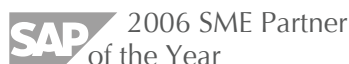
Key Functionality of EzMed

- **Integrated business applications** – including manufacturing, materials management, production planning, order fulfillment with serial number management, integrated financials and accounting, sales and distribution, service management, and quality management
- **DEA-compliant product sales management**
- **FDA, cGMP and QSR-compliant manufacturing**
- **Complaints tracking**
- **Returns management**
- **Medical device manufacture reporting**
- **Trunk stock management**
- **Medical injuries and complaint handling – CAPA**
- **Install base management**
- **Lot recall and genealogy analysis**
- **R&D project cost management**
- **E-business functionality**
- **Business and regulatory analytics**
- **Document management**
- **Streamlined software validation templates and tools, including:** validation master plan, user requirements spec, traceability matrix, test scripts and summary report

ation. The entire software and services solution is delivered within a fixed scope and using a fixed implementation time – exactly what a growing company needs.

Industry Leadership

SAP is considered the clear industry leader when it comes to ERP systems for medical device companies. Of the top 20 medical products companies, 15 use SAP, and SAP counts over 600 life sciences customers among their worldwide user base. Larger companies have, in effect, provided for the development of SAP's industry best practices over the past 30 years. Growing medical device and equipment companies can now reap the benefits of that experience with Answerthink's pre-packaged EzMed solution.



EzMed provides extensive inquiry and reporting capabilities and business process configurations to facilitate compliance with current Good Manufacturing Practices and regulatory requirements from the FDA. Standard business processes within the software support compliance with Sarbanes-Oxley regulations. Sophisticated functionality within EzMed enables compliance with the electronic signature requirements of FDA 21 CFR Part 11 rule and with the quality system regulations of FDA 21 CFR Part 820. Validation of the installed system is facilitated with templates of the most commonly used validation documents, including Validation Master Plan (VMP), Installation Qualification (IQ) documents, Operational Qualification (OQ) documents and Performance Qualification (PQ) documents.

Additionally, EzMed can be further extended with EzCommerce Suite, a unique e-business solution that consists of pre-built, individually deployable Enterprise JavaBeans (EJB) based business applications. EzCommerce integrates directly with SAP and legacy systems to encapsulate business objects and processes needed for customer interaction, catalog aggregation, customer self-service, supplier interaction, vendor self-service, collaborative commerce and business partner and user administration.

The Power of SAP, the Attention of Answerthink

In summary, Answerthink has developed EzMed based on years of experience implementing SAP solutions in emerging companies. With EzMed, Answerthink offers world-class performance more affordably and helps medical device and equipment companies achieve it more effectively than anyone else.

Answerthink and Arbour Group

SAP and other commercial software solutions used by companies in the medical device industries are governed by U.S. regulations including GMP, GLP, and 21 CFR Part 11, and other requirements including GAMP, MHRA and TGA. To ensure regulatory compliance and reduce business risk, commercial business applications need to be stringently validated. Failure to comply can lead to regulatory roadblocks and a costly loss of business.

Arbour Group LLC is a leading global provider of regulatory products and services for computer systems and medical devices in the Life Sciences industries. Arbour Group and Answerthink have teamed to combine Arbour's compliance expertise with Answerthink's preconfigured EzLifeSciences solutions. The resulting compliance solution uniquely maps to the Answerthink/SAP solutions in order to ensure FDA compliance during our accelerated implementation process. Packaged

validation protocols are included to help clients ensure that key SAP components are functional and in compliance with applicable regulations. As a result, the potential for business risk and disruption is minimized, implementation projects are shortened, and validation is no longer on the critical path.

EzMed SAP's All-in-One Solution

EzMed offers you all of this within a single, fixed-scope package:

- Preconfigured SAP software
- Industry Best Practices for High Tech Manufacturing
- Rapid Deployment
- Training and Knowledge Transfer
- Regulatory compliance certified via the Arbour Group

The Answerthink Advantage

Answerthink's Best Practice Solutions Group (BPSG) enables world-class performance through best practice-based business and technology solutions. The Hackett Group, a strategic advisory firm, is a world leader in best practice research, benchmarking, and business transformation services. Hackett helps executives identify and quantify performance gaps compared with the best performing companies; Answerthink specialists design and implement solutions based on Hackett-Certified™ Practices to enable world-class performance levels. Answerthink's BPSG capabilities include business applications implementation and design, technology integration, and offshore application maintenance and support. Answerthink is your ideal partner to select, design, and implement SAP solutions that support Hackett-Certified™ practices.

Answerthink specializes in providing low-cost, on-time delivery and implementation of SAP solutions and excels at helping smaller companies get the highest return from the industry and process functionality of SAP applications. In fact, Answerthink has helped hundreds of growing companies make the move to SAP solutions.

Our approach is simple yet powerful:

1. Understand factually the practices of world-class firms
2. Configure solutions that enable these practices
3. Implement quickly

For more details on how SAP and Answerthink can help you better meet challenges of your growing business

Call 610-234-5678 or visit www.answerthink.com for more information.