

CARL W. DUNLAP

Wakefield, MA 01880

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SAP Skills/Modules: QM, Batch Management, Classification, Serialization
QM integration to MM, PP, PP-PI, SD, PM, WM

SAP Experience Since: 1994

Summary:

15 years professional experience including over 14 years of SAP QM experience at 30 Projects in North America and Europe

SAP Experience includes:

- Quality Notifications including NCMR, Corrective Action, ISO Audit, and Customer Complaints
- QM in Procurement and Supplier Quality (including Certified and Skip Lot)
- SAP QM Electronic Signatures to meet FDA CFR Part 11 Requirements (published whitepaper)
- SAP PLM functionality to support GMP regulations
- QM in Production and Defects Recording
- QM Interfaces and Customer enhancements using ABAP, user exits, BAPI, and BAdI
- Business Process analysis and re-engineering
- Improved Quality process design with significant reduction in inspection time and cost
- Extensive Configuration and Testing (Unit Test, Integration Testing)
- Problem solving using OSS
- Functional and Technical Design Documentation
- QM Project planning and team leadership
- Extensive interfacing with MM/PP/PP-PI/SD/PM/WM modules.
- Multiple Full Life Cycle QM Implementations
- QM Upgrades 3.x to 4.x, and 4.x to ERP (ECC 5.0, ECC 6.0)
- QM Demos, pre-sales, and partner training
- Extensive Batch Management & Classification experience
- Serial Number tracking
- SAP 2.2, 3.0f, 3.1h, 4.0b, 4.5, 4.6c, 4.7 (SAP Enterprise), ECC 5.0, ECC 6.0
- Tested new QM functionality for SAP AG at Headquarters in Waldorf, Germany
- Collaborated with SAP AG developers on QM functionality and enhancements
- Taught QM courses at SAP America Training Centers
- Taught Customized QM Courses at Customer Sites
- Presented to PLM (QM SIG) at ASUG Conferences & Webcasts
 - 2004, 2006, 2007, 2008
 - Highest Rated QM Presentation at Sapphire/ASUG 2008 in Orlando

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SAP QM Projects/Clients:

SAP Customer	Industry
Boeing / Spectrolab	Aerospace / High Tech
Tyco / Raychem	Aerospace / High Tech
Ciba Specialty Chemicals	Chemicals
Hercules	Chemicals
Nova Chemicals	Chemicals
3COM	High Tech / Electronics
Adaptec	High Tech / Electronics
Advanced Energy	High Tech / Electronics
Conexant / Brooktree	High Tech / Electronics
Dell Computer	High Tech / Electronics
Intermec	High Tech / Electronics
Maxtor	High Tech / Electronics
Nortel Networks	High Tech / Electronics
Philips Lighting Electronics	High Tech / Electronics
Siemens Telecommunications	High Tech / Electronics
Temic (Siliconix)	High Tech / Electronics
Texas Instruments	High Tech / Electronics
Triquint Semiconductor	High Tech / Electronics
Deere & Company	Industrial Machinery
Abiomed	Medical Devices
Cardinal Health / Alaris	Medical Devices
Guidant / Abbott Vascular	Medical Devices
Philips Healthcare / ATL Ultrasound	Medical Devices
Respironics	Medical Devices
Siemens Medical / Acuson	Medical Devices
Smith & Nephew	Medical Devices
Siemens Power Corporation	Nuclear
Sealed Air	Packaging Materials
Perrigo	Pharmaceuticals
SAP All-in-One for Pharma	Pharmaceuticals

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Software/System Skills

- SAP R/3 2.2, 3.0, 3.1, 4.0, 4.5, 4.6, 4.7, ECC 5.0, ECC 6.0
- Plumtree Corporate Portal 4.0, 4.5, 5.0
- Siebel Enterprise Applications 99.6, 2000

Professional Experience

04/01 - Present

Senior QM Consultant & Team Lead Cohesion, Inc.

Platinum Level QM Consulting for SAP Customers Worldwide
4 Implementation of SAP ECC 5.0, SAP ECC 6.0
10 Implementations of SAP 4.6c, SAP 4.7
QM Team Lead for multiple Global projects
Customized QM Training for On-Site Delivery
SAP QM Support Services

Smith & Nephew Orthopedics

- Quality Notifications for “Hold It Notice” process
- Batch Management & Batch Status
- Design for Quality & Regulatory processes for newly built DC in Memphis, TN
- Development of Functional Specifications, Test Scripts, and Configuration Documents
- Development of LSMW to load Batches, Classification, and Quality Info Records
- QM Tasks for Cutover

Perrigo

- Project management, requirements gathering, development, testing, QA & support
- Involved in Full Life Cycle QM implementation
- Batch Management and Classification of Finished products
- QM in Production and Incoming inspection
- Maintained & configured all master data objects
- Extensive use of LSMW to load master data
- Design of Physical Sample Process & Flow
- ISO 2859 Sampling Tables, Skip Lots, and Certification
- Physical sample management with sampling procedures
- Designed and Tested for FDA Regulated Environment
- Implemented Flexible inspection with master inspection plans
- Functional and Technical design documentation.
- Extensive Configuration and Testing (Unit Test, Integration Testing)
- Cutover, Go-Live and Production support.

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Nova Chemicals

- Replacement of Honeywell LIMS with SAP QM
- Full SAP QM for RAW Materials, BULK Materials, Finished Materials
- EH&S – QM Interface (Specification Database – Inspection Plans0
- Certificates of Analysis
- Calibrations with QM & PM

SAP All-in-One for Life Sciences (Pharma)

- Development of all SAP QM Scenarios for Life Sciences A1 project
- QM in Procurement
- QM in Manufacturing
- How to Guide for Control Charts
- How to Guide for Digital Signatures
- QM Returns
- Batch Classification with SD
- QM in SD – Certificates

Cardinal Health – CTSi Division (UK)

Phase I

- Implemented Incoming Inspection Functionality in current SAP Environment
- Designed Inspection Plan Master Data so that it is simple to maintain and use
- Utilized Document Management to store Inspection Plan drawings (PRT)
- Use of ISO standards (ISO 2859)
- Dynamic Modification for Skip Lots
- Defects Recording for Incoming Inspection
- Digital Signature for Results Recording
- Simplified Quality Notifications for Defect capture from Production Line
- Utilized LSMW to load all QM Master Data (thousands of materials, inspection plans)
- Improved Process efficiency with simple hardware solutions
 - USB measuring equipment
 - Barcode readers and bar codes on labels/forms

Phase II

- Instrument Results Recording (electronic device history record – eDHR)

Respironics

- Development of Digital Signature Functionality for Quality Notification
- Uses Business Add In (BAI)
- Triggering of signature for Task status change
- Ability to specify activation for Notification Type plus Plan
- Complete Turn Key Project
 - Requirements / Design
 - Integration Testing
 - Technical Documentation
 - Go-Live

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Philips Lighting Electronics (Advance)

- Shop Floor QM for Manufacturing Facility in Mexico
- Trigger of Inspection Lot for Production Order (Early GR function)
- Results Recording
- Control Charts
- Defects Recording
- Interface to ATE Test Equipment
- PPM and custom reports

Guidant, Inc. (now part of Abbott Vascular)

- Global QM Project for Vascular Intervention (VI) Division (California, Ireland, Puerto Rico)
- QM in Procurement and QM/MM Integration
- Defects Recording and Usage Decision
- Dynamic Modification and Quality Level for Procured Materials
- Certified & Approved Supplier Lists
- Dock to Stock and Skip Lots
- Vendor Related Quality Notifications
- Custom ABAP Reports for QM Reporting

Alaris Medical Systems, Inc. (now part of Cardinal Health)

- SAP 4.7 Project as part of Business Process Reengineering (BPR)
- Project management, requirements gathering, development, testing, training, QA, Go-Live, and Support
- Satisfied FDA CFR Part 11 requirements using Electronic Signature in QM Results Recording, Usage Decision, and Quality Notifications
- Quality Notifications to support - NCMR (Non Conforming Material Report), Calibration Problems, and Repairs of Instruments
- SAP Workflow to route Quality Notifications via email (MS Outlook/Exchange)
- QC Receiving Inspection using ISO 2859 Sampling Tables, Skip Lots, and Certification
- Results Recording, Defects Recording, and Usage Decision for Incoming Inspection
- Batch Management and Classification of Sterilized components and finished goods
- Worked with Business Warehouse (BW) team to create info cubes

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Sealed Air Corporation

- Global QM Template for Cryovac Food Packaging Business
- Global QM Configuration and Master Data for ease of maintenance
- Replacement of Proprietary Eurosoft QM System (Europe)
- Replacement of 5 different legacy QM Applications (North America)
- Flexible Inspection Specifications for In-Process Inspection using SAP BAdI (Business Add In)
- Results Recording using Inspection Points
- SPC Charts for tracking Quality Attributes during Production Process
- Tolerance/Specification Limits based on Classification values
- Quality Notifications to support Customer Returns
- Outgoing Certificates of Conformance (COC)
- BW & ABAP Reports for Reporting

08/00 - 04/01

Senior Business Development Manager, Enterprise Applications Plumtree Software, Inc.

- Responsible for all aspects of technology partnerships (co-development, co-marketing, co-selling, co-delivery) in Enterprise Application Software Category (ERP, CRM, BI)
- SAP, Siebel, Actuate, Business Objects, Cognos, Information Builders (IBI), Interface Software, Semio
- Designed strategy and managed Portlet Development projects for SAP R/3, mySAP Workplace, Siebel, Business Objects, Cognos, and Actuate from design to completion.

08/98 - 08/00

SAP Project Manager & Senior QM Consultant BrightStar Information Technology Group, Inc.

Responsible for hiring key resources to expand SAP Practice

Performed the duties of SAP Partnership Manager for all Industry Sectors

Lead Manager for Quality Management, Plant Maintenance, and Service Management Consultants

Quality Management Project Analysis, Scoping and Consulting (3.0, 3.1, 4.0, and 4.5 Projects)

Acuson Corporation (now part of Siemens)

- Customized Results Recording for Serial Numbers (to speed up manufacturing process)
- QM In-Process Inspection for Ultrasound Equipment Manufacturing

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Nortel Networks

- Quality Notifications to Support Corrective Actions, Preventive Actions, and Non Conforming Materials
- SAP Workflow to support routing of Quality Notifications
- SAPScript for custom Layout Sets and Forms for Quality Notifications

Tyco (Raychem)

- Trouble shoot QM problems for existing SAP implementation
- Design SAP QM solution for other Raychem divisions

07/96 - 08/98

Senior QM Consultant & Team Lead TBQ Associates, Inc.

Senior Consultant and Project Manager for SAP QM
Provided application consulting, and implementation assistance on SAP R/3 software Requirements Analysis, Requirements Mapping, Customization and Configuration, System Testing, Training, and Interfacing

Siemens Power Corporation (now Framatone ANP)

- Implementation of SAP QM for Nuclear Fuels Manufacturer
- Use of SAP QM within NRC Regulated Environment
- Results recording and tracking for serial numbered parts for both procurement and production
- Implementation of QM and PM to support Serial Number Hierarchy of Fuel Rods
- Adaptec, Inc.
- Coordinated and scheduled implementation of SAP Quality Management to support receiving inspection, vendor/supplier evaluation, quality data collection during production, and non-conformance reporting
- Improved availability and communication of quality information through elimination of separate disconnected databases with one centralized database- allowing wider access to quality information throughout organization
- Simplified inspection processes through reduction of paper files, improved business flow, and user-friendly interfaces
- Implementation of Quality Notification System to support Global Corrective Action System. Presented benefits of system in the form of ROI and Quality Improvement

Ciba Specialty Chemicals

- Migration of R/3 2.2 system to 3.0f for International Specialty Chemical Producer
- Configured functionality for matching batch specifications to customer and general sales specification requirements
- Generation of Certificates of Analysis (COA)
- Moved to standard SAP programs from custom code.

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01/95 - 06/96

Applications Consultant

SAP America, Inc.

- SAP North American Functional Lead for Quality Management Module of R/3 Client Server Software
- Integrated and customized Quality Management module in the logistics process at diverse customer sites- utilizing standard functionality, and "out of the box" thinking to meet each customer's unique requirements
- Provided standard and customized training on R/3 software at SAP Training centers and customer sites in United States, and Canada. Tested critical 3.0 release of software at SAP AG headquarters in Germany and fed back development requests, bug reports, and product improvement suggestions.
- Documented and scripted "as is" quality processes, designed, conceptualized and reengineered "to be" processes, and created work instructions for user testing and documentation
- Scheduled and coordinated activities with project manager and key team members at client sites to support project related milestones and deliverables
- Effectively used several "Big Six" methodologies for support of implementation activities
- Supported sales organization's multi-million dollar contracts by performing R/3 QM overview presentations, sales demonstrations, proof of concept, and conference room pilots integral to licensing decisions

Education

California State University, Chico

Bachelor of Science in Business Administration, Magna Cum Laude, Honors in GE

Emphasis in Productions and Operations Management

Alumni Involvement

- Instrumental in starting SAP's University Alliance Program, with CSU, Chico as a founding member
- Brought SAP R/3 to California Stat University, Chico where it has been integrated into the college of business curriculum
- Guest Lecturer in Productions and Operations Management and M.I.S. classes
- Responsible for College Recruiting efforts while at TBQ and BrightStar
- College of Business SAP Program awarded several research grants by SAP America in excess of \$300,000
- CSU, Chico is currently a "mega hosting center" for 75+ institutions around the globe