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A Business Navigation System

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Introduction

Business Intelligence works to improve prospects; Business Wisdom works to improve the fundamental operations of the business. In other words, Intelligence systems help to understand the unknown. The demography of visitors buying a certain item from a website is an example. That knowledge can be used by Marketing to increase business prospects and sell. Once known, that knowledge must then be transformed into actions.

Improving business and introducing changes is not easy. QCR is focused on achieving perfection in client operations through the intelligent use of Business Navigation System (BNS) Solutions. We offer a solution that raises the standard for business cost-effectiveness and efficiency and we are the “first mover” in a new category of software. Whether the change is associated with a product (hardware or software), service or governmental policy, it must be implemented flawlessly and maintained rigorously.

Problem Statements

- FDA boosts heparin death toll (UPI)
- Vioxx death toll may hit 2,000 in UK
- Goodyear kept tire problems quiet.
- USDA Orders Largest Meat Recall in U.S. History
- Citing a fire hazard, company embarks on largest recall in consumer electronics history
- Toyota: Recalls may not solve all problems. 8.5 million Toyota cars and trucks recalled
- Tire Trouble: The Ford-Firestone Blowout
- Texas Ship-Inspection Company Implicated in Prestige Tanker Disaster
- Illinois reactors: 102 fines costing \$8,161,000
- Timeline: 15 Years of Product Recalls from Braun, Burger King, Nokia, Mattel and others
- Boeing finds problems with fasteners on 787 test planes
- Largest of food borne disease in a decade has sickened at least 1,220
- Schering to Pay a Fine of \$500 Million to the FDA for repeatedly failing plant inspections
- Pet Food Deaths: FDA Blocks Gluten from China
- Quality Problems Cost Software Companies Up to \$22 Million Annually According to IDC *Survey Reveals Almost Three Quarters Have “Serious Problems” with Defects, Even After Code Review*



- A significant number of hospital deaths are preventable. *Preventable deaths: who, how often, and why?*
- Why is it that we'll tolerate "the equivalent of 390 jumbo jets full of people... dying each year due to likely preventable, in-hospital medical errors, making this one of the leading killers in the U.S.," said Dr. Samantha Collier. *HealthGrades vice president of medical affairs*

A 2009 study from Axendia in life sciences showed that even when corrective action systems were employed, 93% reported a recurrence of the quality issue after problem correction.

The list above is not exhaustive. However it does accentuate the fact that problem resolution is still a necessary part of every company's culture regardless of industry.

Previous Options

Traditional process improvement methodologies (SixSigma, TQM, etc.) assume that nothing is known about the situation and a need to collect, organize, analyze, report, assign, implement and follow-up on a solution is prescribed (DMAIC, etc.). This usually starts with the customer.

Only after the situation becomes frequent enough to be costly and worth the time to expend the resources needed to research a root cause will attempts be made to "fix it". Traditional tools and methodologies will not allow companies to be successful harnessing new frontiers. The world is interconnected and supply chains increase in complexity; a solution is needed for this "fix it" approach.

The BNS Solution

The importance of the concept called QUALITY increases in every aspect of society as the future draws nearer. Our vision is to realize the elimination of preventable problems. As our world

becomes increasingly interconnected some problems have profound detrimental effects on larger portions of society. We will have to come to terms with our need to produce goods and services without errors if we are to be successful with optimizing resource utilization and ensuring optimal cost efficiencies in all processes across our organizations, be they service, engineering or manufacturing related enterprises.

While the traditional approach assumes all information is not known, Our solution employs wisdom. Wisdom is the coordination of "knowledge and experience" and "its deliberate use to improve well-being." (Allen, 2008)

BNS possesses the field-proven ability to progress from accounting for and reporting on program status to active prevention in each detail of work. BNS has developed into a methodology for ensuring that any process regardless of industry is performed correctly — the first and every time.

By using the BNS solution to take the potentially negative human element out of processes, BNS customers have saved and/or avoided millions of dollars in fines for compliance irregularities; transportation, maintenance and rework costs; while at the same time effected efficiencies that have yielded a significant ROI on their BNS investment. It should also be noted that our BNS exceeds 21 CFR Part 11 compliance and ISO 9000 requirements.

The BNS solution offers the only Quality Execution Systems (QES) application available today that delivers real-time decision-making to ensure compliance with existing rules, regulations, procedures and requirements. BNS literally eliminates the possibility of error.

Savings

Our clients save money by forcing compliance in operations. Savings are achieved when processes are executed correctly the first time and each subsequent time.

Proven Savings: Ten years ago we developed a capability that saved one major medical device company over \$1.2 million dollars in the pilot area alone by assuring compliance with the Good Manufacturing Practices (GMPs) of the FDA. BNS provides automatic collection of information



mandated by the FDA's Quality System Regulation (QSR) 820.184 and eliminates or reduces:

- NCRs (Nonconformance Reports) costs
- Problem Solving (investigations and corrective actions, paperwork etc.) costs
- Rework and reevaluation costs
- IT Burden and costs
- MRAs (Material Return Authorizations)
- Recalls/ Customer Service Issues/Costs
- Recording, filing and reporting costs

Just In Time Knowledge Base

People are often referred to as a company's greatest asset. They have tremendous flexibility and the capability to accept and innately reason on a vast amount of stimuli coming at the same instant. Humans, however, have a considerably short attention span particularly when under stress and tend to have limitations on knowledge retention. Even when trained, workers can be forgetful and recall less than perfect training guidelines and processes. The National Training Center's pyramid graph of Average Learning Retention Rates begins with 5% retention for lectures and increases to only 75% retention when practicing by doing.¹ These rates demonstrate that relying on training only is problematic especially with complicated procedures.

Whether it's a demonstrated 25% lapse in memory or just a 5% lapse, disastrous results can occur. BNS offers the solution to eliminate this risk. The traditional approach is to hire and train associates to perform work. The shortcomings of this approach are well documented in industry:

- Imprecise retention rates and knowledge
- Inconsistency of materials and trainers
- Insufficient detail or accuracy especially in on-the-job training

BNS takes a different approach by bundling the process with multimedia "Expert" training. We rely on schooling, training and certifications to arm people for the workforce. In more and more cases however, training is outdated before it is completed. Binding with a multimedia collaborative knowledge base of expert information that is always current, always available and designed to be used at the point of activity overcomes the only two reasons for having quality problems: lack of knowledge and lack of attention.

Compliance

The director of manufacturing at one of the largest medical device facilities in the States stood up and said it was the first time he has ever used the word never in a presentation but: Since installing the BNS STEP system they have "NEVER" had a mistake or omission in the processes being controlled. They have never had an unqualified person perform work, never used the wrong tool/equipment, never used expired material, and never had a recall or a returned product due to manufacturing oversight.

The director stated that they have achieved ZERO DEFECTS and comply with all FDA's GMP's and paperwork 100% of the time. Before implementing the BNS solution in the initial area, manufacturing blood and urine analysis machines, they were seeing 1200 corrective action requests per year (approx. \$1000 each). After implementing the BNS solution they achieved, ZERO corrective action requests. In fact they say STEP doesn't allow them "to ever make a mistake".

Implementation

STEP (System To Eliminate Problems) is the implementation of BNS. STEP applications have been designed from the ground up using a .Net-compliant and Web services-based architecture. This enables applications to be easily integrated with other enterprise applications.

STEP provides integrations to leading ERP and PLM systems using Enterprise Application Integration (EAI) tools such as TIBCO, WebMethods and BizTalk, resulting in faster implementations, lower Total Cost of



Ownership and greater return from an investment in enterprise systems. It also provides a flexible integration framework for reducing the time required to connect islands of information.

STEP provides integration with test equipment, controls and machinery through OPC (open connectivity), SECS/GEM (Serial communication and Generic Model for Communications and Control of Manufacturing Equipment) and other protocols.

STEP incorporates Business Objects (Crystal Report) and Microsoft Excel for generating reports, based on individual customer-driven report definitions.

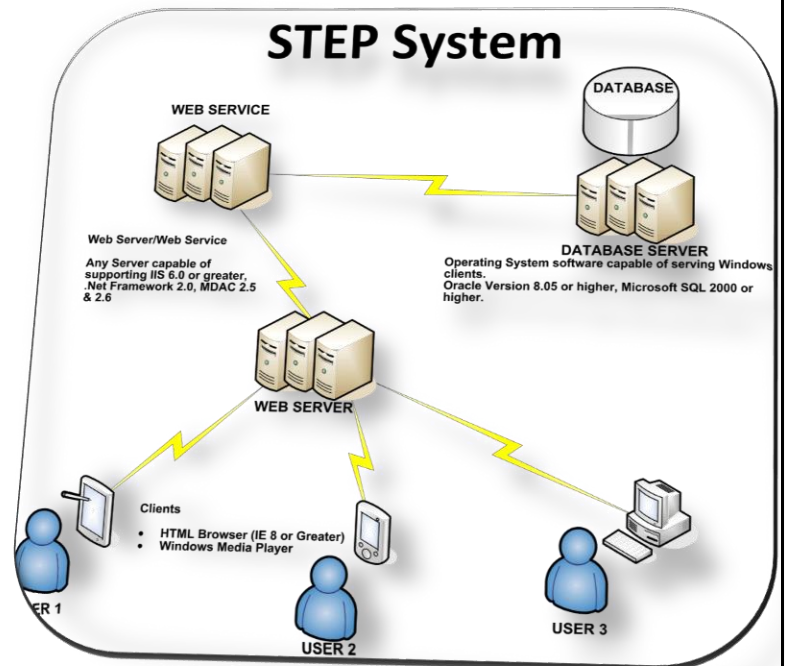
Adobe Acrobat Reader is also used for the purpose of exporting and viewing the reports to workstations that do not have the access to Crystal Report or Microsoft Excel.

STEP uses the ODBC data connection protocol, which gives customers more flexibility on the type of server they may choose. We have the flexibility of using both Oracle and SQL Server databases to support any BNS implementation.

STEP connects to an XML web service to transport data between the website (presentation layer) and the database (data layer). The XML Web service is utilized as a method of accessing the data and performing tasks such as inserting, updating, and deleting.

Summary

Every company has a Culture either planned or unplanned. As business becomes more interconnected this culture becomes more important to enterprises. Companies need to assess exactly what their culture is in relation to its impact on quality, process codification and standardization. Enterprises today cannot afford to waste resources on correcting preventable problems.



Simply put, our solution mistake-proofs business processes. We systematically enforce compliance with existing business rules, regulations, and requirements.

A key benefit is the savings associated with locking down processes at the point of activity so that tasks are performed correctly every time, using real-time decision-assisting. Our solution can eliminate the possibility executing tasks and processes incorrectly.

QCR provides the only wisdom based, real-time mistake-proofing solution deployed at the point of activity. Error free products and services can now be designed and built as defined. Our system is ideal for complex work, heavily-regulated industries and high liability businesses. STEP can be deployed through any interface that can see the Internet.

About QCR

QCR, has been providing consulting and software tools to improve the quality and productivity of business processes for 20 years. It is the goal of QCR to provide the industry with the next step in business management systems. QCR is a privately held Texas corporation founded in 1986 under the name Process Integrity. It has a proven track record, and a proven history of enterprise-sized customers.