



IFS APPLICATIONS™ FOR

# MEDICAL DEVICES



## OUR SOLUTION'S DNA

When we first set out to create IFS Applications over 25 years ago, our goal was to make the most usable business software on the market. And to help us achieve that ambition, we put simplicity at the forefront of everything we did.

**We still do.**

We decided that we would make only one product, which can be easily configured to match the specific requirements of a broad range of industries.

**We still do.**

We decided that we would build IFS Applications on standards so our customers would not be locked into any particular technology.

**We still do.**

We decided to design IFS Applications as a component-based structure so it can be easily extended and updated.

**We still do.**

We decided that each software component must be totally compatible with every other, yet capable of running independently.

**We still do.**

We decided to build a product that could handle change and long-term evolution.

**We still do.**

And, that we would make the most user-friendly business software on the market.

**We still do that, too.**

## **AGILITY—FROM ENGINEERING TO CUSTOMER RELATIONSHIPS MANAGEMENT**

IFS provides you with an agile, scalable suite of business software that covers all your needs from engineering all the way through a broad array of business processes to customer relationship management. What's more, our people know your industry challenges as well as you do—and will go the extra mile with you to ensure that you are well prepared to meet the issues and opportunities that arise in a constantly changing world. Designed with and for our customers in the medical devices industry, our solution combines industry-specific software with a full suite of ERP applications. We call it Industry Excellence. Our customers call it IFS Applications.



# IFS APPLICATIONS™ FOR MEDICAL DEVICES MANAGEMENT FOR IMPROVED C

**For companies in the medical devices industry, IFS Applications™ for Medical Devices supports the entire range of business processes from engineering of new products through manufacturing and delivery to after sales. Component-based for maximum scalability and flexibility, the solution enables companies in the industry to enhance customer relationships, speed up time to market, and achieve a faster return on investment. It also includes comprehensive supply chain and asset lifecycle management functionality.**

## FDA COMPLIANCE

The medical devices industry is regulated by FDA regulations. Any system working under these must comply with Current Good Manufacturing Practices, CGMP, which control the design, manufacturing, distribution, and servicing of medical devices. For medical device manufacturers, these rules are defined in Title 21 CFR Part 820, Quality System Regulations. IFS Applications for Medical Devices includes functionality for electronic records, electronic signatures and audit trails in line with Title 21 CFR Part 11. IFS Applications has already proven its ability to help customers comply with FDA requirements.

## FLEXIBLE ENGINEERING AND PRODUCTION CAPABILITIES

Companies manufacturing complex products usually offer customer-specific functionality and design. For these companies, IFS Applications includes functionality for product engineering and design that supports change management with engineering change requests (ECR) and engineering change orders (ECO).

In addition, strong mixed-mode manufacturing capabilities ensure simple and effective production, with the option of more sophisticated solutions via the configure-to-order functionality.

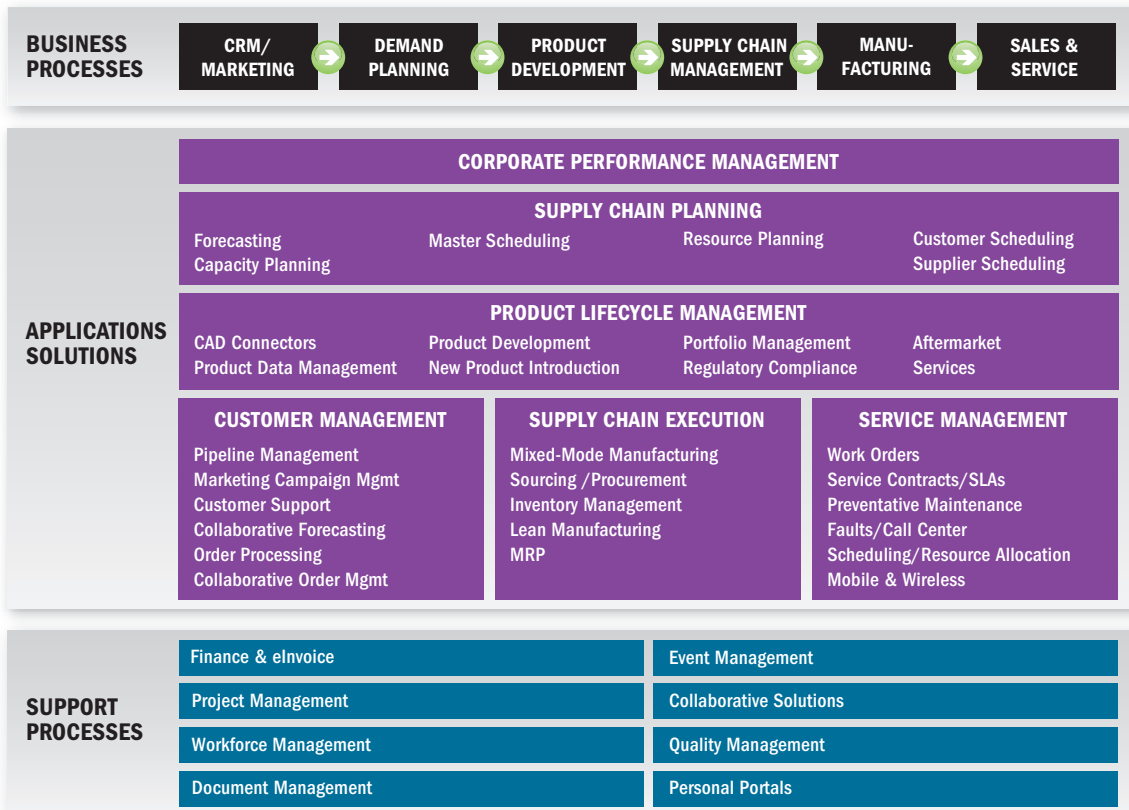
## TRACEABILITY AND ACCOUNTABILITY

Since traceability requirements apply throughout a product's life cycle, IT support for after sales is especially critical. IFS Applications for Medical Devices offers tracking functionality based on lot/batch and serial number that ensures that companies can trace the manufacturing process for a product after it has been sold and offer customers comprehensive product lifecycle management. Companies are given real-time access to accurate technical data, change orders and other documentation for individual devices, radically improving the accountability

## FUNCTIONALITY FOR FDA COMPLIANCE

- Electronic Signatures
- Electronic Records
- Audit Trails
- Device Master Record
- Device History Record

# AL DEVICE—PRODUCT LIFE CYCLE CUSTOMER RELATIONSHIPS



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stipulated in FDA regulations for maintaining device history records (DHR) and device master records (DMR). The result is easier service and support as well as enhanced customer relationships. IFS provides transparent touchpoints for all who are involved in a customer relationship, supporting business proposals and decisions in every interaction. The flexibility guaranteed by the component architecture of IFS Applications makes it easier to tailor customer relationship management solutions that fit the needs of individual enterprises.

#### **FLEXIBILITY AND SCALABILITY**

IFS Applications for Medical Devices equips companies to meet and beat the challenges of industry today. The entire IFS Applications suite is multi-lingual and offers multi-currency capabilities, enabling companies to easily handle the complexities arising from current trends toward globalization and expansion via acquisitions and mergers.

For startups, the component architecture of the solution means that enterprises can start off small, implementing only the functionality they need to get started, and then add on the components they require as they grow and operations expand—and do so without disrupting operations. This means faster, easier implementation and training, quicker go live, and lower investment costs.

#### **SEE CHANGES IN REAL TIME—AND REACT FASTER**

In addition to downstream traceability for all your finished products, IFS Applications gives you complete visibility along your entire supply chain for the components you need to produce your goods, regardless of what part of the world you source them from. You can easily see whether components have been delayed—and why—or if changes that may have been made affect compliance.

Real-time visibility gives you the agility to take rapid remedial action. And whether your production is run from a single site or based on a multi-site setup, you can do all this from a single point in your organization.

#### **COMPREHENSIVE SOLUTION**

In addition to industry-specific applications, IFS offers a comprehensive suite of integrated business applications that cover the entire needs of companies in the industry.

#### **ENTERPRISE ASSET MANAGEMENT**

To begin with, IFS offers a completely integrated enterprise asset management package that provides production plants with the tools for maintenance management, spare part management, procurement and work order management. The analytical capacity combined with preventive maintenance functionality has a proven track record of cutting costs and increasing asset reliability.

#### **STRATEGIC DECISION SUPPORT**

For long-term strategic decision-making, IFS' business intelligence capabilities provide management with performance data to facilitate analysis and reporting. For example, the business performance capabilities make it much easier to follow up and analyze sales activities and compare them with inventory levels at any given point in time. In addition, our data warehousing techniques allow business information to be easily accessed from IFS Applications and other sources.

#### **INTEGRATED HUMAN RESOURCE AND FINANCIAL MANAGEMENT**

IFS Applications for Medical Devices also includes solutions for human resource management and financials. Areas such as time & attendance and training administration are highly automated and dramatically simplified, with much of the work being done by employees themselves. This increases accuracy, speeds up processes and cuts administration costs.

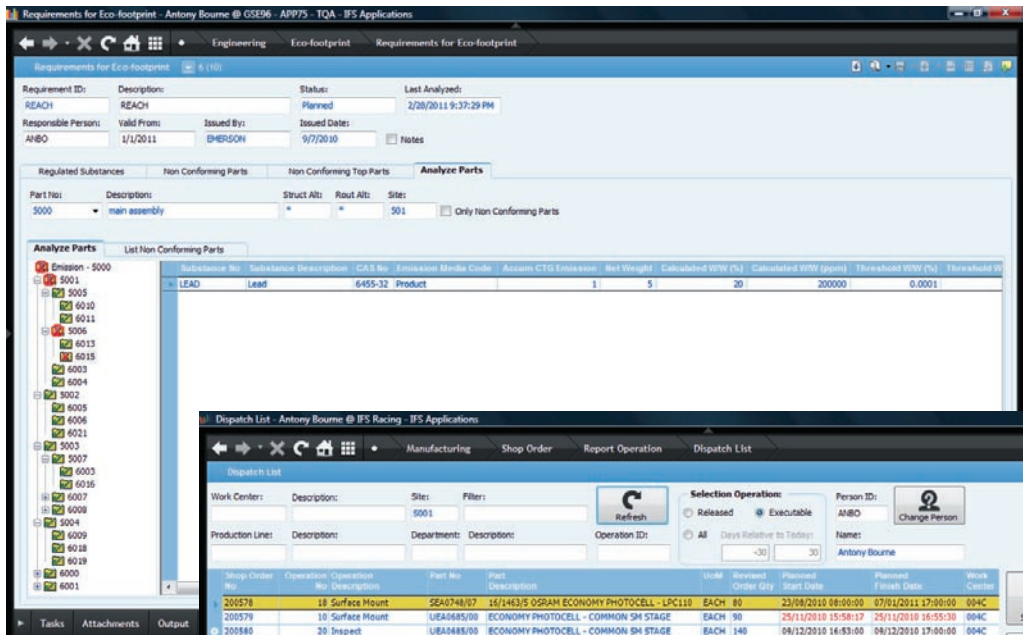
With IFS Financials, you get a comprehensive view of your business from a variety of perspectives. For example, you can easily spot and scrutinize financial transactions in detail to get even greater control at all levels of your organization—wherever you operate and whatever local legislation requires.

**MORE EFFICIENT COLLABORATION**

IFS Applications is built to support collaboration with partners, customers and suppliers. User-friendly IFS Enterprise Explorer makes your business more agile and your employees more productive. Moreover, secure, scalable web services optimize flexibility and availability while ensuring maximum control. Portals broaden the range of sales channels, adding flexibility to traditional mail order services, for

example. They also allow customers more easily to supplement or repeat orders and to track deliveries en route. The result is smoother, more efficient flows, less administration, lower costs, and faster return on investment.

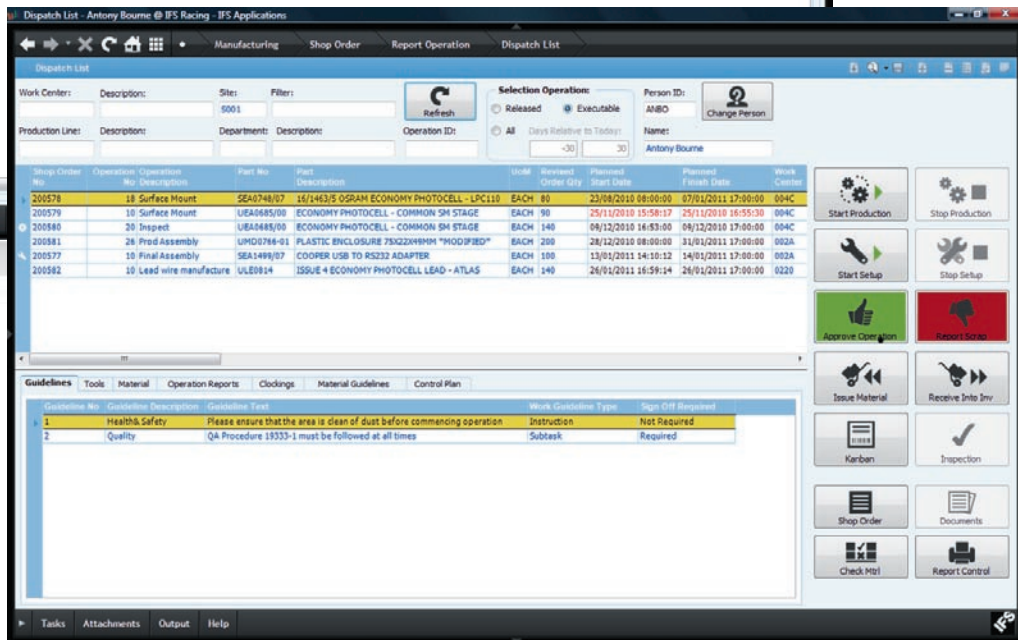
And since the solution is component-based, it can be implemented as and when required, growing and changing as a company evolves and expands its operations.



**ECO-FOOTPRINT:** Built-In support for legislative requirements

**SHOP FLOOR MANAGEMENT:**

A number of shop floor reporting functions are contained within a user-friendly screen allowing touch screen capabilities



## ABOUT IFS AND IFS APPLICATIONS

IFS is a public company (OMX STO: IFS) founded in 1983 that develops, supplies, and implements IFS Applications™, a component-based extended ERP suite built on SOA technology. IFS focuses on agile businesses where any of four core processes are strategic: service & asset management, manufacturing, supply chain and projects. The company has more than 2,000 customers and is present in 50+ countries with 2,700 employees in total.

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