



V A L I D A T I O N S E R V I C E S

BIOLOGICS

BIOTECH

COSMETICS

FOOD

MEDICAL DEVICE

PHARMACEUTICAL

Blue Marlin Systems, Inc's Life Science practice offers a full range of services to comply with US FDA and International regulations.

VALIDATION SERVICES

Assessing ERP Systems - SAP, ORACLE, JDE

Assessing Manufacturing Execution Systems

Assessing Documentation Systems

Assessing Laboratory Information Systems

Assessing Electronic Batch Recording Systems

Gap Analysis and Master Validation Planning

Design Specifications

IQ/OQ/PQ Protocols and Final Reports

Part 11 Remediation Services

Interfaces between ERP and External Systems

Vendor Audits

Test Scripting

Electronic and Digital Signatures

TRAINING SEMINARS

Assessing your ERP Installation for Part 11 Compliance

Compliance procedures for Clinical Supply Chain

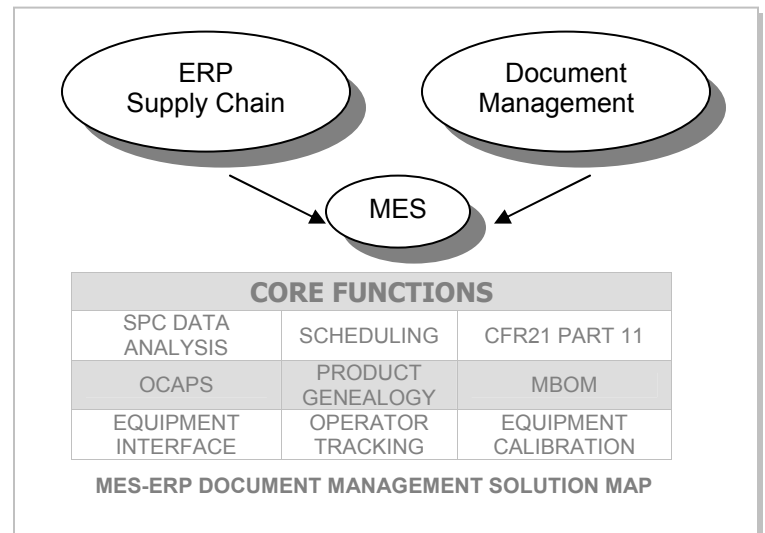
IT Programming techniques for FDA Part 11 environments

www.bluemarlinsys.com for complete Training list

VALIDATING MANUFACTURING EXECUTION SYSTEMS (MES)

Manufacturing Execution Systems

Blue Marlin Systems is supporting BROOKS-PRI AUTOMATION, INC. (NASDAQ: BRKS), one of the largest automation companies, with Methodology and Validation services for their Life Sciences products. This includes designing and implementing interfaces between Automation systems developed by BROOKS-PRI and host ERP systems such as SAP R/3 and ORACLE.



COMPANY BACKGROUND

Based in Dover, New Jersey, Blue Marlin Systems is a global supplier of ERP, E-Commerce and IT outsource solutions. The Life Sciences practice at Blue Marlin provides validation and technical support for ERP applications and their interfaces to MES, LIMS, and Document Management software. Through a network of industry, technology regulatory alliances, Blue Marlin Systems also offers consulting, project management/execution, and help desk support for ERP applications with a strategic emphasis on global supply chain management.

KEY RELATIONSHIPS

Regulatory Consulting

AAC CONSULTING GROUP, INC. one of the largest providers of FDA regulatory services is partnering with Blue Marlin Systems to expand their offering for consulting, training, and remediation services for computer system validation. (Press release at bluemarlinsys.com/newsroom)

OUR TEAM

Our staff has extensive hands on experience in FDA regulated industries:

- QA audits and Best Practice Design for Pharmaceutical and Medical Devices*
- Global Supply Chain Design and ERP Implementations*
- Integration of MES/MRP for product costing, production planning and warehousing and distribution*
- Data Base management and integration*
- E Business tools such as CRM and IVR.*

WANT TO LEARN MORE?

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